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Healthy eating interventions delivered in early childhood education and care settings for improving the diet of children aged six months to six years (Review)

Yoong SL, Lum M, Wolfenden L, Jackson J, Barnes C, Hall AE, McCrabb S, Pearson N, Lane C, Jones JZ, Nolan E, Dinour L, McDonnell T, Booth D, Grady A

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[Intervention Review]

Healthy eating interventions delivered in early childhood education and care settings for improving the diet of children aged six months to six years

Sze Lin Yoong^{1,2,3,4}, Melanie Lum^{2,3,4}, Luke Wolfenden^{2,3,4}, Jacklyn Jackson^{3,4}, Courtney Barnes^{2,3,4}, Alix E Hall^{3,4}, Sam McCrabb^{3,4}, Nicole Pearson^{2,3,4}, Cassandra Lane^{2,3,4}, Jannah Z Jones^{2,3,4}, Erin Nolan^{3,4}, Lauren Dinour⁵, Therese McDonnell⁶, Debbie Booth⁷, Alice Grady^{2,3,4}

¹Global Centre for Preventive Health and Nutrition, Institute for Health Transformation, School of Health and Social Development, Faculty of Health, Deakin University, Victoria, Australia. ²Hunter New England Population Health, Hunter New England Local Health District, Wallsend, Australia. ³School of Medicine and Public Health, University of Newcastle, Callaghan, Australia. ⁴Hunter Medical Research Institute, New Lambton, Australia. ⁵College of Education and Human Services, Montclair State University, Montclair, New Jersey, USA. ⁶School of Nursing, Midwifery and Health Systems, University College Dublin, Dublin, Ireland. ⁷Auchmuty Library, University of Newcastle, Callaghan, Australia

Contact: Sze Lin Yoong, serene.yoong@health.nsw.gov.au.

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ABSTRACT

Background

Dietary intake during early childhood can have implications on child health and developmental trajectories. Early childhood education and care (ECEC) services are recommended settings to deliver healthy eating interventions as they provide access to many children during this important period. Healthy eating interventions delivered in ECEC settings can include strategies targeting the curriculum (e.g. nutrition education), ethos and environment (e.g. menu modification) and partnerships (e.g. workshops for families). Despite guidelines supporting the delivery of healthy eating interventions in this setting, little is known about their impact on child health.

Objectives

To assess the effectiveness of healthy eating interventions delivered in ECEC settings for improving dietary intake in children aged six months to six years, relative to usual care, no intervention or an alternative, non-dietary intervention. Secondary objectives were to assess the impact of ECEC-based healthy eating interventions on physical outcomes (e.g. child body mass index (BMI), weight, waist circumference), language and cognitive outcomes, social/emotional and quality-of-life outcomes. We also report on cost and adverse consequences of ECEC-based healthy eating interventions.

Search methods

We searched eight electronic databases including CENTRAL, MEDLINE, Embase, CINAHL, PsycINFO, ERIC, Scopus and SportDiscus on 24 February 2022. We searched reference lists of included studies, reference lists of relevant systematic reviews, the World Health Organization International Clinical Trials Registry Platform, ClinicalTrials.gov and Google Scholar, and contacted authors of relevant papers.

Selection criteria

We included randomised controlled trials (RCTs), including cluster-RCTs, stepped-wedge RCTs, factorial RCTs, multiple baseline RCTs and randomised cross-over trials, of healthy eating interventions targeting children aged six months to six years that were conducted within the ECEC setting. ECEC settings included preschools, nurseries, kindergartens, long day care and family day care. To be included, studies had to include at least one intervention component targeting child diet within the ECEC setting and measure child dietary or physical outcomes, or both.

Data collection and analysis

Pairs of review authors independently screened titles and abstracts and extracted study data. We assessed risk of bias for all studies against 12 criteria within RoB 1, which allows for consideration of how selection, performance, attrition, publication and reporting biases impact outcomes. We resolved discrepancies via consensus or by consulting a third review author. Where we identified studies with suitable data and homogeneity, we performed meta-analyses using a random-effects model; otherwise, we described findings using vote-counting approaches and via harvest plots. For measures with similar metrics, we calculated mean differences (MDs) for continuous outcomes and risk ratios (RRs) for dichotomous outcomes. We calculated standardised mean differences (SMDs) for primary and secondary outcomes where studies used different measures. We applied GRADE to assess certainty of evidence for dietary, cost and adverse outcomes.

Main results

We included 52 studies that investigated 58 interventions (described across 96 articles). All studies were cluster-RCTs. Twenty-nine studies were large (≥ 400 participants) and 23 were small (< 400 participants). Of the 58 interventions, 43 targeted curriculum, 56 targeted ethos and environment, and 50 targeted partnerships. Thirty-eight interventions incorporated all three components. For the primary outcomes (dietary outcomes), we assessed 19 studies as overall high risk of bias, with performance and detection bias being most commonly judged as high risk of bias.

ECEC-based healthy eating interventions versus usual practice or no intervention may have a positive effect on child diet quality (SMD 0.34, 95% confidence interval (CI) 0.04 to 0.65; $P = 0.03$, $I^2 = 91\%$; 6 studies, 1973 children) but the evidence is very uncertain. There is moderate-certainty evidence that ECEC-based healthy eating interventions likely increase children's consumption of fruit (SMD 0.11, 95% CI 0.04 to 0.18; $P < 0.01$, $I^2 = 0\%$; 11 studies, 2901 children). The evidence is very uncertain about the effect of ECEC-based healthy eating interventions on children's consumption of vegetables (SMD 0.12, 95% CI -0.01 to 0.25; $P = 0.08$, $I^2 = 70\%$; 13 studies, 3335 children). There is moderate-certainty evidence that ECEC-based healthy eating interventions likely result in little to no difference in children's consumption of non-core (i.e. less healthy/discretionary) foods (SMD -0.05 , 95% CI -0.17 to 0.08; $P = 0.48$, $I^2 = 16\%$; 7 studies, 1369 children) or consumption of sugar-sweetened beverages (SMD -0.10 , 95% CI -0.34 to 0.14; $P = 0.41$, $I^2 = 45\%$; 3 studies, 522 children).

Thirty-six studies measured BMI, BMI z-score, weight, overweight and obesity, or waist circumference, or a combination of some or all of these. ECEC-based healthy eating interventions may result in little to no difference in child BMI (MD -0.08 , 95% CI -0.23 to 0.07; $P = 0.30$, $I^2 = 65\%$; 15 studies, 3932 children) or in child BMI z-score (MD -0.03 , 95% CI -0.09 to 0.03; $P = 0.36$, $I^2 = 0\%$; 17 studies; 4766 children). ECEC-based healthy eating interventions may decrease child weight (MD -0.23 , 95% CI -0.49 to 0.03; $P = 0.09$, $I^2 = 0\%$; 9 studies, 2071 children) and risk of overweight and obesity (RR 0.81, 95% CI 0.65 to 1.01; $P = 0.07$, $I^2 = 0\%$; 5 studies, 1070 children).

ECEC-based healthy eating interventions may be cost-effective but the evidence is very uncertain (6 studies). ECEC-based healthy eating interventions may have little to no effect on adverse consequences but the evidence is very uncertain (3 studies).

Few studies measured language and cognitive skills ($n = 2$), social/emotional outcomes ($n = 2$) and quality of life ($n = 3$).

Authors' conclusions

ECEC-based healthy eating interventions may improve child diet quality slightly, but the evidence is very uncertain, and likely increase child fruit consumption slightly. There is uncertainty about the effect of ECEC-based healthy eating interventions on vegetable consumption. ECEC-based healthy eating interventions may result in little to no difference in child consumption of non-core foods and sugar-sweetened beverages. Healthy eating interventions could have favourable effects on child weight and risk of overweight and obesity, although there was little to no difference in BMI and BMI z-scores. Future studies exploring the impact of specific intervention components, and describing cost-effectiveness and adverse outcomes are needed to better understand how to maximise the impact of ECEC-based healthy eating interventions.

PLAIN LANGUAGE SUMMARY

How successful are healthy eating programmes in preschools, kindergartens and childcare settings?

Key messages

- Healthy eating programmes delivered in early childhood education and care (ECEC) settings (e.g. preschools, kindergarten, family day care) may improve child diet quality, likely increase fruit consumption, may have favourable effects on vegetable consumption, and likely

have no impact on consumption of less healthy foods and sugar-sweetened drinks. They may have favourable effects on child weight and may reduce the risk of being overweight or obese.

- We don't know if healthy eating interventions save money or cause unwanted effects because very few studies provided information about these points.
- We found little evidence from low- and middle-income countries, but healthy eating programmes in high-income countries may benefit child health. We don't know how to support educators and staff to implement these programmes in practice. We need more research about delivering programmes and about their effect in low-income countries.

Why is it important to improve young children's diet?

Having a poor diet puts people at risk of many long-term diseases including heart disease, type 2 diabetes and certain types of cancers. Research estimates that over 11 million deaths worldwide are caused by having an unhealthy diet. Dietary behaviours and preferences are established early in life and persist into adulthood.

What are healthy eating programmes?

Healthy eating programmes aim to encourage children to eat a healthier diet. They may involve changes to lessons and the culture in preschools, kindergartens and day care centres (early childhood education and care (ECEC) settings), and working with children's families, teachers and healthcare staff. For example, introducing new fruits and vegetables to children, changing the menu to include healthier options or providing families with information about child healthy eating. Healthy eating programmes may establish lifelong healthy eating patterns, reduce excessive weight gain and improve overall health.

What did we want to find out?

We wanted to find out what impact healthy eating interventions have on child diet and health. We were interested in changes to diet, weight, language and cognitive performance, social, emotional and quality of life outcomes in children aged six months to six years attending preschool, long day care, nurseries, kindergartens and family day care services. We also wanted to know the cost of interventions and whether they had any potential unwanted effects.

What did we do?

We searched for studies that compared healthy eating programmes against no action, delayed delivery of the programme, or a programme that did not aim to change child diet.

We compared and summarised the results of the studies and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 52 studies that looked at the effects of 58 healthy eating programmes in ECEC settings for children aged six months to six years. All studies were published in high and high-middle-income countries. The programmes were very different from each other. They:

- lasted from 4 weeks to 3 years;
- were delivered by a range of people including healthcare providers, ECEC staff, and researchers;
- used different delivery methods (telephone, face-to-face, online, printed materials); and
- measured results in a variety of ways (e.g. parent or staff surveys, observations of children's eating, and weighing foods before and after meals).

Overall, the programmes aimed to:

- change the ECEC environment (e.g. staff demonstrated healthy eating to children, and provided healthier foods);
- change the curriculum (e.g. they provided lessons about foods and healthy eating); and
- establish partnerships (e.g. they provided educational resources to families); and
- increase children's physical activity (e.g. by structured physical activity lessons and encouraging less screen time).

Healthy eating programmes may lead to small improvements in child diet quality, increase fruit consumption by 0.11 servings, potentially improve vegetable consumption by 0.12 servings and may have no effect on consumption of less healthy foods and sugar-sweetened drinks. Further, we found child weight is potentially reduced by 230 g and for every 100 children, 19 would have better weight status.

However, we found no evidence of impact on body mass index. The programmes may be cost-effective and likely to have no unwanted effects, although few studies reported these points. Few studies reported on other learning, social and developmental outcomes.

What are the limitations of the evidence?

Our confidence in the evidence is low because the healthy eating programmes were conducted, delivered and assessed in different ways. Also, many of the people who received the healthy eating programmes were aware that they were being assessed and this can sometimes influence how they report their effects. For example, parents who reported their child's diet may have been more inclined to give positive answers because they felt they were doing what society expected or because they were grateful for the support and wanted to please the researchers. Also, not all studies provided information about everything we were interested in and there was often missing data when children were followed up after the study.

How up-to-date is the evidence?

The evidence is up-to-date to February 2022.

SUMMARY OF FINDINGS

Summary of findings 1. Comparison of early childhood education and care-based healthy eating interventions for improving the diet of children aged six months to six years

Comparison of early childhood education and care-based healthy eating interventions for improving the diet of children aged six months to six years

Patient or population: children aged six months to six years

Setting: ECEC services (including centre-based and family day care)

Intervention: healthy eating interventions

Comparison: no intervention (including usual care, minimal support or delayed intervention) or alternative, non-dietary intervention

Outcome	Anticipated absolute effects (95% CI)*		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	What happens
	Risk with control	Risk with healthy eating interventions				
Diet quality	Mean score (SD) of 57.80 (10.82) ^a on the Healthy Eating Index (scale 0–100 points; higher scores = better diet quality)	SMD of 0.34 is equivalent to a score 3.68 points better in diet quality	SMD 0.34 SD higher (0.04 higher to 0.65 higher)	1973 children (6 RCTs)	⊕○○○ Very low ^b	ECEC-based healthy eating interventions may increase diet quality slightly but the evidence is very uncertain.
Fruit consumption	Mean (SD) servings of fruit 2.06 (1.15) ^c	SMD of 0.11 is equivalent to an increase of 0.13 servings of fruit	SMD 0.11 SD higher (0.04 higher to 0.18 higher)	2901 children (11 RCTs)	⊕⊕⊕○ Moderate ^d	ECEC-based healthy eating interventions likely increase fruit consumption slightly. This increase corresponds to approximately 20% of the daily in-care fruit requirements for this age group. We were unable to pool 7 studies in the meta-analysis; 4 studies reported positive effects of the intervention, while 3 studies reported negative effects.
Vegetable consumption	Mean (SD) servings of vegetables 1.50 (1.18) ^c	SMD of 0.12 is equivalent to an increase of 0.14 servings of vegetables	SMD 0.12 SD higher (0.01 lower to 0.25 higher)	3335 children (13 RCTs)	⊕○○○ Very low ^e	The evidence is very uncertain about the effect of ECEC-based healthy eating interventions on child consumption of vegetable servings. We were unable to pool 8 studies in the meta-analysis 7 studies reported positive effects of the intervention, while 1 study reported negative effects.

Non-core foods (i.e. less healthy or discretionary) consumption	Times non-core foods were consumed: mean 0.6; SD 0.85 ^f	SMD of -0.05 is equivalent to 0.04 less times non-core foods were consumed	SMD 0.05 SD lower (0.17 lower to 0.08 higher)	1369 children (7 RCTs)	⊕⊕⊕○ Moderate ^g	ECEC-based healthy eating interventions likely result in little to no difference in non-core foods consumption. We were unable to pool 3 studies in the meta-analysis; 2 studies reported favourable effects of the intervention, while 1 study reported unfavourable effects.
Sugar-sweetened beverage consumption	Portions or servings: mean 1.85; SD 1.60 ^c	SMD of -0.10 is equivalent to 0.16 fewer portions or servings of sugar-sweetened beverages	SMD 0.10 SD lower (0.34 lower to 0.14 higher)	522 children (3 RCTs)	⊕⊕⊕○ Moderate ^h	ECEC-based healthy eating interventions likely result in little to no difference in sugar-sweetened beverage consumption. We were unable to pool 3 studies in the meta-analysis; 2 studies reported favourable effects and 1 study reported unfavourable effects of the intervention.
Cost-effectiveness	6 studies reported on various intervention costs (i.e. total cost of intervention, projected lifetime savings, cost for participants, average cost-effectiveness ratio, and relative value index) as measured via surveys, records or logs. 1 study reported that healthy eating interventions were cost-effective, 2 studies reported cost per child, and 3 studies reported intervention delivery costs, all of which varied across studies.	-	-	101 services (6 RCTs)	⊕○○○ Very low ⁱ	ECEC-based healthy eating interventions may be cost-effective but the evidence is very uncertain.
Adverse consequences	3 studies reported no additional adverse consequences (i.e. incidents, negative feedback or parent complaints) as measured via staff self-report.	-	-	62 services (3 RCTs)	⊕○○○ Very low ^j	ECEC-based healthy eating interventions may have little to no effect on adverse consequences but the evidence is very uncertain.

* The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% confidence interval). The basis of assumed risk is provided in footnotes.

CI: confidence interval; **ECEC:** early childhood education and care; **RCT:** randomised controlled trial; **SD:** standard deviation; **SMD:** standardised mean difference

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aBaseline estimates and standard deviation used from [Vaughn 2021](#).

^bDowngraded one level for risk of bias: three RCTs were assessed as high risk of bias across three domains and one RCT was assessed a high risk of bias across one domain. Downgraded two levels for heterogeneity: $I^2 = 91%$; $> 75%$ considered considerable heterogeneity. Downgraded one level as publication bias was strongly detected via visual inspection of funnel plots, which indicated two outliers.

^cBaseline estimates and standard deviation used from [Kornilaki 2021](#).

^dDowngraded one level for risk of bias: seven RCTs were assessed as high risk of bias across three or more domains, two RCTs were assessed high risk of bias across two domains.

^eDowngraded one level for risk of bias: eight RCTs were assessed as high risk of bias across three or more domains, three RCTs were assessed high risk of bias across two domains. Downgraded one level for heterogeneity: $I^2 = 70%$; 50%-75% considered substantial heterogeneity. Downgraded one level as publication bias was strongly suspected from visual inspection of funnel plots, which indicated an outlier.

^fBaseline estimates and standard deviation used from [Yoong 2020a](#).

^gDowngraded one level for risk of bias: five RCTs were assessed as high risk of bias across three or more domains, two RCTs were assessed high risk of bias across two domains.

^hDowngraded one level for risk of bias: two RCTs were assessed as high risk of bias across three or more domains.

ⁱDowngraded one level for heterogeneity as there was some degree of heterogeneity of the measures used to assess this outcome. Downgraded two levels for indirectness as RCTs did not directly answer this research question, with different outcomes assessed. Downgraded two levels for imprecision due to small number of services analysed: 101 services were included in cost analysis. Downgraded one level for publication bias as RCTs were relatively small, all including fewer than 50 services; publication bias may be present.

^jDowngraded one level for indirectness as RCTs did not directly answer this research question, although similar outcomes were assessed. Downgraded two levels for imprecision due to small number of services analysed: 62 services were included in the analysis of this outcome. Downgraded one level for publication bias: all four RCTs were relatively small, all including fewer than 40 services for this outcome analysis; publication bias may be present.

BACKGROUND

Description of the condition

Dietary risk factors, including low fruit and vegetable consumption and consumption of non-core foods high in sodium, are the primary causes of death and disability globally (GBD 2017 Diet Collaborators). In 2017, dietary risk factors were collectively responsible for 11 million deaths and 255 million disability adjusted life years (DALYs) among adults (GBD 2017 Diet Collaborators). Extensive epidemiological evidence documents the association between poor diet and a range of chronic conditions including ischaemic heart disease, diabetes, respiratory diseases and certain types of gastrointestinal cancers (World Cancer Research Fund 2018). Internationally, both adults and children from low-, medium- and high-income countries do not meet population dietary recommendations for fruit, vegetables and whole-grain foods, and overconsume non-core foods (i.e. less healthy/discretionary foods) including sugar-sweetened beverages, processed meats and sodium (Development Initiatives 2018; GBD 2017 Diet Collaborators).

Early childhood is a foundational period for establishing healthy eating patterns that track into later life. A number of longitudinal studies show that dietary intake in early childhood can influence child growth, general health and developmental trajectories (Guerrero 2016; Koning 2016; Shrestha 2015; Waxman 2003). For example, unhealthy dietary intake in children as young as three years of age has been found to influence cardiovascular disease markers, including obesity, dyslipidaemia and high blood pressure, which can persist into adulthood (Berenson 1998; Castellano 2014; Rodrigues 2013; Turco 2018). Additionally, longitudinal studies demonstrate that the consumption of fruit and vegetables in childhood persist into later childhood and is associated with reductions in non-communicable diseases in adulthood (Maynard 2003; Ness 2005).

Description of the intervention

Leading health authorities, including the World Health Organization (WHO), have identified early childhood and education care (ECEC) services as important settings for public health action to promote child healthy eating (WHO 2012). These settings typically provide care, education and developmental activities for children outside their home, prior to formal compulsory schooling. ECEC services reach a large number of children aged up to six years (approximately 80% to 90% of young children in high-income countries) for prolonged periods of time (up to 30 hours per week; Baxter 2015; European Commission 2021; Kamerman 2007; OECD 2019). In many countries, children attend such services for the majority of the day, where they consume up to 70% of their daily energy requirements (Soanes 2001). In addition, authorities in many countries have developed regulations and guidelines for the sector that recommend that ECEC services create health-promoting environments to support young children with achieving recommendations outlined in national dietary guidelines (Australian Government 2009; Benjamin-Neelon 2011; Jackson 2021).

Given this, healthy eating interventions delivered in ECEC present a significant opportunity to improve population dietary intake and reduce the burden of disease associated with dietary risk factors. A Cochrane systematic review examining interventions

to improve fruit and vegetable intake in preschool-aged children (including both in attendance at ECEC and at home) found some evidence that child-feeding interventions and multicomponent interventions significantly increased child fruit and vegetable intake (Hodder 2020). Previous reviews, which have included a range of study designs, have also explored characteristics of ECEC settings associated with child diet (Matwiejczyk 2018; Van de Kolk 2019; Ward 2015; Yoong 2020b). These reviews report that several ECEC policies and practices, including: ECEC educator feeding practices (Ward 2015); increasing the availability and exposure to healthier options; increasing knowledge of educators and children via healthy eating education; parental/carer involvement; and supportive healthy eating policies (Matwiejczyk 2018; Van de Kolk 2019), may be associated with improved child dietary intake within the setting.

How the intervention might work

A number of theories and models have been used to explain how ECEC-based healthy eating interventions may work to influence child dietary intake. These include the socio-ecological model, social cognitive theory and social learning theory (Matwiejczyk 2018). Collectively, these theories posit that behaviour (e.g. child dietary intake) is influenced by a combination of personal and environmental factors and the social interactions and context in which these experiences occur, and are important determinants of child behaviour in the early years (Korin 2016; Nixon 2012). They suggest that interventions delivered in ECEC may influence child diet through targeting children and their parents, carers, educators and family (as key social influences), as well as the environmental characteristics that facilitate behaviour change (e.g. food availability). Healthy eating intervention strategies delivered in ECEC might include: the provision of healthy eating education and training to educators and parents/carers (to target knowledge and self-efficacy); supporting educators to implement positive feeding practices and role model healthy eating (to create a positive environment); modifying the environment of ECEC settings (including interventions to increase the availability of healthier foods and increasing implementation of healthy eating policies); or building partnerships between the service and parents/carers via the provision of resources or family participation in curriculum planning or interactive hands-on activities (Matwiejczyk 2018; Stacey 2017). Such theories are consistent with the three main components highlighted within the WHO Health Promoting Schools Framework: health curriculum; ethos and environment of schools; and partnerships/engagement with healthcare, community, families or a combination of these (Langford 2014). Although this framework was developed for the school setting, there are similarities in the context, structure and operational characteristics of ECEC settings and schools, and as such will be used to characterise interventions included within this review.

Why it is important to do this review

Despite recommendations to implement healthy eating programmes in ECEC, little is known about the impact of ECEC-based interventions on child dietary outcomes. An umbrella review of 12 systematic reviews describing healthy eating interventions in the ECEC setting reported mixed findings surrounding the effectiveness of such interventions on child diet (Matwiejczyk 2018). The most recent review describing ECEC-specific healthy eating interventions included 71 studies of any design published

up to April 2015, and undertook a narrative synthesis of included studies (Sisson 2016). Using vote-counting approaches, the review found that 87% of included healthy eating interventions ($n = 39$) delivered in ECEC had the intended effect on the target behaviour. Although more recent systematic reviews that include ECEC-based healthy eating interventions have been published (Morgan 2020; Nathan 2019; Van de Kolk 2019), none have summarised the evidence from randomised controlled trials (RCTs), which provide the most direct evidence of intervention effectiveness. Further, many previous reviews have lacked important information relevant to support decision-making and guide future practice, including cost-effectiveness of such interventions, their broader co-benefits (e.g. social/emotional and language and cognition), the presence of any unintended adverse consequences or their impacts on health equity (Wolfenden 2009). Such information is considered to be particularly important to support healthcare decision-making and allow for optimal allocation of resources.

As such, there remains considerable uncertainty overall regarding the impact of healthy eating interventions delivered in the ECEC setting, the components that may be associated with child dietary intake, the potential benefits on other child outcomes and limited detail on outcomes of interest (e.g. adverse consequences, economic analysis) to guide policy makers and practitioners in deciding to invest in such programmes for population-level implementation.

OBJECTIVES

To assess the effectiveness of healthy eating interventions delivered in ECEC settings for improving dietary intake in children aged six months to six years, relative to usual care, no intervention or an alternative, non-dietary intervention. The specific primary dietary outcomes included were: i) diet quality; ii) fruit consumption; iii) vegetable consumption; iv) fruit and vegetable consumption combined; v) non-core foods (i.e. less healthy/discretionary foods) consumption; and vi) sugar-sweetened beverage consumption.

Secondary objectives were to assess the impact of ECEC-based healthy eating interventions on child physical outcomes (e.g. child BMI, BMI z-score, weight, risk of overweight and obesity); language and cognitive outcomes (e.g. assessment of general development, early executive function); social/emotional outcomes (e.g. outcomes related to mental and behavioural outcomes); and quality-of-life outcomes. The review also summarised any cost/economic analysis and related adverse consequences of ECEC-based healthy eating interventions.

METHODS

Criteria for considering studies for this review

Types of studies

This review included RCTs (including cluster-RCTs, stepped-wedge RCTs, factorial RCTs, multiple baseline RCTs, and randomised cross-over trials) as these designs are considered the highest quality to establish causality and quantify intervention effects (McKenzie 2022b).

We excluded cluster-RCTs with fewer than two intervention sites and two control sites, as per Cochrane Effective Practice and Organisation of Care (EPOC) recommendations (EPOC 2021).

Types of participants

The primary targets of the interventions of the included studies were children aged between six months and six years (inclusive). Theories and models, such as the social ecological model, posit that child behaviour is influenced by individual, interpersonal, organisational, community and public policy factors (Korin 2016). As such, interventions that target parents, carers and ECEC staff as part of healthy eating interventions were also included as they are the primary providers of food to children and strongly influence child behaviour in the early years.

Participants in the studies included:

- children aged between six months to six years (inclusive) attending the ECEC service. Studies including children older than six years were included if the mean age of the study sample at baseline was six years or under or if more than 50% of the included population were aged six months to six years;
- parents, guardians or carers responsible for the care of children aged six months to six years; and
- professionals responsible for care provided to children attending the ECEC service, including service directors, educators, volunteers, cooks, or other employed staff.

We excluded studies that exclusively targeted children aged between zero and six months, as dietary interventions are likely different for this group, who rely solely on breast milk/human milk substitutes as their primary sources of nutrients. Studies targeting children with special needs or clinical conditions (e.g. those with a diagnosed disease or health condition) were also excluded due to potential differences in feeding practices or nutrition requirements.

Types of interventions

The review included healthy eating interventions that were delivered within an ECEC service to facilitate healthy eating for young children. The ECEC setting consists of formal paid or government-subsidised services such as preschools, nurseries, long day-care centres and kindergartens, as well as family day-care services (also known as family child-care homes and child minding, in which a small group of children is offered care within the educator's home), that offer care for children six years and under, prior to compulsory schooling (OECD 2014). We included interventions that targeted both the ECEC and other settings, such as the home, as long as the intervention was primarily delivered in ECEC (i.e. assessed as more than 50% of the intervention strategies were delivered within ECEC services or influenced the operation of ECEC services, or both).

For this review, healthy eating interventions could target children, parents, caregivers or educators' behaviour, centre environments, or broader policy context or other environments, or a combination of any of the above, that aimed to influence child diet. The WHO Health Promoting Schools Framework highlights three components that are integral to supporting settings-based health promotion, including: health curriculum; ethos and environment of schools; and partnerships/engagement with healthcare, community, families or a combination of these (Langford 2014). Specifically, the type of interventions are likely to include health curriculum (e.g. healthy eating education, formal and informal teaching and learning experiences to children), ethos and environment (e.g. healthy eating policies, food availability,

food service modification, staff training, nudge interventions) and partnerships or engagement (e.g. working with other organisations in the community, parents, families, healthcare providers).

To be eligible, interventions were required to include at least one Health Promoting Schools' component targeting child diet in the ECEC setting. Interventions that targeted other risk factors were included as long as there was a clear intervention component that sought to influence child diet. Both single- and multi-component interventions (i.e. interventions that include more than one component to influence child diet) were included. There were no restrictions on intervention duration.

We excluded interventions that focused specifically on examining malnutrition or malnourishment, as well as those focusing on obesity-management interventions (i.e. those that only included children classified as overweight or obese).

Control

We included studies that reported the outcomes of an intervention versus no intervention (control), delayed intervention (wait-list control), an active, alternative intervention that did not directly seek to influence child diet, or usual care. Some examples of usual care include the delivery of specific jurisdiction-funded health promotion programmes that target healthy eating in ECEC services (e.g. Munch & Move within New South Wales, Australia (Hardy 2010)), and subsidised programmes specifically targeting low-income populations (e.g. the Child and Adult Care Food Program in the USA (Chriqui 2020)). These programmes typically include training and support for ECEC providers to promote healthier food environments. We excluded studies that compared two healthy eating interventions only (with no control) as the review was primarily focused on understanding the effect of ECEC-based healthy eating interventions overall relative to a control, usual care or non-healthy eating intervention.

Types of outcome measures

We included studies only if they measured at least one dietary or physical (i.e. anthropometric) outcome. We only included studies that had a follow-up assessment that was at least three months or longer from baseline, regardless of active intervention length, as we were interested in understanding the longer-term impact of healthy eating interventions delivered in the ECEC setting.

Primary outcomes

Given the number of dietary outcomes examined within the studies, we limited our analysis of child dietary intake outcomes to those outlined in a core outcome set for early intervention studies to prevent obesity in early childhood (Brown 2022). Such measures included assessments of child intake that occurred during attendance at ECEC or overall dietary intake.

This included:

- overall diet quality (typically diet scores measuring the amount, quality and variety of foods consumed in a child's diet);
- consumption of fruit or vegetables, or fruit and vegetables combined (g/servings, percentage of children consuming);
- consumption of non-core foods as defined by the study (g/servings/times, percentage of children consuming); and
- consumption of sugar-sweetened beverages (g/ounces/mL).

Studies captured dietary intake using objective methods, such as plate waste audits or direct observations (Ball 2007), as well as subjective methods (e.g. parent-reported dietary intake), such as short diet questions, food frequency questionnaires, food diaries and 24-hour recalls. We excluded measures of foods or beverages that did not directly assess child consumption such as food provided to children (i.e. served or listed on ECEC menus), purchasing and selection of food and beverages.

Secondary outcomes

We included the following secondary outcomes.

Physical outcomes

We focused primarily on child anthropometry as outlined in the core outcome set for early childhood obesity prevention studies (Brown 2022). We included both objective (measured by trained researchers or ECEC staff) and subjective (parent-reported) measures of anthropometry.

This included:

- absolute weight in kilograms (kg);
- Body mass index (BMI);
- BMI z-score (using age-appropriate cut-offs (WHO 2021));
- risk of overweight and obesity; and
- waist circumference.

Language and cognitive performance outcomes

We included any measure of child language and cognitive performance (Lichtenberger 2005). This was likely to be subjective measures related to academic performance and cognitive function (parent- or ECEC staff-reported assessments) and could include:

- Kaufman Assessment Battery for Children (Lichtenberger 2009);
- Wechsler Preschool and Primary Scale of Intelligence (Wechsler 1989); and
- The Early Years Toolbox for Assessing Early Executive Function, Language, Self-Regulation, and Social Development (Howard 2017).

Social/emotional outcomes

We included any measure of child social and emotional outcomes. This was likely to be subjective measures (e.g. parent- or ECEC staff-reported assessments) related to mental health, emotional regulation and social behaviour (e.g. Child Social Behavior Questionnaire (Warden 2003)).

Quality-of-life outcomes

We included any measure of child quality of life. This was likely to be subjective measures reported by parents or ECEC staff (e.g. the Paediatric Quality of Life Inventory (Varni 2001)).

Cost

We included any estimates of the intervention absolute cost or assessment of the intervention cost-effectiveness, as assessed via internal project records, questionnaires or other measures. This could include:

- crude cost of programme to service;
- cost-effectiveness ratio;

- intervention delivery costs;
- average cost-effectiveness ratio; and
- relative value index.

Adverse consequences

We included any unintended adverse consequences of the interventions that could be assessed via questionnaires, surveys, direct observations, or ECEC service audits, and may be related to:

- child health (e.g. potential child injury (burns, cuts) during experiential learning activities); and
- staff or parent attitudes (e.g. complaints about healthy eating policies, feedback).

We excluded adverse consequences related to participation in the non-healthy eating component of interventions (e.g. injuries from participation in physical activity lessons).

Search methods for identification of studies

We undertook a search based on the search strategy used in a previously conducted Cochrane Review (Wolfenden 2020), adapted by a research librarian (DB) to suit our research question. The search was based on the following domains using Medical Subject Headings (MeSH) for 'diet/nutrition' and 'ECEC' and 'RCT' and 'humans' (Glanville 2020). Our search terms for each electronic database are outlined in Appendix 1.

Electronic searches

We undertook a systematic search using the following databases on 24 February 2022:

- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 2) in the Cochrane Library;
- MEDLINE (OVID) (1946 to present);
- Embase (OVID) (1947 to present);
- CINAHL Complete (EBSCO) (Cumulative Index to Nursing and Allied Health Literature; 1937 to present);
- PsycINFO (OVID) (1806 to present);
- ERIC (Proquest) (1966 to present);
- SCOPUS (Scopus) (1996 to present); and
- SPORTDiscus (EBSCO) (1930 to present).

We placed no language or time restrictions on the searches.

Searching other resources

Unpublished or grey literature searches

In addition to electronic database searches, we searched for relevant unpublished or grey literature publications using the following terms; 'childcare centre and/or center' and 'nutrition intervention':

- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch/);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov); and
- Google Scholar (scholar.google.com.au) (first 100 results).

Searching other resources

Additional searches included:

- handsearching reference lists of included studies;
- handsearching reference lists of relevant systematic reviews identified in the electronic search strategy; and
- contacting authors of relevant protocol papers identified by the electronic database searches.

Data collection and analysis

Selection of studies

Pairs of review authors (SY, ML, AL, JJ, CB, NP, SMc, LD, AG, TMcD) independently screened titles and abstracts of all studies using Covidence software. We resolved conflicts via consensus and via discussion with a third review author where necessary.

We obtained full-text articles for any study that could not clearly be excluded on the basis of study title and abstract. Pairs of review authors (SY, ML, AL, JJ, CB, LD, AG, TMcD) independently reviewed full-text articles in Covidence for their eligibility. Where we were unable to resolve discrepancies by consensus, we consulted a third review author to inform study inclusion. Authors of potentially relevant studies (SY, LW, CB, NP, JZJ, AG) were not involved in screening and adjudication for studies in which they were involved at title or full-text stage.

Data extraction and management

Pairs of independent, unblinded review authors (SY, ML, CB, JZJ, CL, JJ, AL, NP, SMc, TMcD) extracted data independently for included studies, using Microsoft Excel. A third review author (SY, AG, JJ) assessed any discrepancies for final decision-making.

For included studies, we used a piloted and adapted version of the Cochrane Public Health data extraction template to extract data on the following.

- Study characteristics: first author, publication year, country, study design, sample size
- ECEC characteristics: type of service (centre-based (preschool or long day care) or family day care), operational characteristics (public or private; full-time or part-time), location (urban or rural), socioeconomic characteristics (low-, middle- or high-income)
- Participant characteristics: age, gender, ethnicity, socioeconomic status
- Intervention characteristics: name of the programme, intervention description, duration, intensity of the intervention, intervention components, settings, dose and where they are implemented, statistical analysis, and classification according to the WHO Health Promoting Schools Framework
- Outcome definitions and time points of outcome measurement
- Study results relevant to our review outcomes
- Dropout rate
- Financial cost of the intervention
- Unintended adverse consequences of the intervention
- Funding source
- Conflict-of-interest statements

When data were only available in graph form, we extracted them using an online graph reader (automeris.io/WebPlotDigitizer).

We extracted data on all relevant outcomes, however, limited our analysis to that described above.

Authors of included studies (SY, LW, CB, NP, JZJ, AG) were not involved in the data extraction or risk of bias assessments for these studies.

Assessment of risk of bias in included studies

Two review authors (LD, ML, TD, AG, JJ) independently assessed risk of bias for individual studies, using the Cochrane risk of bias tool (RoB 1), described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), consistent with that outlined in the review protocol (Yoong 2021). Where required, a third review author (SY, ML for where SY was an author) adjudicated discrepancies regarding risk of bias that could not be resolved via consensus. We undertook data extraction in *Microsoft Excel* and assessed the following domains.

- random sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and research personnel by each outcome (detection bias);
- blinding of outcome assessment for each outcome (detection bias);
- incomplete outcome data reporting for each outcome (attrition bias);
- selective outcome reporting (reporting bias); and
- other sources of bias.

Where applicable, we also assessed risk of bias domains that are specific to cluster-RCTs, including:

- recruitment bias;
- baseline imbalance;
- loss of clusters;
- incorrect analysis; and
- contamination.

For studies that reported data on cost or adverse consequences in the intervention groups only, we assessed the following risk of bias domains, as we decided that other types of bias would not impact on these outcomes due to the nature of the design:

- random sequence (selection bias);
- allocation (selection bias);
- performance bias;
- detection bias;
- attrition bias; and
- reporting bias.

Based on risk of bias assessment, we judged risk of bias as ‘low’, ‘high’, or ‘unclear’ for each domain (Higgins 2011). We defined high overall study risk of bias as scoring high risk on three or more of the assessed risk of bias domains for the primary outcome. We conducted risk of bias assessments at the individual outcome level, as well as by overall study risk of bias (Higgins 2011). The risk of bias outcomes for all outcomes is presented in table form. For the

primary outcomes (dietary outcomes), we included these results narratively in text.

Measures of treatment effect

We focused on estimating the main effect of randomisation (i.e. intention to treat). Where two or more studies measured outcomes in the same way, we pooled quantitative measures of the primary and secondary outcomes in either a meta-analysis or a narrative synthesis. We selected the primary and secondary outcomes that allowed us to best answer the primary review aim.

Where all studies assessed an outcome using the same measure and metric (e.g. BMI, kg) we reported the measure of effect as the mean difference (MD). If studies used different measures or metrics to report the same outcome, we used the standardised mean difference (SMD) as the measure of effect. Where outcomes were binary, we estimated risk ratios (RR). We calculated 95% confidence intervals (CIs) and reported them with all measures of intervention effects (Deeks 2022). We used postintervention values in preference to change-from-baseline data, consistent with recommendations in the *Cochrane Handbook for Systematic Reviews of Interventions* and to maximise the number of studies that could be pooled (Deeks 2022). As all included studies were cluster-RCTs, we used cluster-adjusted estimates in our analysis.

Where studies did not provide standard deviations (SDs), we used other measures of variance provided including standard errors, CIs and P values to calculate SDs using the formulas outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2022). For economic outcomes, we undertook a brief economic commentary consistent with that outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* where sufficient data existed (Aluko 2022).

Unit of analysis issues

We extracted data from all included studies. For all studies, we assessed data at the level of individuals within a cluster level. For cluster-RCTs that did not appropriately account for clustering, we imputed missing intracluster correlation coefficient (ICC) values with the median ICC of other included studies in this review (median ICC = 0.02; Higgins 2022).

For multi-arm studies where multiple interventions were relevant to the aims of the review, we combined the estimates from multiple arms as we were interested in the overall impact of healthy eating interventions on child outcomes. We combined these data with data from parallel-arm studies in the meta-analyses. For factorial studies, we included only the main effect estimates of the intervention.

In the instance where a single study contributed multiple outcomes for the same group (i.e. one study reporting on two measures of fruit consumption), we selected the measure with the highest quality assessment methods (i.e. validated over non-validated scale). For studies that used the same questionnaire or measurement method to assess outcomes within the same group (e.g. they used the same questionnaire to assess servings of fruit and proportion of children meeting guidelines for fruit), we selected the measure that allowed for direct comparison with population-level guidelines (e.g. servings of fruit consumed overall rather than proportion of children consuming fruit) or were most commonly reported in the studies. For studies with multiple follow-up periods, we used

outcome data immediately postintervention where the follow-up time point was at least three months post-baseline.

Dealing with missing data

We assessed and reported missing outcome data and dropouts as reported by individual studies, including numbers, characteristics and reasons for dropout, in the included studies. For data that were not reported by individual studies and are essential for the calculation of an effect estimate, variability (e.g. SD) or other values important for inclusion in the meta-analysis (e.g. ICC), we took the following measures. If possible, we calculated missing values using other reported data in the study (e.g. 95% CIs). Where only the total sample size was reported, we assumed that the groups had equal sizes. We assumed missing ICC values to be 0.02 as this was the median of other studies included in the review. Where additional data were required for inclusion in the meta-analysis, we contacted the study authors and requested provision of the unpublished data. We documented evidence of potential reporting bias in the risk of bias tables.

Assessment of heterogeneity

We undertook meta-analysis for our primary and secondary outcomes. We evaluated heterogeneity using forest plots and examined them for asymmetry. In addition, we quantified statistical heterogeneity by calculating the I^2 statistic (Higgins 2003). Where study heterogeneity was considerable (defined as $I^2 > 75%$), we carried out prespecified subgroup analyses to explore its causes and present a narrative description of study characteristics to explain heterogeneity (Deeks 2022).

Assessment of reporting biases

We assessed reporting bias by comparing published reports with information provided in trials registers and protocols. We explored reporting bias in each of the meta-analyses that we conducted by plotting contour-enhanced funnel plots and visually assessing them for asymmetry and outliers. We also evaluated the presence of reporting bias by undertaking a subgroup analysis comparing smaller (< 400 participants) and larger studies (≥ 400 participants) where there was more than one study in the subgroup.

Data synthesis

The primary analysis included all interventions, as the primary purpose of the review was to assess the impact of healthy eating interventions delivered in ECEC settings on child outcomes. For both primary and secondary review outcomes, we used a random-effects meta-analysis to calculate pooled effects due to variation in key study characteristics, including differences in interventions and target participants. A mix of change-from-baseline and postintervention measurements were reported across studies and we combined these measurements. For outcomes where studies used the same outcome measure and metric, we estimated the treatment effect as the MD and combined it in one meta-analysis. This included the following outcomes: BMI, BMI z-score, absolute weight and waist circumference. For outcomes where studies used different outcome measures or metrics, we calculated the treatment effect as the SMD, and conducted separate meta-analyses for postintervention scores and change-from-baseline scores. We did this for all dietary outcomes, language and cognitive outcomes and social/emotional outcomes. For binary outcomes including risk of overweight and obesity, we reported risk ratios.

We completed the analysis using Review Manager Web (RevMan Web 2023) software. Where SMDs were used, we presented the results directly as well as re-expressed the SMDs to represent more clinically significant outcomes (e.g. servings of foods; Schünemann 2022a).

In instances where studies examined the same underlying constructs (i.e. fruit servings) but we could not combine data in a meta-analysis (due to insufficient/missing data or outcomes not described in the same way), we conducted a narrative synthesis using vote-counting approaches based on direction of effect in accordance with the procedures outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2022a). We classified effects based on direction of effect only. An intervention was 'positive' if the effect favoured the intervention and 'negative' if it did not favour the intervention, regardless of whether the effect crossed the null. We also generated harvest plots to provide a visual representation of direction of effect for all relevant dietary outcomes where there were more than two studies using recalculated SMDs where data were available. We presented this by service socioeconomic status and high or low risk of bias, consistent with that prespecified in the protocol (Yoong 2021). For these studies, we calculated SMDs, MDs and relative risks, where sufficient data existed to do so, and described direction of effect where it was not possible to calculate effects (Campbell 2020). For the narrative synthesis, we used vote-counting approaches to assess the consistency of effects to allow for assessment of certainty.

Subgroup analysis and investigation of heterogeneity

Where there were five or more studies overall and more than one study in each arm, we undertook subgroup analyses by the WHO Health Promoting Schools' components (i.e. health curriculum versus usual care/no intervention, ethos and environment versus usual care/no intervention, and partnerships versus usual care/no intervention) as long as the intervention included the component (regardless of whether it was a multicomponent intervention).

We undertook a subgroup analysis by high- and low-socioeconomic status where there were five or more studies included in the meta-analysis and more than one study in a subgroup, regardless of level of heterogeneity. Low socioeconomic status was as defined by the primary studies, including: where the majority of participants were located in areas of low socioeconomic status, as reported by the authors in the table of characteristics; only recruiting ECECs participating in programmes targeted at low-socioeconomic status populations (e.g. Head Start, Child and Adult Care Food Program); or where targeting populations frequently affected by systemic inequities (e.g. African Americans).

We conducted a number of subgroup analyses to explore the potential causes of heterogeneity, where the I^2 statistic was more than 75%. Where sufficient data were available (five studies or more studies included and more than one study in each arm), we undertook the following subgroup analyses (all specified a priori):

- population: child age (six months to two years (inclusive), and over two years);
- intervention: delivery using different modalities (such as telephone, internet, face-to-face combined) and delivery by different personnel (research, ECEC staff, healthcare

professionals, other experts) and setting (family day care or centre-based ECEC); and

- outcome: outcome assessed at 3 to 12 months from baseline (inclusive) and more than 12 months from baseline.

We did not undertake subgroup analyses by high-income and low-/middle-income countries as no studies took place in low- or lower-middle-income countries. We conducted subgroup analyses via statistical comparison as recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2022). In this instance, we only interpreted between-subgroup differences.

Sensitivity analysis

For all outcomes, we undertook a sensitivity analysis excluding studies that we had classified as high risk of bias (defined as assessed as high risk of bias on three or more domains). We also undertook sensitivity analyses excluding any industry-funded study.

Summary of findings and assessment of the certainty of the evidence

We used GRADE (Guyatt 2011; Schünemann 2022b) to assess the overall certainty of the available evidence for the following review outcomes (i.e. overall diet quality, fruit consumption, vegetable consumption, non-core foods consumption, sugar-sweetened beverage consumption; and key anthropometric outcomes including BMI, BMI z-score, prevalence of overweight and obese, and weight. Additionally, we summarised assessments related to cost data and adverse consequences. We presented these results in the summary of findings table using GRADEpro GDT software. Based on GRADE assessments, we considered level of certainty to be high, moderate, low or very low. This table also reports the number of included studies and participants, the treatment effect estimate and the assessment of the overall certainty of the body of evidence for that outcome. We also converted the SMDs to a common metric for all dietary outcomes. For diet quality, this was the Healthy Eating Index (scale of 0 to 100), for fruit, vegetables and sugar-sweetened beverages this was servings or portions, and for non-core foods this was times consumed. Two review authors independently made these assessments (SY, ML, SMc). We involved a third review author where we were unable to reach a consensus.

As per GRADE recommendations, we assessed the outcome measures against five relevant GRADE criteria to obtain an overall GRADE rating and provided an overall level of certainty of the evidence.

We considered the following criteria for lowering the level of certainty:

- risk of bias (serious defined as more than 50% of studies with a rating of high risk of bias on three or more domains and very serious as more than 75% of studies with a rating of high risk of bias on three or more domains);
- inconsistency (serious defined as I^2 statistic ranged between 50% to 75% (inclusive), very serious defined as I^2 statistic more than 75%);
- indirectness;
- imprecision (small total analysed sample in meta-analysis defined as < 400 participants); and
- publication bias.

As all studies were randomised trials, all outcomes began with a rating of high-certainty evidence and we downgraded them as applicable according to the above criteria. For the outcomes that were summarised and not synthesised via meta-analysis (i.e. cost and adverse consequences), we used the guidance outlined by Murad 2017 to assess the certainty of the evidence for these outcomes as well as the risk of bias domains described above. We documented our decisions to downgrade the certainty of the evidence for each criterion in the summary of findings table footnotes. In the summary of findings table we included all interventions compared to no intervention, usual-care control or an alternative, non-dietary intervention, with a time-period of three months or more following baseline data collection.

RESULTS

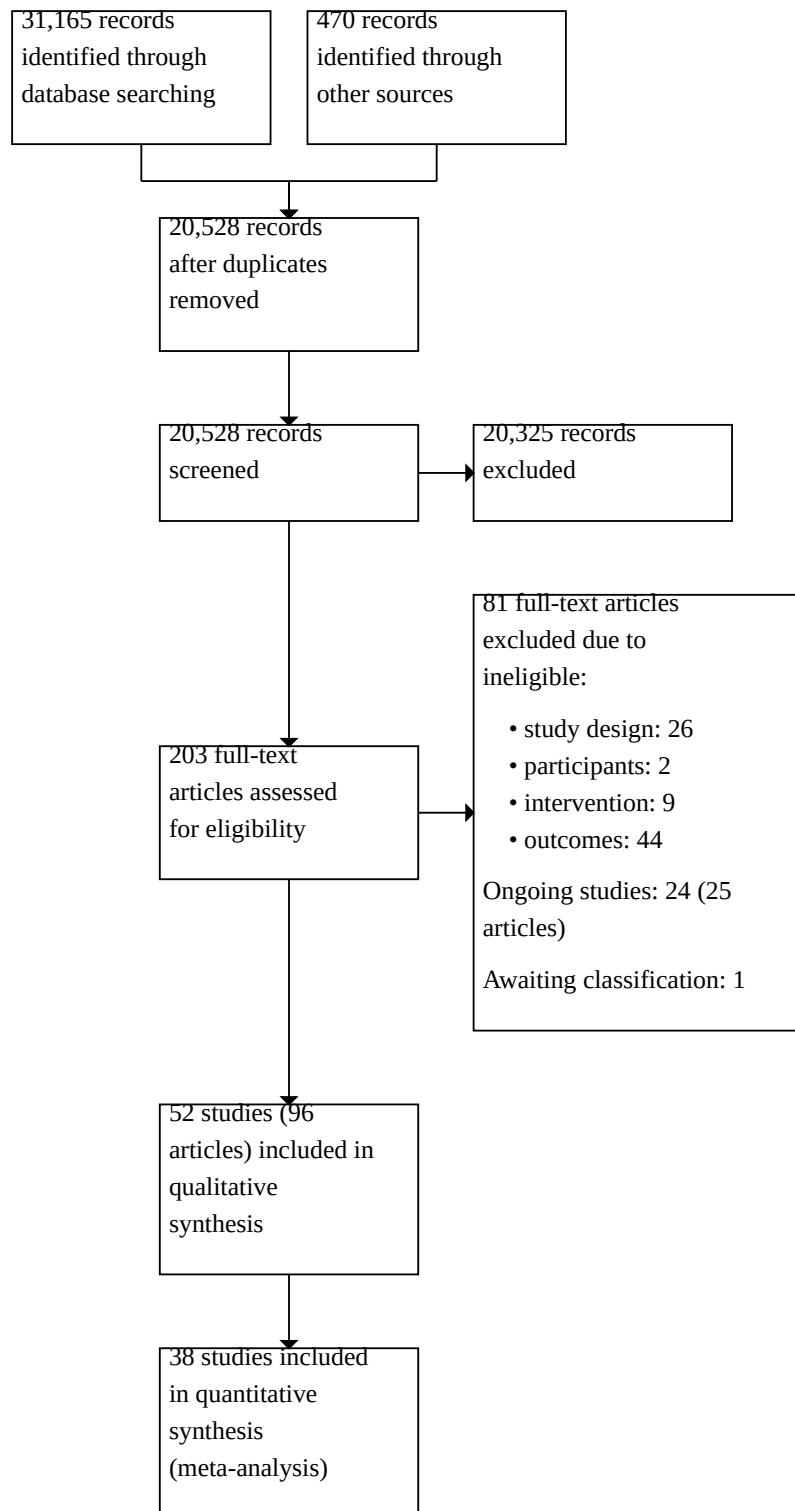
Description of studies

See [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of the search

We searched databases from their inception up to 24 February 2022. Results from the electronic search found 31,165 citations (see [Figure 1](#) (Moher 2009)). We identified an additional 470 records from our screening of reference lists of relevant reviews and included studies, and handsearching key journals. Following the removal of duplicates, we screened 20,528 titles and abstracts. Following title and abstract screening, we obtained 203 full texts for full-text screening.

Figure 1. Figure 1: Flow diagram



We included 52 studies that included 58 interventions (described across 96 articles), in this review (Alkon 2014; Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018).

We contacted authors of 13 included studies (Başkale 2011; De Bock 2011; De Coen 2012; Hodgkinson 2019; Kobel 2019; Lumeng 2017; Morris 2018; Natale 2014a; Natale 2014b; Natale 2021; Peñalvo 2015; Pinket 2016; Stookey 2017) to obtain additional data needed for inclusion in the meta-analysis and authors from six (46.2%) studies provided such data (Başkale 2011; Kobel 2019; Kornilaki 2021; Lumeng 2017; Morris 2018; Pinket 2016).

Included studies

See Characteristics of included studies.

Most included studies were undertaken in the USA (20 studies; Alkon 2014; Davis 2016; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Lumeng 2017; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Roberts-Gray 2018; Stookey 2017; Vaughn 2021; Ward 2020a; Witt 2012; Yeh 2018), Australia (6 studies; Jones 2015; Morris 2018; Pearson 2022; Seward 2018; Yoong 2020a; Zask 2012) and Israel (4 studies; Eliakim 2007; Lerner-Geva 2014; Nemet 2011a; Nemet 2011b). There were three studies in the UK (Hodgkinson 2019; Kipping 2019; Nekitsing 2019a), two each in Belgium (De Coen 2012; Vereecken 2009), Germany (De Bock 2011; Kobel 2019), the Netherlands (Toussaint 2021; Zeinstra 2018) and Norway (Blomkvist 2021; Kristiansen 2019), and one each in Greece (Kornilaki 2021), Spain (Peñalvo 2015), Colombia (Céspedes 2013), China (Hu 2009), Italy (Iaia 2017), Turkey (Başkale 2011), Canada (Leis 2020), Switzerland (Puder 2011), Finland (Ray 2020), and Mexico (Reyes-Morales 2016). One study was based in several European countries including Belgium, Bulgaria, Germany, Greece, Poland and Spain (Pinket 2016).

Four studies were conducted in countries classified as upper-middle-income (Başkale 2011; Céspedes 2013; Hu 2009; Reyes-Morales 2016). One cross-country study was conducted in five high-income countries and one upper-middle-income country (Pinket 2016). The remaining studies were conducted in high-income countries.

All studies were cluster-RCTs, with one being a 2 x 2 factorial trial (Nekitsing 2019a).

- Forty-seven studies included one intervention group and one control group (Alkon 2014; Başkale 2011; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel

2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yoong 2020a; Zask 2012; Zeinstra 2018).

- Four studies included two intervention groups and one control group (Blomkvist 2021; Lerner-Geva 2014; Lumeng 2017; Yeh 2018)
- One study reported on three intervention groups and one control (Nekitsing 2019a).

Of the 52 control groups:

- 14 were delayed intervention (Alkon 2014; Céspedes 2013; De Bock 2011; Fernandez-Jimenez 2019; Grummon 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Morris 2018; Namenek Brouwer 2013; Ray 2020; Roberts-Gray 2018; Vaughn 2021; Zask 2012);
- nine were alternative interventions that did not seek to influence child diet (Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Natale 2014a; Natale 2014b; Natale 2021; Ward 2020a); and
- 29 were usual care (Başkale 2011; Blomkvist 2021; Davis 2016; De Coen 2012; Eliakim 2007; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Lerner-Geva 2014; Lumeng 2017; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Reyes-Morales 2016; Seward 2018; Stookey 2017; Toussaint 2021; Vereecken 2009; Witt 2012; Yeh 2018; Yoong 2020a; Zeinstra 2018).

Usual-care control services continued their ECEC programme as usual, which may have included receiving training to implement health promotion programmes, which may have been broadly funded within a particular jurisdiction (e.g. Munch & Move in New South Wales, Australia, Sure Start in the UK, Head Start in the USA, Child and Adult Care Food Program in the USA, Mexican Social Security Institute in Mexico).

Two studies were conducted in family day care (Gans 2022; Ward 2020a), while the remaining studies took place in centre-based care (e.g. preschool, long day care, kindergarten, nurseries). The unit of randomisation was most frequently the ECEC service (e.g. centre-based care or family day care; 45 studies; Alkon 2014; Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Pearson 2022; Peñalvo 2015; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018), followed by rooms within an ECEC service (5 studies; Eliakim 2007; Lumeng 2017; Nemet 2011a; Nemet 2011b; Puder 2011), and communities/municipalities (2 studies; De Coen 2012; Pinket 2016).

The majority of studies (n = 48) reported on funding sources.

- Two studies reported that they received no funding support (Başkale 2011; Lerner-Geva 2014).
- One study received funding support from industry (Iaia 2017).
- Forty-two studies received funding support from government or charity organisations (Alkon 2014; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Jones 2015; Kipping 2019; Kobel 2019; Kristiansen 2019; Leis 2020; Lumeng 2017; Natale 2014a; Natale 2014b; Natale 2021; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Yeh 2018; Yoong 2020a; Zask 2012).
- Three studies reported receiving funding support from government or charity organisations and additional funding or in-kind support from industry (Nekitsing 2019a; Puder 2011; Zeinstra 2018).
- Four studies did not report on funding sources (Kornilaki 2021; Morris 2018; Namenek Brouwer 2013; Witt 2012).

Participants

- We considered 29 studies to be large, with 400 or more participants (Alkon 2014; Céspedes 2013; Davis 2016; De Coen 2012; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Hu 2009; Iaia 2017; Kobel 2019; Kristiansen 2019; Leis 2020; Lumeng 2017; Natale 2014b; Natale 2021; Nemet 2011a; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Yoong 2020a; Zask 2012).
- Twenty-three studies were small, with fewer than 400 participants (Başkale 2011; Blomkvist 2021; De Bock 2011; Eliakim 2007; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Jones 2015; Kipping 2019; Kornilaki 2021; Lerner-Geva 2014; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Nekitsing 2019a; Nemet 2011b; Pearson 2022; Seward 2018; Toussaint 2021; Witt 2012; Yeh 2018; Zeinstra 2018).

The largest study recruited 4964 children from 309 centre-based ECEC services (Pinket 2016). All studies, excluding one (Blomkvist 2021), included a sample of children over the age of two years.

Twenty-four studies were conducted in a low-socioeconomic status sample (Alkon 2014; Céspedes 2013; Davis 2016; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Jones 2015; Lumeng 2017; Natale 2014a; Natale 2014b; Natale 2021; Nemet 2011a; Nemet 2011b; Puder 2011; Stookey 2017; Toussaint 2021; Ward 2020a; Witt 2012; Yeh 2018), 11 studies were conducted in a sample that was not considered low-socioeconomic status (Başkale 2011; De Coen 2012; Eliakim 2007; Kipping 2019; Lerner-Geva 2014; Morris 2018; Pearson 2022; Peñalvo 2015; Ray 2020; Roberts-Gray 2018; Seward 2018), and 17 studies did not provide sufficient information to permit clear judgement (Blomkvist 2021; De Bock 2011; Hu 2009; Iaia 2017; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Namenek Brouwer 2013; Nekitsing 2019a; Pinket 2016; Reyes-Morales 2016; Vaughn 2021; Vereecken 2009; Yoong 2020a; Zask 2012; Zeinstra 2018).

Interventions

Of the 58 interventions 37 interventions included strategies that incorporated all three Health Promoting Schools' components (health curriculum, ethos and environment, and partnership).

- Forty-three interventions (in 39 studies) included curriculum strategies (Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hu 2009; Iaia 2017; Kobel 2019; Kornilaki 2021; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Witt 2012; Yeh 2018; Zask 2012).
- Fifty-six interventions (in 50 studies) included ethos and environment strategies (Alkon 2014; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018).
- Fifty interventions (in 47 studies) included partnership strategies (Alkon 2014; Başkale 2011; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kristiansen 2019; Leis 2020; Lumeng 2017; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012).

All interventions occurred in the ECEC setting, however, 22 studies also included the home setting (Davis 2016; De Bock 2011; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hodgkinson 2019; Kipping 2019; Kobel 2019; Kristiansen 2019; Lumeng 2017; Natale 2014a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Reyes-Morales 2016; Roberts-Gray 2018; Vereecken 2009), and three included the community (Davis 2016; De Coen 2012; Iaia 2017).

Intervention components were delivered by:

- the research team (43 interventions, 39 studies; Başkale 2011; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2011; Grummon 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale

2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Yeh 2018; Yoong 2020a; Zeinstra 2018);

- ECEC staff (50 interventions, 44 studies; Blomkvist 2021; Davis 2016; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hodgkinson 2019; Iaia 2017; Jones 2015; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Zask 2012; Zeinstra 2018)
- ECEC staff or healthcare staff, or both (31 interventions, 28 studies; Alkon 2014; Başkale 2011; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Gans 2022; Hodgkinson 2019; Iaia 2017; Jones 2015; Leis 2020; Lumeng 2017; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Puder 2011; Seward 2018; Stookey 2017; Ward 2020a; Yeh 2018; Yoong 2020a; Zask 2012).

Interventions were delivered via one or more modes, including:

- face-to-face (57 interventions, 51 studies; Alkon 2014; Başkale 2011; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018);
- telephone (12 interventions, 11 studies; Alkon 2014; De Coen 2012; Gans 2022; Jones 2015; Kipping 2019; Kornilaki 2021; Leis 2020; Lumeng 2017; Seward 2018; Ward 2020a; Yoong 2020a);
- online (20 interventions, 20 studies; Alkon 2014; Blomkvist 2021; De Coen 2012; Gans 2022; Jones 2015; Kipping 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Morris 2018; Nekitsing 2019a; Pearson 2022; Peñalvo 2015; Ray 2020; Seward 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Yoong 2020a); and
- written communication (50 interventions, 46 studies; Alkon 2014; Blomkvist 2021; Céspedes 2013; Davis 2016; De Coen 2012; Eliakim 2007; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018;

Seward 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Zask 2012).

Thirty-one studies described the theoretical basis of the interventions. Theoretical frameworks included:

- Piaget's Cognitive Development Theory (Başkale 2011);
- Social Cognitive Theory (Céspedes 2013; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Kipping 2019; Kobel 2019; Lumeng 2017; Natale 2021; Ray 2020; Roberts-Gray 2018; Vaughn 2021; Ward 2020a);
- Transtheoretical Model (Céspedes 2013; Fitzgibbon 2005);
- Socioecological Model (Davis 2016; De Coen 2012; Gans 2022; Grummon 2019; Kobel 2019; Natale 2014a; Puder 2011; Roberts-Gray 2018; Vaughn 2021; Ward 2020a);
- Social Learning Theory (De Bock 2011; Hodgkinson 2019);
- Zajonc's Exposure Effect (De Bock 2011);
- Self-Determination Theory (Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Ray 2020; Ward 2020a);
- Health Belief Model (Fitzgibbon 2013; Zask 2012);
- Damschroder's Consolidated Framework for Implementation Research (Jones 2015);
- Socioeconomic Framework (Kipping 2019);
- Funds of Knowledge (Kornilaki 2021; Morris 2018);
- Adult Learning Theory (Natale 2021);
- Reach Effectiveness Adoption Implementation and Maintenance Framework (Natale 2014b; Natale 2021);
- Behaviour Change Wheel (Pearson 2022);
- PRECEDE-PROCEED Model (Pinket 2016);
- Theory of Planned Behaviour (Ray 2020);
- Theory of Reasoned Action (Roberts-Gray 2018);
- Exchange Theory (Vaughn 2021);
- Social Marketing Approach (Vaughn 2021);
- Theoretical Domains Framework (Seward 2018; Yoong 2020a);
- Technology Acceptance Model (Yoong 2020a); and
- Competence Motivational Theory (Zask 2012).

Intervention duration ranged from between four to six weeks (Kornilaki 2021), and three years (Peñalvo 2015).

Outcomes

Thirty-eight studies reported on at least one child dietary intake outcome (Başkale 2011; Blomkvist 2021; De Bock 2011; De Coen 2012; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014b; Natale 2021; Nekitsing 2019a; Pearson 2022; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yoong 2020a; Zeinstra 2018). Studies assessed a range of continuous dietary outcomes, including: consumption of food groups (e.g. fruit, vegetables, snacks, breads and cereals, dairy, meat and alternatives, non-core foods); consumption of specific foods (e.g. carrots, pumpkin, grapes, yoghurt, French fries, biscuits); consumption of beverage types (e.g. sugar-sweetened beverages, water); consumption of specific beverages (e.g. soft drink, tea, plain milk, 100% fruit juice);

intake of macronutrients (e.g. fibre, fat, energy); intake of specific dietary components (e.g. sodium, sugars, saturated fatty acids); diet quality components (e.g. fruit, vegetables, whole grains); and overall diet quality.

The included studies assessed dietary outcomes using:

- parent- or ECEC staff-reported surveys, recall or diaries (19 studies; [Başkale 2011](#); [Blomkvist 2021](#); [De Bock 2011](#); [De Coen 2012](#); [Fitzgibbon 2005](#); [Fitzgibbon 2006](#); [Grummon 2019](#); [Hu 2009](#); [Iaia 2017](#); [Kobel 2019](#); [Kornilaki 2021](#); [Lerner-Geva 2014](#); [Morris 2018](#); [Natale 2014b](#); [Natale 2021](#); [Pinket 2016](#); [Puder 2011](#); [Ray 2020](#); [Reyes-Morales 2016](#));
- in-care observations by researchers (6 studies; [Gans 2022](#); [Jones 2015](#); [Kipping 2019](#); [Namenek Brouwer 2013](#); [Roberts-Gray 2018](#); [Ward 2020a](#));
- weighed plate waste (5 studies; [Leis 2020](#); [Nekitsing 2019a](#); [Pearson 2022](#); [Witt 2012](#); [Zeinstra 2018](#)), or
- a combination of two measures (8 studies; [Fitzgibbon 2011](#); [Fitzgibbon 2013](#); [Kristiansen 2019](#); [Lumeng 2017](#); [Seward 2018](#); [Vaughn 2021](#); [Vereecken 2009](#); [Yoong 2020a](#)).

Fifteen studies reported that the measure used was validated ([De Coen 2012](#); [Gans 2022](#); [Jones 2015](#); [Kipping 2019](#); [Kornilaki 2021](#); [Leis 2020](#); [Lerner-Geva 2014](#); [Morris 2018](#); [Namenek Brouwer 2013](#); [Natale 2014b](#); [Natale 2021](#); [Pearson 2022](#); [Pinket 2016](#); [Ray 2020](#); [Roberts-Gray 2018](#)), one study reported that one of the two measures used was validated ([Vereecken 2009](#)), and the remaining studies did not report on the validity of the measure. We extracted all data relating to dietary outcomes.

Thirty-six studies reported on at least one anthropometric outcome ([Alkon 2014](#); [Başkale 2011](#); [Céspedes 2013](#); [Davis 2016](#); [De Bock 2011](#); [De Coen 2012](#); [Eliakim 2007](#); [Fernandez-Jimenez 2019](#); [Fitzgibbon 2005](#); [Fitzgibbon 2006](#); [Fitzgibbon 2011](#); [Fitzgibbon 2013](#); [Grummon 2019](#); [Hodgkinson 2019](#); [Hu 2009](#); [Iaia 2017](#); [Kipping 2019](#); [Kobel 2019](#); [Kornilaki 2021](#); [Lerner-Geva 2014](#); [Lumeng 2017](#); [Natale 2014a](#); [Natale 2014b](#); [Natale 2021](#); [Nemet 2011a](#); [Nemet 2011b](#); [Peñalvo 2015](#); [Puder 2011](#); [Roberts-Gray 2018](#); [Stookey 2017](#); [Toussaint 2021](#); [Vaughn 2021](#); [Ward 2020a](#); [Witt 2012](#); [Yoong 2020a](#); [Zask 2012](#)). Continuous anthropometric outcomes included: BMI and BMI z-score; weight, weight z-score and weight-for-age z-score; body mass percentage; mid-upper arm circumference; waist circumference; skinfold thickness (e.g. sum, triceps, subscapular); fat-free index and fat-free mass index. Dichotomous anthropometric outcomes (as reported by studies) included: children classified as overweight, obese, at risk of being overweight or obese, at a healthy weight or underweight; and children classified with mid-upper arm circumference percentile (≤ 10 , > 10 to < 85 , or ≥ 85). Studies collected all anthropometric data using objective measures.

Language and cognitive outcomes were reported by two studies ([Puder 2011](#); [Ray 2020](#)). All outcomes were continuous and included: cognitive self-regulation; attention; and spatial working memory. Measures included the Konzentrations-Handlungsverfahren für Vorschulkinder ([Ettrich 2006](#)), Intelligence and Development Scales ([Grob 2009](#)), and items from the Child Social Behavior Questionnaire ([Warden 2003](#)). One study reported that the measure was validated.

Social or emotional outcomes were reported by two studies ([Fernandez-Jimenez 2019](#); [Ray 2020](#)). The outcomes, emotional comprehension and emotional self-regulation, were both continuous. Measures included the Test of Emotion Comprehension ([Pons 2004](#)), and items from the Child Social Behavior Questionnaire ([Warden 2003](#)). Neither study reported the validity of the measures.

Quality-of-life outcomes were reported by three studies ([Kipping 2019](#); [Puder 2011](#); [Yoong 2020a](#)). All were parent-reported and validated. They included total quality of life and quality-of-life components (e.g. physical function, emotional function, social function, nursery function). Measures were Paediatric Quality of Life Inventory ([Varni 2001](#)), and parent proxy version of KIDSCREEN-10 ([Ravens-Sieberer 2010](#)).

Costs related to the intervention were available for six studies ([Iaia 2017](#); [Kipping 2019](#); [Leis 2020](#); [Natale 2014b](#); [Stookey 2017](#); [Yoong 2020a](#)). Cost outcomes included: total cost of intervention; projected lifetime savings; cost for participants (e.g. cost per service, parental weekly food spend); average cost-effectiveness ratio and relative value index. Measures included: detailed staffing and financial records; nursery logs; parent-completed questionnaire; micro-costing; and service questionnaire; or were not reported. No study reported on the validity of cost measures.

Adverse consequences outcomes were explicitly reported by three studies ([Kipping 2019](#); [Pearson 2022](#); [Seward 2018](#)), including: increased occurrence of injury among children or staff; (incident or) adverse event; negative feedback; parent complaints or concerns; and percentage of meal waste. A further four studies reported that no adverse consequences were reported ([Eliakim 2007](#); [Fernandez-Jimenez 2019](#); [Fitzgibbon 2005](#); [Fitzgibbon 2006](#)), however, no specific measures or outcomes were reported. No study reported on the validity of adverse consequences measures.

Length of follow-up from baseline ranged between three months ([Blomkvist 2021](#); [Grummon 2019](#); [Kornilaki 2021](#); [Morris 2018](#); [Natale 2014a](#); [Witt 2012](#)), to three years ([Peñalvo 2015](#)), across outcomes.

Excluded studies

Following our review of 203 full texts, we excluded 81 articles for the following reasons: study design (n = 26), participants (n = 2), intervention (n = 9) and outcomes (n = 44). See [Figure 1](#).

Studies awaiting classification

We identified one study that we were unable to classify due to limited study information ([ChiCTR2200060958](#); [Characteristics of studies awaiting classification](#)).

Ongoing studies

We identified 13 relevant ongoing RCT protocols ([Armstrong 2019](#); [Barnes 2020](#); [Beckerman 2019](#); [Cosco 2021](#); [Helland 2016](#); [Lee 2019](#); [Malden 2018](#); [Mehdizadeh 2018](#); [Reeves 2018](#); [Sisson 2019](#); [Watt 2014](#); [Yin 2019](#); [Zarnowiecki 2021](#)), and 11 trial registrations, which did not have published or unpublished outcomes ([ISRCTN33134697](#); [NCT01890681](#); [NCT02580123](#); [NCT03575884](#); [NCT03601299](#); [NCT03668678](#); [NCT04082247](#); [NCT04140032](#); [NCT04164277](#); [NCT04711525](#); [NCT05112185](#); [Characteristics of ongoing studies](#)).

Risk of bias in included studies

See [Characteristics of included studies](#).

The risk of bias assessment for each study across all outcomes is summarised within [Figure 2](#) and support for judgements are provided in the [Characteristics of included studies](#) table. The risk of

bias assessments for the primary outcome are described in detail below. Risk of bias assessments are also summarised for each study in the main meta-analysis for each outcome (see [Analysis 1.1](#); [Analysis 2.1](#); [Analysis 3.1](#); [Analysis 4.1](#); [Analysis 5.1](#); [Analysis 6.1](#); [Analysis 7.1](#); [Analysis 8.1](#); [Analysis 9.1](#); [Analysis 10.1](#); [Analysis 11.1](#); [Analysis 12.1](#)).

Figure 2. Figure 2. Risk of bias summary

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias): Diet outcomes	Blinding of participants and personnel (performance bias): Physical outcomes	Blinding of participants and personnel (performance bias): Language and cognitive performance outcomes	Blinding of participants and personnel (performance bias): Quality of life outcomes	Blinding of participants and personnel (performance bias): Social/emotional outcomes	Blinding of participants and personnel (performance bias): Cost	Blinding of participants and personnel (performance bias): Adverse consequences	Blinding of outcome assessment (detection bias): Diet outcomes	Blinding of outcome assessment (detection bias): Physical outcomes	Blinding of outcome assessment (detection bias): Language and cognitive performance outcomes	Blinding of outcome assessment (detection bias): Quality of life outcomes	Blinding of outcome assessment (detection bias): Social/emotional outcomes	Blinding of outcome assessment (detection bias): Cost	Blinding of outcome assessment (detection bias): Adverse consequences	Incomplete outcome data (attrition bias): Diet outcomes	Incomplete outcome data (attrition bias): Physical outcomes	Incomplete outcome data (attrition bias): Language and cognitive performance outcomes	Incomplete outcome data (attrition bias): Quality of life outcomes	Incomplete outcome data (attrition bias): Social/emotional outcomes	Incomplete outcome data (attrition bias): Cost	Incomplete outcome data (attrition bias): Adverse consequences	Selective reporting (reporting bias)	Recruitment bias	Baseline imbalance	Loss of clusters	Incorrect analysis	Contamination	Other bias	
Alkon 2014	?	?	+							+														?	?	?	+	+	?	?	
Başkale 2011	+	?	?	+						?	+						+	+							?	?	+	?	?	?	?
Blomkvist 2021	+	+	+							+						+									+	+	+	+	?	?	+
Céspedes 2013	+	+	+							+															?	+	+	+	+	+	+
Davis 2016	+	+	+							+															?	+	+	+	+	?	?
De Bock 2011	?	?	+	+						+	+						+	+							+	?	?	+	+	?	?
De Coen 2012	?	+	+	+						+	+						+	+							?	+	+	+	+	?	?
Eliakim 2007	?	?	+							+															?	?	+	+	+	?	?
Fernandez-Jimenez 2019	?	?	+		+					+		?													+	+	+	+	+	?	?
Fitzgibbon 2005	?	?	+	+						+	+						+	+							?	?	?	+	+	?	?
Fitzgibbon 2006	?	?	+	+						+	+						+	+							?	?	+	+	+	?	?
Fitzgibbon 2011	?	?	+	+						+	+						+	+							?	?	+	+	?	?	?
Fitzgibbon 2013	?	?	+	+						+	+						+	+							?	?	?	+	+	?	?
Gans 2022	+	+	+							+							?								+	+	+	?	+	?	+
Grummon 2019	?	?	+	+						+	+						+	+							+	+	+	?	+	?	+
Hodgkinson 2019	+	+	+							+							+								+	+	+	+	?	?	+
Hu 2009	+	?	+	+						+	+						+	+							?	?	+	?	+	?	?
Iaia 2017	+	?	+	+			?			+	+						+	+							?	?	+	+	+	?	?
Jones 2015	+	+	+							?	+						?	?							?	+	?	+	+	?	?
Kipping 2019	+	+	+	+		+		?	?	+	+		+			?	?	+	+	+	+	+	+		?	+	+	?	+	?	?
Kobel 2019	?	?	+	+						+	+						+	?							?	?	+	+	+	?	?

Figure 2. (Continued)

Kipping 2019	+	+	-	+	-	?	?	+	+	-	?	?	-	-	-	-	?	+	-	?	-	-	?	+
Kobel 2019	?	?	-	+				-	+				-	?				?	?	+	-	-	?	?
Kornilaki 2021	+	?	-	+				-	+				?	+				+	?	?	?	-	?	-
Kristiansen 2019	?	+	-					?					-					?	+	+	?	-	?	+
Leis 2020	+	?	?			?		+				?	-				?	-	?	+	+	+	+	?
Lerner-Geva 2014	?	?	-	+				-	+				?	?				?	+	+	?	+	?	+
Lumeng 2017	+	?	?	+				?	+				+	+				?	+	+	+	+	+	+
Morris 2018	+	+	-					-					?					?	+	+	?	-	?	-
Namenek Brouwer 2013	+	+	-					+					?					?	+	?	+	-	?	-
Natale 2014a	?	?		+					+				-					?	?	?	-	-	?	?
Natale 2014b	-	?	-	+		+		-	+		+		?	?		+		?	-	?	?	+	?	+
Natale 2021	+	?	-	+				-	+				?	?				?	?	-	?	+	?	+
Nekitsing 2019a	+	+	-					+					-					?	+	+	+	+	?	?
Nemet 2011a	+	?		+					+				+					?	?	+	?	+	?	+
Nemet 2011b	+	?		+					+				+					?	?	+	+	+	?	?
Pearson 2022	+	+	?			?		+				?	+				?	-	+	+	-	+	+	+
Peñalvo 2015	?	?		+					+				+					+	?	?	-	+	?	?
Pinket 2016	+	+	-					-					?					?	+	+	?	-	+	+
Puder 2011	+	+	?	+	+	?		?	?	+	+	?	?	+	+	+	?	?	+	+	+	+	?	?
Ray 2020	+	+	-		?	?		-	-	-			?	?	?			?	+	?	?	+	?	?
Reyes-Morales 2016	+	?	-					-					?					?	-	+	?	-	?	+
Roberts-Gray 2018	?	?	?	+				+	+				+	+				+	?	+	+	+	?	?
Seward 2018	+	+	-			?		-				?	?			+		+	?	?	-	+	?	?
Stookey 2017	+	+	+			?		+				?		-		+		?	?	?	-	+	?	-
Toussaint 2021	+	?		+					+				?					-	?	?	?	+	?	?
Vaughn 2021	+	+	?	+				?	+				?	?				?	+	+	?	-	?	+
Vereecken 2009	?	+	-					-					-					?	?	?	?	?	?	?
Ward 2020a	+	+	?	+				+	+				+	+				?	?	?	?	+	?	+
Witt 2012	?	?	?					+					-					?	?	?	?	+	?	-
Yeh 2018	?	?		+					+				?					?	?	?	?	-	?	?
Yoong 2020a	?	+	?	+	-	?		+	+	-		?	-	-	-	?		+	-	?	-	+	?	+
Zask 2012	?	?		+					+				?					+	?	?	?	-	?	?
Zeinstra 2018	?	?	?					+					?					?	?	+	?	?	?	?

Allocation

We assessed 29 studies as low risk of bias for random sequence generation as studies used methods such as computerised random number functions, randomisation tables, opaque envelopes, or drawing names from a hat to generate random sequences, and allocation was either completed by an independent entity (e.g. uninvolved party, independent statistician, coordinating centre) or after baseline data collection, thereby preventing allocation from being pre-empted (Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; Gans 2022; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kornilaki 2021; Leis 2020; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Pinket 2016; Puder 2011; Ray 2020; Reyes-Morales 2016; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Ward 2020a). We assessed 22 studies as unclear risk of bias for random sequence generation as they did not describe the random sequence generation procedure for the primary outcome (Alkon 2014; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006;

Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Kobel 2019; Kristiansen 2019; Lerner-Geva 2014; Natale 2014a; Peñalvo 2015; Roberts-Gray 2018; Vereecken 2009; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018). We assessed one study as high risk of bias for random sequence generation as services were added to the control arm following randomisation and these additional centres do not appear to have been randomly chosen or assigned (Natale 2014b).

We assessed 21 studies as low risk for allocation bias as an independent statistician conducted allocation after baseline data collection (Blomkvist 2021; Céspedes 2013; Davis 2016; Gans 2022; Hodgkinson 2019; Jones 2015; Kipping 2019; Kristiansen 2019; Morris 2018; Namenek Brouwer 2013; Nekitsing 2019a; Pearson 2022; Pinket 2016; Puder 2011; Ray 2020; Seward 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Yoong 2020a). We assessed 30 studies as unclear risk as the method of allocation concealment was either not reported or it was unclear whether participants were aware of their allocation prior to recruitment

(Alkon 2014; Başkale 2011; De Bock 2011; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hu 2009; Iaia 2017; Kobel 2019; Kornilaki 2021; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Natale 2014a; Natale 2014b; Natale 2021; Nemet 2011a; Nemet 2011b; Peñalvo 2015; Reyes-Morales 2016; Roberts-Gray 2018; Toussaint 2021; Witt 2012; Yeh 2018; Zask 2012; Zeinstra 2018). We assessed one study as high risk of selection bias as ECEC services were aware of their treatment allocation prior to recruitment (De Coen 2012).

Blinding

Thirty-eight studies measured dietary outcomes. We assessed most of them as high risk of performance bias due to participants and ECEC service staff not being blind to group allocation (27 studies; Blomkvist 2021; De Bock 2011; De Coen 2012; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Lerner-Geva 2014; Morris 2018; Namenek Brouwer 2013; Natale 2014b; Natale 2021; Nekitsing 2019a; Pinket 2016; Ray 2020; Reyes-Morales 2016; Seward 2018; Vereecken 2009). For the remaining 11 studies with dietary outcomes, we assessed the risk of performance bias as unclear due to insufficient information on whether the lack of blinding would affect the outcome (Başkale 2011; Leis 2020; Lumeng 2017; Pearson 2022; Puder 2011; Roberts-Gray 2018; Vaughn 2021; Ward 2020a; Witt 2012; Yoong 2020a; Zeinstra 2018).

For 12 studies that measured dietary outcomes, we assessed the risk of detection bias as low because children's intake was either measured, observed or obtained from the parent or ECEC staff by a blinded outcome assessor (Fitzgibbon 2005; Gans 2022; Jones 2015; Leis 2020; Namenek Brouwer 2013; Nekitsing 2019a; Pearson 2022; Roberts-Gray 2018; Ward 2020a; Witt 2012; Yoong 2020a; Zeinstra 2018). We assessed 21 studies that measured dietary outcomes as high risk of detection bias because parents reported children's dietary intake, yet blinding of parents was either not reported, not possible, or likely broken (Blomkvist 2021; De Bock 2011; De Coen 2012; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hu 2009; Iaia 2017; Kipping 2019; Kobel 2019; Kornilaki 2021; Lerner-Geva 2014; Morris 2018; Natale 2014b; Natale 2021; Pinket 2016; Ray 2020; Reyes-Morales 2016; Seward 2018; Vereecken 2009). For the remaining five studies with dietary outcomes, we assessed the risk of detection bias as unclear due to multiple measurement methods used or unclear blinding (Başkale 2011; Kristiansen 2019; Lumeng 2017; Puder 2011; Vaughn 2021).

Incomplete outcome data

We assessed the risk of attrition bias as low for dietary outcomes for 10 studies as either data were available for all or most participants (with similar loss and reasons for loss between treatment groups) or we conducted sensitivity analysis to assess the impact of missing data (Başkale 2011; Fitzgibbon 2011; Grummon 2019; Hu 2009; Iaia 2017; Lumeng 2017; Pearson 2022; Puder 2011; Roberts-Gray 2018; Ward 2020a). We assessed the risk of bias as high for dietary outcomes for 14 studies due to the magnitude of missing data, large difference in proportions of participants followed up between treatment groups or use of complete-case analyses instead of the intention-to-treat principle (Blomkvist 2021; De Bock 2011; De Coen 2012; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2013; Kipping 2019; Kobel 2019; Kristiansen 2019; Leis 2020; Nekitsing 2019a; Vereecken 2009; Witt 2012; Yoong 2020a). We assessed risk of

attrition bias for dietary outcomes as unclear for 14 studies, as they provided insufficient information regarding loss to follow-up or due to the treatment of missing data (Gans 2022; Jones 2015; Kornilaki 2021; Lerner-Geva 2014; Morris 2018; Namenek Brouwer 2013; Natale 2014b; Natale 2021; Pinket 2016; Ray 2020; Reyes-Morales 2016; Seward 2018; Vaughn 2021; Zeinstra 2018).

Selective reporting

We assessed the risk of reporting bias as low for 13 studies, as the reported outcomes aligned with those outlined in a published protocol paper or trial registration (Blomkvist 2021; Fernandez-Jimenez 2019; Gans 2022; Grummon 2019; Hodgkinson 2019; Kipping 2019; Kornilaki 2021; Peñalvo 2015; Puder 2011; Roberts-Gray 2018; Seward 2018; Yoong 2020a; Zask 2012). For five studies, we assessed the risk of reporting bias as high, either because findings of prespecified outcomes were incompletely reported in the study or the study included outcomes that were not prespecified in the published protocol paper (De Bock 2011; Jones 2015; Leis 2020; Pearson 2022; Toussaint 2021). We assessed risk of reporting bias as unclear for the remaining 34 studies either because a published protocol paper or trial registration record was not identified, outcomes were vaguely or incompletely described in the protocol or trial registration or not all prespecified outcomes were reported in the study (Alkon 2014; Başkale 2011; Céspedes 2013; Davis 2016; De Coen 2012; Eliakim 2007; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Hu 2009; Iaia 2017; Kobel 2019; Kristiansen 2019; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pinket 2016; Ray 2020; Reyes-Morales 2016; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Zeinstra 2018).

Other potential sources of bias

All included studies were cluster-RCTs. As such, we assessed the potential risk of additional cluster-related biases.

Recruitment

We assessed the risk of recruitment to cluster bias as low for 16 studies as recruitment occurred prior to cluster randomisation (Blomkvist 2021; Céspedes 2013; Davis 2016; Gans 2022; Jones 2015; Kristiansen 2019; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Namenek Brouwer 2013; Nekitsing 2019a; Pearson 2022; Pinket 2016; Puder 2011; Ray 2020; Vaughn 2021). Eight studies recruited following cluster randomisation, so we deemed them to have high risk of bias as (De Coen 2012; Fernandez-Jimenez 2019; Grummon 2019; Hodgkinson 2019; Kipping 2019; Natale 2014b; Reyes-Morales 2016; Yoong 2020a). For the remaining 28 studies, we assessed recruitment bias as unclear due to insufficient information regarding participant recruitment (Alkon 2014; Başkale 2011; De Bock 2011; Eliakim 2007; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Hu 2009; Iaia 2017; Kobel 2019; Kornilaki 2021; Leis 2020; Natale 2014a; Natale 2021; Nemet 2011a; Nemet 2011b; Peñalvo 2015; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Zask 2012; Zeinstra 2018).

Baseline imbalance

We assessed 27 studies as low risk of bias for baseline imbalance because either there were no baseline imbalances that were likely

to influence the outcomes or adjusted analytic models controlled for any imbalances (Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Gans 2022; Hodgkinson 2019; Hu 2009; Iaia 2017; Kobel 2019; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Morris 2018; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Pinket 2016; Puder 2011; Reyes-Morales 2016; Roberts-Gray 2018; Vaughn 2021; Zeinstra 2018). We assessed three studies as high risk of bias due to baseline imbalances that were likely to influence the outcomes, but were not accounted for in the analysis (Fitzgibbon 2006; Fitzgibbon 2011; Natale 2021). For the remaining 22 studies, we assessed the risk of baseline imbalance bias as unclear due to insufficient information reported regarding baseline data (Alkon 2014; De Bock 2011; Fitzgibbon 2005; Fitzgibbon 2013; Grummon 2019; Jones 2015; Kipping 2019; Kornilaki 2021; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Peñalvo 2015; Ray 2020; Seward 2018; Stookey 2017; Toussaint 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012).

Loss of clusters

Regarding risk of bias due to loss of clusters, we assessed 20 studies as low risk of bias as either there was no loss of clusters, lost clusters were replaced prior to intervention or loss of clusters comprised a small percentage (< 20%; Higgins 2011), of the overall sample (Alkon 2014; Blomkvist 2021; Céspedes 2013; Davis 2016; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2013; Grummon 2019; Iaia 2017; Jones 2015; Leis 2020; Lumeng 2017; Namenek Brouwer 2013; Nekitsing 2019a; Nemet 2011b; Puder 2011; Roberts-Gray 2018). We assessed the risk of bias for loss of clusters as high for 10 studies as the loss of clusters could have impacted the results (De Bock 2011; Hodgkinson 2019; Kipping 2019; Kobel 2019; Natale 2014a; Pearson 2022; Peñalvo 2015; Seward 2018; Stookey 2017; Yoong 2020a). For the remaining 22 studies, risk of bias was unclear due to insufficient reporting regarding loss of clusters or the impact of lost clusters on the outcomes was unclear (Başkale 2011; Fitzgibbon 2011; Gans 2022; Hu 2009; Kornilaki 2021; Kristiansen 2019; Lerner-Geva 2014; Morris 2018; Natale 2014b; Natale 2021; Nemet 2011a; Pinket 2016; Ray 2020; Reyes-Morales 2016; Toussaint 2021; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Zask 2012; Zeinstra 2018).

Incorrect analysis

For risk of bias due to incorrect analysis, we assessed most studies as low risk of bias because clustering was taken into account in the analysis (38 studies; Alkon 2014; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Iaia 2017; Jones 2015; Kristiansen 2019; Leis 2020; Lerner-Geva 2014; Lumeng 2017; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Pearson 2022; Peñalvo 2015; Pinket 2016; Puder 2011; Ray 2020; Roberts-Gray 2018; Seward 2018; Stookey 2017; Toussaint 2021; Vaughn 2021; Ward 2020a; Witt 2012; Yoong 2020a; Zask 2012). We assessed 10 studies as high risk of bias as there was no accounting for clustering (Eliakim 2007; Hu 2009; Kipping 2019; Kobel 2019; Kornilaki 2021; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Reyes-Morales 2016; Yeh 2018). For the remaining four studies, we assessed the risk of bias due to incorrect analysis as unclear due

to insufficient information reported (Başkale 2011; Blomkvist 2021; Vereecken 2009; Zeinstra 2018).

Contamination

We assessed the risk of contamination bias as low for five studies (Leis 2020; Lumeng 2017; Pearson 2022; Pinket 2016; Toussaint 2021). We assessed the remaining 47 studies as unclear risk of bias due to insufficient information provided (Alkon 2014; Başkale 2011; Blomkvist 2021; Céspedes 2013; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Iaia 2017; Jones 2015; Kipping 2019; Kobel 2019; Kornilaki 2021; Kristiansen 2019; Lerner-Geva 2014; Morris 2018; Namenek Brouwer 2013; Natale 2014a; Natale 2014b; Natale 2021; Nekitsing 2019a; Nemet 2011a; Nemet 2011b; Peñalvo 2015; Puder 2011; Ray 2020; Reyes-Morales 2016; Roberts-Gray 2018; Seward 2018; Stookey 2017; Vaughn 2021; Vereecken 2009; Ward 2020a; Witt 2012; Yeh 2018; Yoong 2020a; Zask 2012; Zeinstra 2018).

Other bias

In terms of additional sources of bias, we assessed 22 studies as low risk of bias as there were no clear sources of other bias (Blomkvist 2021; Céspedes 2013; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Gans 2022; Grummon 2019; Hodgkinson 2019; Hu 2009; Kipping 2019; Kristiansen 2019; Lerner-Geva 2014; Lumeng 2017; Natale 2014b; Natale 2021; Nemet 2011a; Pearson 2022; Pinket 2016; Reyes-Morales 2016; Vaughn 2021; Ward 2020a; Yoong 2020a). We assessed five studies as high risk of bias because no funding statement was provided or because of potentially confounding, effect-modifying, and time-varying factors (Kornilaki 2021; Morris 2018; Namenek Brouwer 2013; Stookey 2017; Witt 2012). For 25 studies, we assessed the risk of other sources of bias as unclear because no conflict of interest statement was reported or there was insufficient information to assess whether an important risk of bias exists, or both (Alkon 2014; Başkale 2011; Davis 2016; De Bock 2011; De Coen 2012; Eliakim 2007; Fernandez-Jimenez 2019; Fitzgibbon 2005; Iaia 2017; Jones 2015; Kobel 2019; Leis 2020; Natale 2014a; Nekitsing 2019a; Nemet 2011b; Peñalvo 2015; Puder 2011; Ray 2020; Roberts-Gray 2018; Seward 2018; Toussaint 2021; Vereecken 2009; Yeh 2018; Zask 2012; Zeinstra 2018).

Overall risk of bias for primary outcome (across domains)

For dietary outcomes, we judged 19 studies to be at overall high risk of bias (assessed as high risk of bias on three or more domains; Blomkvist 2021; De Bock 2011; De Coen 2012; Fitzgibbon 2006; Fitzgibbon 2011; Fitzgibbon 2013; Grummon 2019; Hu 2009; Kipping 2019; Kobel 2019; Kornilaki 2021; Morris 2018; Namenek Brouwer 2013; Natale 2014b; Natale 2021; Reyes-Morales 2016; Seward 2018; Vereecken 2009; Yoong 2020a).

Assessment of reporting bias

Visual inspection of the funnel plots for the primary outcome found potential publication bias (as assessed via presence of outliers) for diet quality (in both directions from the pooled treatment effect) and vegetable consumption (in a positive direction from the treatment effect). Comparison of small and large studies for fruit, fruit and vegetable, non-core foods and sugar-sweetened beverage consumption found no subgroup differences in effects (see Figure 3; Figure 4; Figure 5; Figure 6; Figure 7).

Figure 3. Funnel plot: diet quality

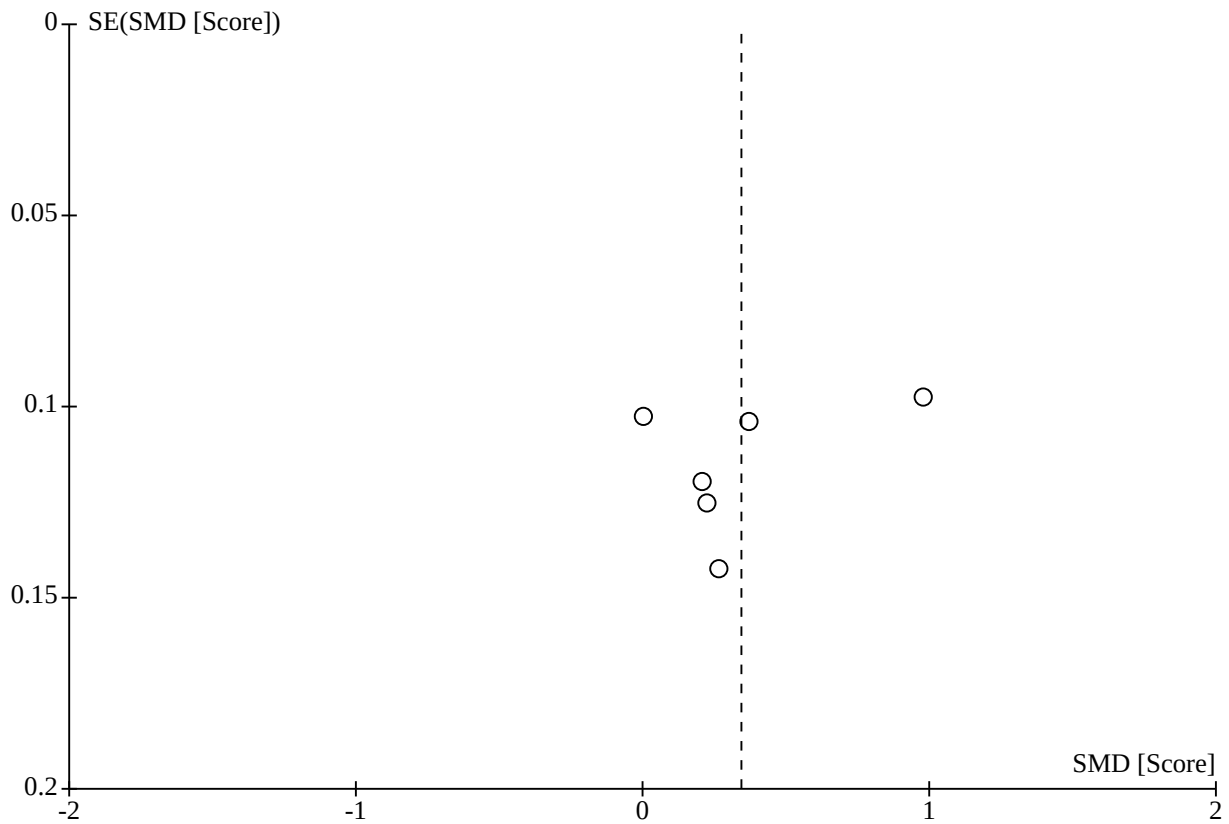


Figure 4. Funnel plot: fruit consumption

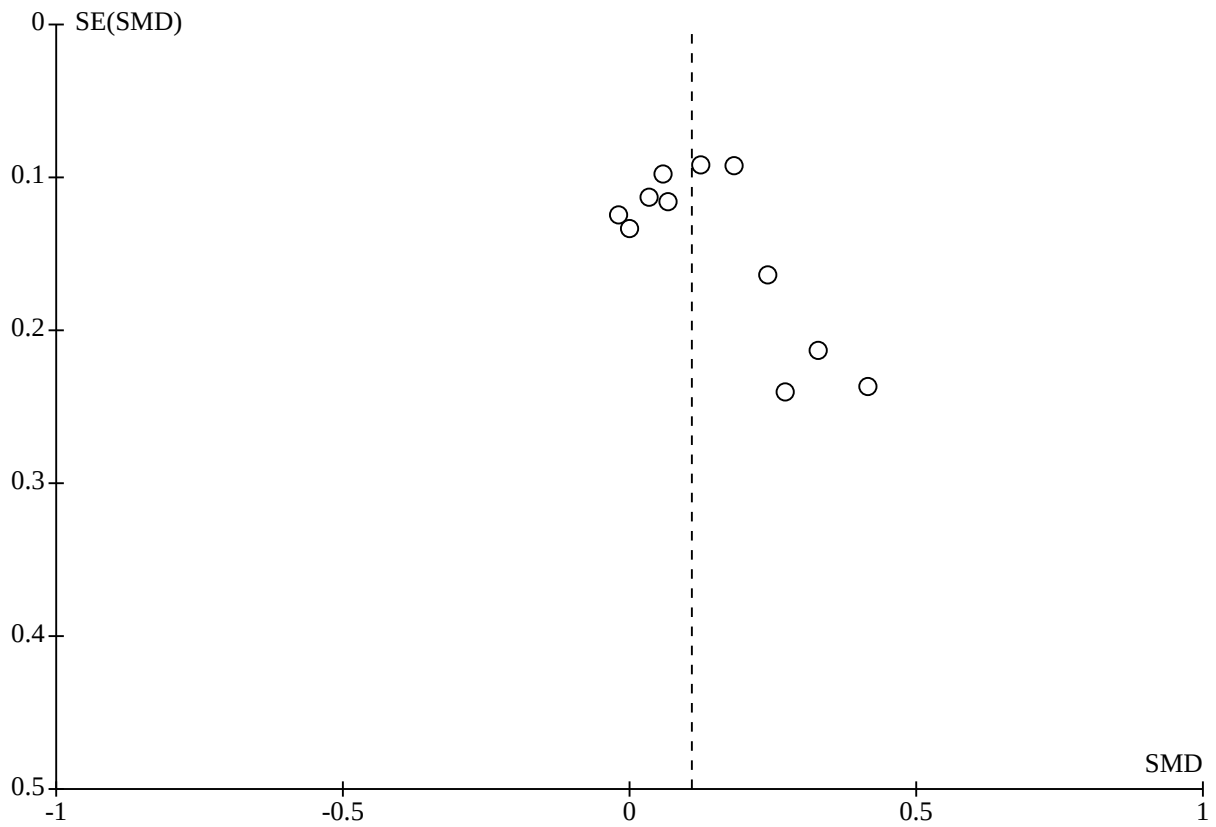


Figure 5. Funnel plot: vegetable consumption

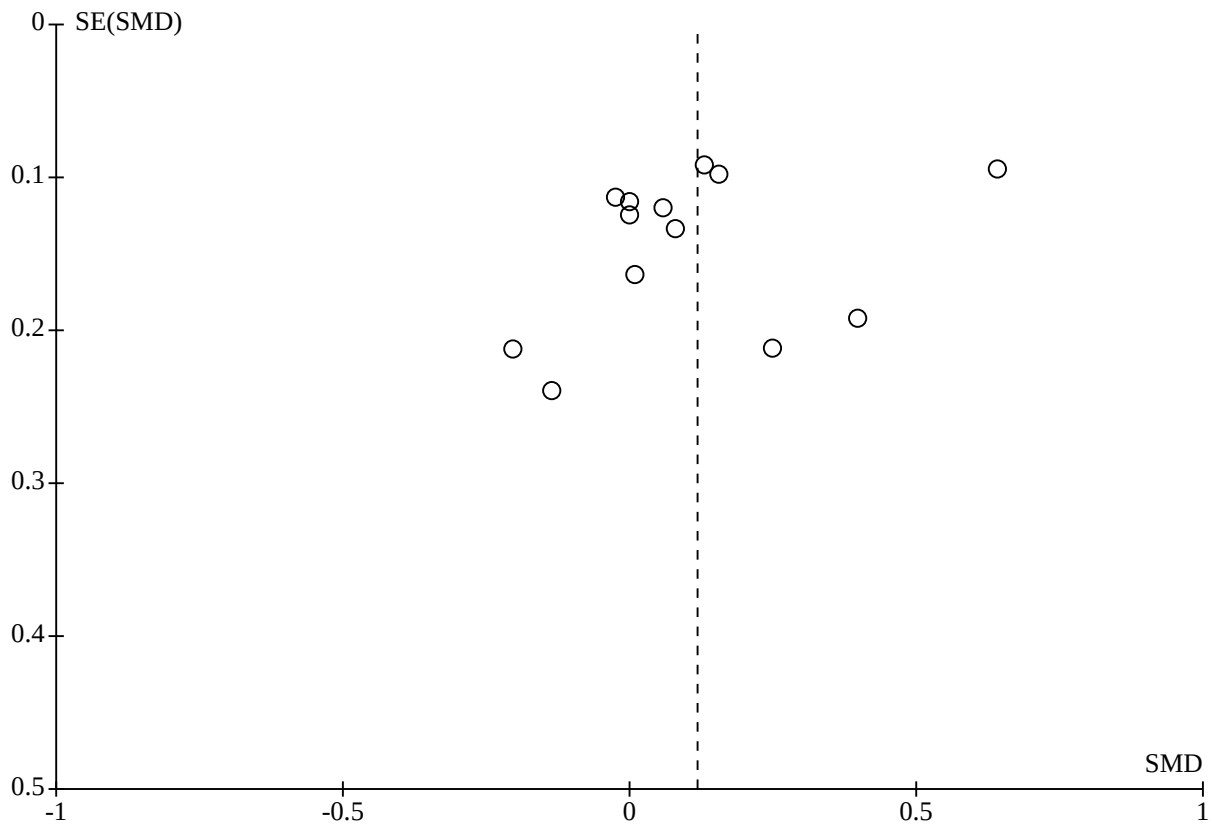


Figure 6. Funnel plot: non-core foods (i.e. less healthy/discretionary) consumption

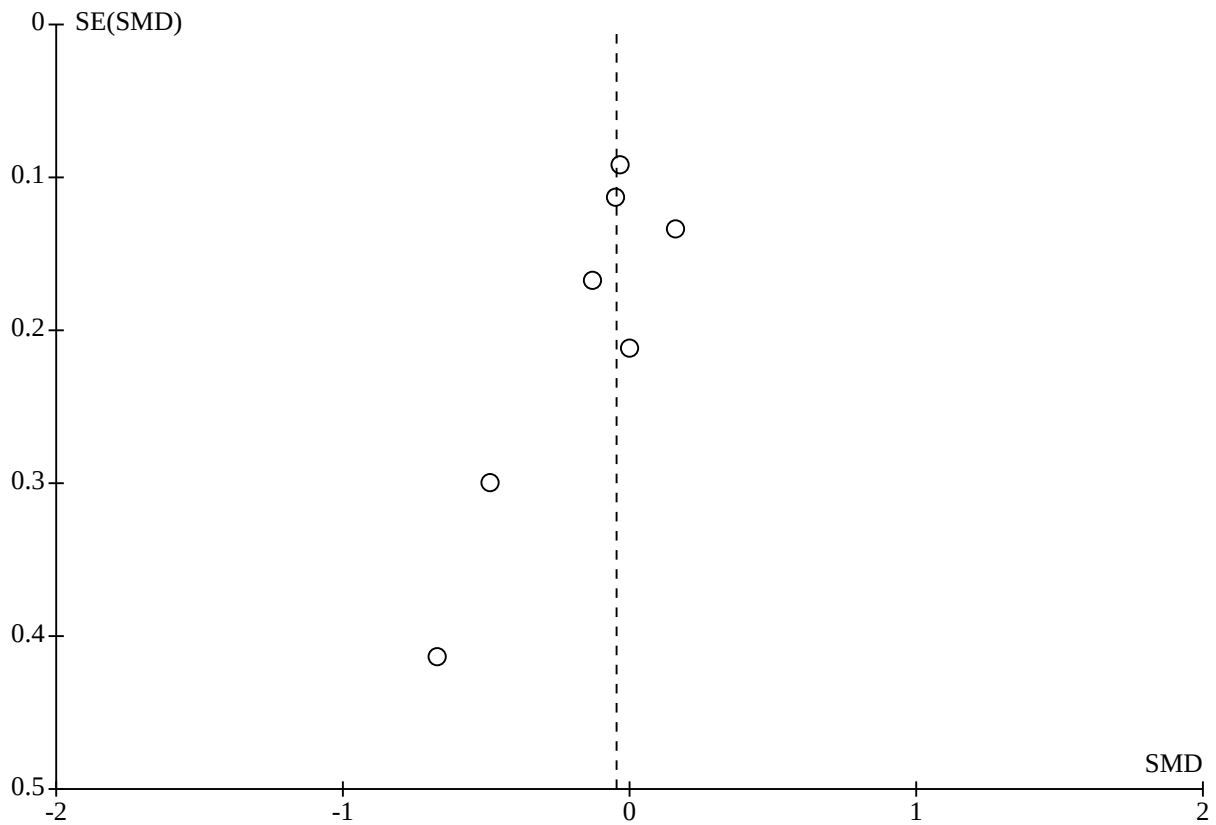
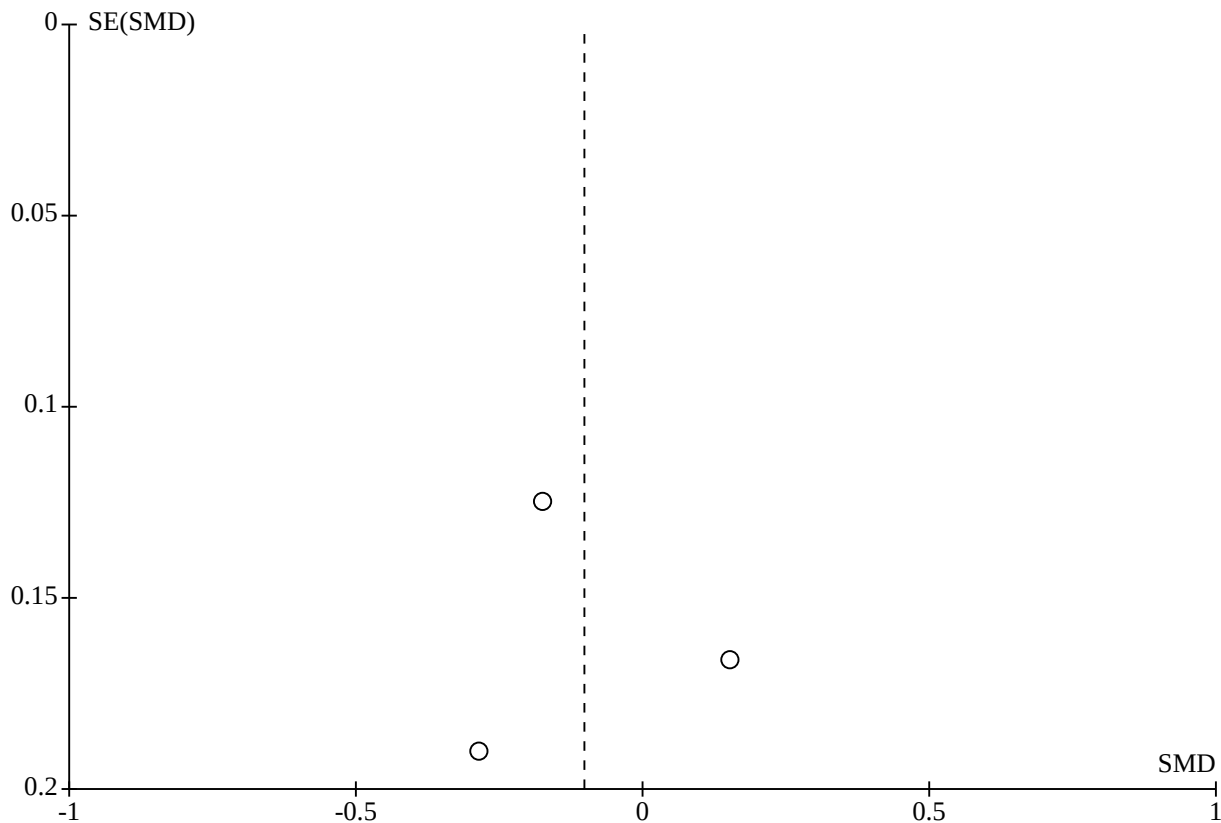


Figure 7. Funnel plot: sugar-sweetened beverage consumption



Effects of interventions

See: [Summary of findings 1 Comparison of early childhood education and care-based healthy eating interventions for improving the diet of children aged six months to six years](#)

See [Summary of findings 1](#) for the main comparison and [Table 1](#) for studies not pooled in the meta-analysis.

Primary outcomes: dietary intake

Diet quality

Six studies reported on some measure of overall diet quality in studies when comparing an ECEC-based healthy eating intervention with usual practice or no intervention. All measures were scale-based using either educator or parent self-reported measures ([Seward 2018](#); [Yoong 2020a](#)), direct observations ([Ward 2020a](#)), or a combination of observations in care and parent self-report at home ([Fitzgibbon 2011](#); [Gans 2022](#)). All were reported as continuous data, with higher scores indicating better diet quality, and were assessed as differences between groups at follow-up.

Pooled analysis including all six studies provided very low-certainty evidence that ECEC-based healthy eating interventions may improve child diet quality score relative to control (SMD 0.34, 95% CI 0.04 to 0.65; $P = 0.03$, $I^2 = 91\%$; 1973 children; [Analysis 1.1](#)). A SMD of 0.34 is equivalent to a score 3.68 points better in diet quality. We assessed the certainty of evidence as very low due to assessment of high overall risk of bias for three studies, high heterogeneity between studies ($I^2 = 91\%$) and strong detection of

publication bias as assessed via visual inspection of funnel plots. When we carried out a sensitivity analysis excluding the three studies at high risk of bias, results were no longer statistically significant, and the effect size was smaller (SMD 0.21, 95% CI -0.03 to 0.45; $P = 0.08$, $I^2 = 70\%$; 957 children; [Analysis 1.2](#)). We did not conduct a sensitivity analysis excluding industry-funded studies as there were none.

Subgroup analyses

Health Promoting Schools Framework

Two studies with 639 participants included curriculum strategies as part of the healthy eating intervention and had a lower pooled effect (SMD 0.10, 95% CI -0.11 to 0.32) on diet quality, compared to four studies that did not target curriculum strategies (SMD 0.46, 95% CI 0.08 to 0.84; 1334 children). However, no subgroup effect was noted ($P = 0.10$, $I^2 = 62\%$; [Analysis 1.3](#)). All six studies targeted ethos and environment, and partnerships, and as such, we could not undertake any subgroup analysis by the components.

Socioeconomic status

In the subgroup analysis by socioeconomic status, three studies were classed as specifically undertaken with low-socioeconomic status groups and had a lower pooled effect (SMD 0.30, 95% CI 0.16 to 0.44; 834 children) compared to three that were undertaken with high/unclear socioeconomic status groups (SMD 0.40, 95% CI -0.22 to 1.01; 1139 children). However, no subgroup effect was noted ($P = 0.76$; $I^2 = 0\%$; [Analysis 1.4](#)).

Other subgroup analyses

As the I^2 statistic was higher than 75%, we undertook prespecified subgroup analysis to explore heterogeneity by intervention modality and delivery personnel (Analysis 1.5; Analysis 1.6). The subgroup analysis suggests that delivery modalities that included a combination of face-to-face, telephone and online interventions ($I^2 = 62\%$), and delivery personnel that included healthcare professionals ($I^2 = 62.0\%$) may have contributed to the high heterogeneity of studies. We did not undertake subgroup analyses by setting, nor follow-up period, given that only one study was included in the subgroups.

Fruit consumption

Eighteen studies reported on fruit consumption outcomes, 15 of which reported on servings or portions, times (e.g. per day) or weight (e.g. grams) of fruit consumption. We undertook a pooled analysis including 11 of the 15 studies that reported on servings or portions, times or weight of fruit consumption. All outcomes were continuous and were assessed as difference between groups at follow-up. Pooled analysis provides moderate-

certainty evidence favouring those receiving the healthy eating intervention on servings of fruit consumed (SMD 0.11, 95% CI 0.04 to 0.18; $P < 0.01$; $I^2 = 0\%$; 2901 children; Analysis 2.1). A SMD of 0.11 is equivalent to an increase of 0.13 servings of fruit. We downgraded the certainty of evidence due to assessment of overall high risk of bias for seven studies. When we carried out a sensitivity analysis excluding the studies at high risk of bias, results were no longer statistically significant, with the effect size reduced (SMD 0.05, 95% CI -0.08 to 0.17; $P = 0.44$; $I^2 = 0\%$; 996 children; Analysis 2.2). We did not conduct a sensitivity analysis excluding industry-funded studies as there were none.

We were unable to include four of the 15 studies in the meta-analysis due to insufficient data (e.g. missing SD, missing sample size). An additional three studies reported on outcomes that were inappropriate for pooling due to substantial differences in the way the outcomes were reported (Natale 2014b; Natale 2021; Witt 2012). Witt 2012 reported on the percentage of fruit snacks children consumed in care, as assessed using a weighed food record, and Natale 2014b and Natale 2021 reported on rate of fruit consumption (per week). Four of the seven studies showed positive effects in the intervention group (see Figure 8 for harvest plot).

Figure 8. Harvest plot presenting direction of effect for studies not included in the meta-analysis for fruit consumption, vegetable consumption, non-core foods consumption and sugar-sweetened beverage consumption

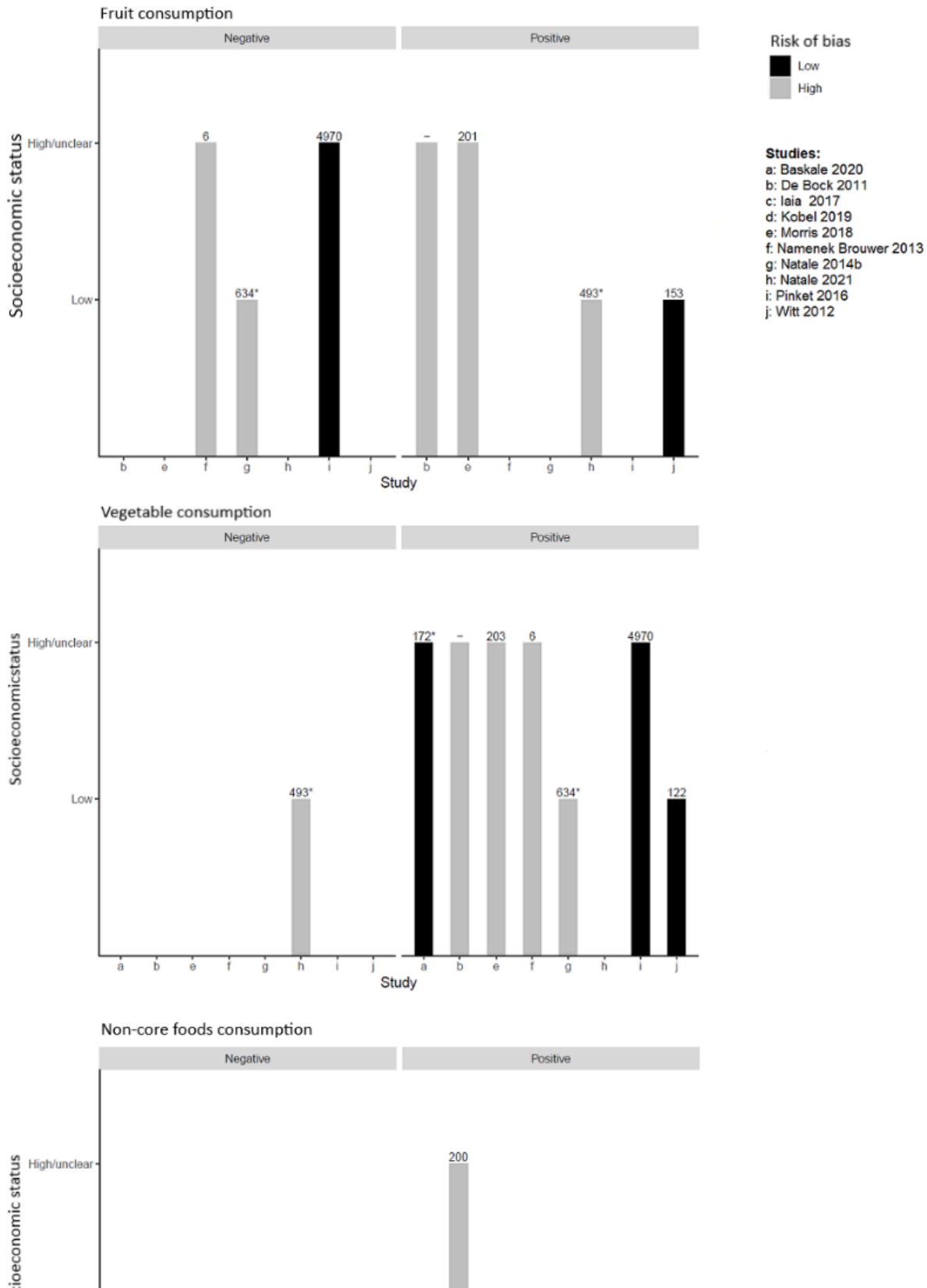
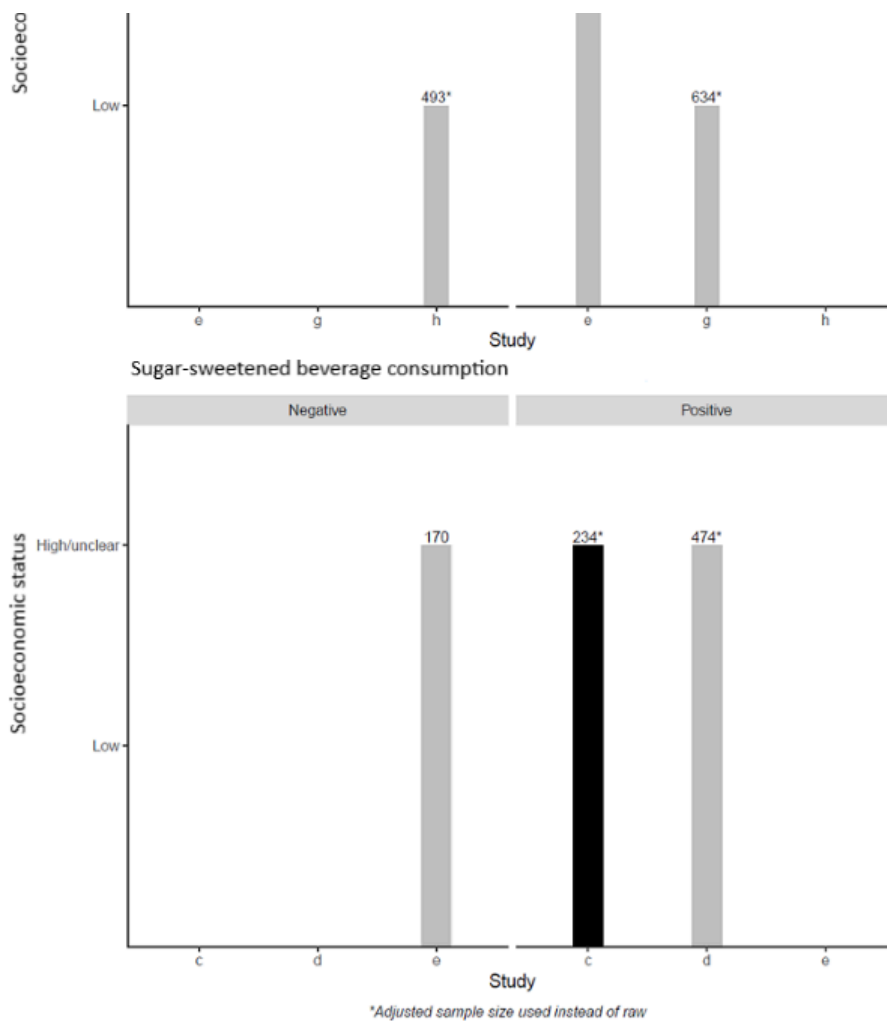


Figure 8. (Continued)



Subgroup analyses

Health Promoting Schools Framework

Seven studies with 2037 children targeted the curriculum and had a pooled effect of SMD 0.08 (95% CI -0.01 to 0.17), compared to four studies that did not target the curriculum (SMD 0.17, 95% CI 0.03 to 0.32; 864 children). No subgroup effect was noted ($P = 0.31$, $I^2 = 3.9\%$; [Analysis 2.3](#)). All studies targeted ethos and environment and only one did not target partnerships. As such, we did not undertake subgroup analysis by these components.

Socioeconomic status

Four studies were classed as undertaken with a low-socioeconomic status population. No subgroup effect was noted ($P = 0.75$, $I^2 = 0\%$; [Analysis 2.4](#)).

Other subgroup analyses

As we did not identify high statistical heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake further subgroup analyses.

Vegetable consumption

In total, 21 studies reported on vegetable consumption, with 17 of these studies reporting on servings or portions, times or weight of vegetable consumption. We undertook a pooled analysis with 13 of the 17 studies comparing an ECEC-based healthy eating intervention with usual practice/no-intervention control. Pooled analysis of vegetable servings consumed provides very low-certainty evidence with an estimated pooled effect of SMD 0.12 (95% CI -0.01 to 0.25; $P = 0.08$, $I^2 = 70\%$; 3335 children; [Analysis 3.1](#)). A SMD of 0.12 is equivalent to an increase of 0.14 servings of vegetables. We downgraded the certainty of evidence because we assessed eight studies at high overall risk of bias, there was considerable heterogeneity ($I^2 = 70\%$), and strong detection of publication bias as assessed via visual inspection of funnel plots. The effect size was reduced in the sensitivity analysis excluding those at high risk of bias (SMD 0.06, 95% CI -0.05 to 0.17; $P = 0.25$, $I^2 = 0\%$; 1276 children; [Analysis 3.2](#)). We did not conduct a sensitivity analysis excluding industry-funded studies as there were none.

Of the 17 studies, we were unable to include four in the meta-analysis due to insufficient data (e.g. missing SD, missing sample

sizes; De Bock 2011; Morris 2018; Namenek Brouwer 2013; Pinket 2016). An additional four studies reported on outcomes deemed as not appropriate for pooling in the meta-analysis due to differences in the way the outcomes were reported (Başkale 2011; Natale 2014b; Natale 2021; Witt 2012). Witt 2012 reported on the percentage of vegetable snacks children consumed in care, as assessed using a weighed food record, Başkale 2011 reported on weekly consumption of vegetables on a scale of 1 to 5, and both Natale 2014b and Natale 2021 measured rate of vegetable consumption (per week). Seven of the eight studies demonstrated improvements in the intervention group (see Figure 8 for harvest plot).

Subgroup analyses

Health Promoting Schools Framework

Nine studies with 2400 children targeted the curriculum in their healthy eating intervention and had a pooled effect of SMD 0.07 (95% CI -0.01 to 0.16), compared to four studies that did not target the curriculum (SMD 0.21, 95% CI -0.19 to 0.60; 935 children). No subgroup effect was noted ($P = 0.52$, $I^2 = 0\%$; Analysis 3.3). Eleven studies with 3042 children targeted partnerships in their healthy eating intervention and had a pooled effect of SMD 0.11 (95% CI -0.04 to 0.25) compared to two studies that did not target partnerships (SMD 0.19, 95% CI -0.19 to 0.57; 293 children). No subgroup effect was noted ($P = 0.69$; $I^2 = 0\%$; Analysis 3.4). All studies targeted ethos and environment, and as such, we could not undertake any subgroup analysis by these domains.

Socioeconomic status

Four studies were classed as specifically undertaken with low-socioeconomic status populations, and had a pooled effect of SMD -0.04 (95% CI -0.19 to 0.11; 717 children), compared to nine that were undertaken with high socioeconomic status populations (SMD 0.19, 95% CI 0.03 to 0.35; 2618 children). We observed a subgroup effect favouring the studies undertaken with high socioeconomic status populations ($P = 0.04$, $I^2 = 75.8\%$; Analysis 3.5).

Other subgroup analyses

- As we did not identify high statistical heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

Fruit and vegetable consumption

Six studies measured the consumption of fruit and vegetables together. We undertook a pooled analysis including four of the five studies that reported on servings of fruit and vegetables combined, comparing an ECEC-based healthy eating intervention with usual practice. Findings from the pooled analysis found no evidence of an effect on those receiving the intervention on servings of fruit and vegetable consumed (SMD 0.05, 95% CI -0.05 to 0.15; $P = 0.36$, $I^2 = 0\%$; 1547 children; see Analysis 4.1). The effect was increased in the sensitivity analysis excluding those at high risk of bias (SMD 0.08, 95% CI -0.05 to 0.21; $P = 0.23$, $I^2 = 0\%$; 919 children; Analysis 4.2). We did not conduct a sensitivity analysis excluding industry-funded studies as there were none.

We were unable to include one of the five studies in the meta-analysis due to missing data (Morris 2018). An additional study reported on an outcome (i.e. proportion of children consuming four or more servings of fruit) not included in the meta-analysis

(Iaia 2017). Both studies demonstrated favourable effects in the intervention group.

Subgroup analyses

Due to the small number of studies included in the meta-analysis (fewer than five), we did not undertake any subgroup analyses.

Non-core foods (less healthy/discretionary foods) consumption

Eleven studies that compared an ECEC-based healthy eating intervention with usual practice or no intervention reported on consumption of non-core foods (i.e. less healthy/discretionary). We included seven of the eight studies that reported on servings or portions, times or weight of non-core foods consumption in the meta-analysis. Pooled analysis including seven studies provides moderate-certainty evidence that healthy eating interventions likely result in little to no difference in number of times non-core foods are consumed (SMD -0.05, 95% CI -0.17 to 0.08; $P = 0.48$, $I^2 = 16\%$; 1369 children; Analysis 5.1). A SMD of -0.05 is equivalent to consuming non-core foods 0.04 times fewer per day. We assessed the certainty of evidence as moderate due to five studies assessed as overall high risk of bias. The pooled effect was higher (less favourable) when we excluded studies at high risk of bias, however, we included only two studies in this analysis (SMD 0.11, 95% CI -0.11 to 0.34; $P = 0.31$, $I^2 = 0\%$; 316 children; Analysis 5.2). We did not conduct a sensitivity analysis excluding industry-funded studies as there were none.

Of the seven studies, we were unable to include one study in the meta-analysis due to missing data (Morris 2018), and two further studies because they used measures we deemed not appropriate for pooling; Natale 2014b and Natale 2021 reported on the rate of snack consumption (per week). Two of the three studies favoured the intervention (see Figure 8 for harvest plot).

Subgroup analyses

Health Promoting Schools Framework

Three studies targeted the curriculum in their healthy eating intervention and had a smaller pooled effect (SMD -0.05, 95% CI -0.18 to 0.08; 982 children), compared to four studies that did not target the curriculum (SMD -0.13, 95% CI -0.48 to 0.22; 387 children). No subgroup effect was noted ($P = 0.69$, $I^2 = 0\%$; Analysis 5.3). All studies targeted ethos and environment, and only one study did not actively target partnerships and as such, we could not undertake any subgroup analysis by those components.

Socioeconomic status

We did not undertake a subgroup analysis by socioeconomic status as only one study was classed as taking place in a low-socioeconomic status population.

Other subgroup analyses

As we did not identify any high statistical heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

Sugar-sweetened beverage consumption

Seven studies comparing an ECEC-based healthy eating intervention with usual practice or no intervention reported on portions or servings of sugar-sweetened beverages consumed. Pooled analysis including three studies provides moderate-

certainty evidence that healthy eating interventions probably result in little to no difference in portions/servings of sugar-sweetened beverages consumed for those receiving the healthy eating intervention (SMD -0.10 , 95% CI -0.34 to 0.14 ; $P = 0.41$, $I^2 = 45\%$; 522 children; [Analysis 6.1](#)). A SMD of -0.10 is equivalent to 0.16 fewer portions or servings of sugar-sweetened beverage. We downgraded the certainty of evidence as we assessed two studies at high overall risk of bias. We did not conduct a sensitivity analysis as only one study was classed as low risk of bias.

We were unable to include one of the five studies that reported on servings/ounces (1 ounce = approximately 28 g) due to missing data ([Morris 2018](#)). An additional two studies used different measures including proportion of children not consuming any sugar-sweetened beverages daily ([Iaia 2017](#)), and proportion of children consuming sugar-sweetened beverages daily ([Kobel 2019](#)). Two of the three studies favoured the intervention (see [Figure 8](#) for harvest plot).

Subgroup analyses

Due to the small number of studies included in the meta-analysis (fewer than five), we did not undertake any subgroup analyses.

Secondary outcomes

BMI

Seventeen studies measured BMI. Pooled analysis of 15 studies found that ECEC-based healthy eating interventions may result in little to no difference in child BMI (MD -0.08 , 95% CI -0.23 to 0.07 ; $P = 0.30$, $I^2 = 65\%$; 3932 children; [Analysis 7.1](#)). Excluding those studies that had some industry contribution did not change the effect size (MD -0.10 , 95% CI -0.28 to 0.07 ; $P = 0.26$, $I^2 = 69\%$; 3319 children; [Analysis 7.2](#)). We assessed the certainty of evidence for BMI as low due to high heterogeneity and evidence of potential publication bias. We did not conduct a sensitivity analysis excluding by study quality as no studies were classified as high risk of bias. Two studies did not provide any data on BMI and were not included in the meta-analysis ([De Bock 2011](#); [Kornilaki 2021](#)). These studies reported that the intervention found no significant intervention effects on child BMI.

Subgroup analyses

Health Promoting Schools Framework

Thirteen studies targeted the curriculum in their healthy eating intervention and had a lower (more favourable) pooled effect (MD -0.13 , 95% CI -0.29 to 0.03 ; 3506 children) compared to two studies that did not target the curriculum (MD 0.27 , 95% CI -0.15 to 0.68 ; 426 children). No subgroup effect was noted ($P = 0.08$, $I^2 = 66.9\%$; [Analysis 7.3](#)). We did not undertake a subgroup analysis by ethos and environment as only one study did not actively target this as part of the intervention. All studies targeted partnership, and as such we could not undertake any subgroup analysis.

Socioeconomic status

Eleven studies with 2804 children were categorised as specifically undertaken with a low-socioeconomic status population and had a lower (more favourable) pooled effect (MD -0.10 , 95% CI -0.29 to 0.08) compared to four studies undertaken with high/unclear socioeconomic status groups (MD 0.02 , 95% CI -0.17 to 0.22 ; 1128 children). No subgroup effect was noted ($P = 0.36$, $I^2 = 0\%$; [Analysis 7.4](#)).

Other subgroup analyses

As we did not identify high statistical heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

BMI z-score

Twenty studies reported on BMI z-score outcomes; 19 studies reported on BMI z-score and one study reported on annual changes in BMI z-score ([Stookey 2017](#)). We were able to pool data from 17 of the 19 studies that reported on BMI z-scores, which found that healthy eating interventions may result in little to no difference in child BMI z-scores (MD -0.03 , 95% CI -0.09 to 0.03 ; $P = 0.36$, $I^2 = 0\%$; 4766 children; [Analysis 8.1](#)). We assessed the certainty of evidence for BMI z-score as high. The effect was reduced in the sensitivity analysis excluding studies at high risk of bias (MD -0.01 , 95% CI -0.08 to 0.06 ; $I^2 = 0\%$; $P = 0.80$, 14 studies, 3645 children; [Analysis 8.2](#)). We did not conduct a sensitivity analysis excluding industry-funded studies as there were only one study.

One study reported on a different measure (i.e. annual changes in BMI z-score) which we were unable to pool in the meta-analysis ([Stookey 2017](#)). We were also unable to include two of the 19 studies that reported BMI z-score in the meta-analysis as they did not provide total sample data ([Natale 2014a](#); [Peñalvo 2015](#)). All three studies found favourable effects of the intervention on child BMI z-score.

Subgroup analyses

Health Promoting Schools Framework

Twelve studies targeted the curriculum in their healthy eating intervention and had a lower (more favourable) pooled effect (MD -0.03 , 95% CI -0.09 to 0.04 ; 3867 children), compared to five studies that did not target the curriculum (MD 0.00 , 95% CI -0.17 to 0.18 ; 899 children). No subgroup effect was noted ($P = 0.75$, $I^2 = 0\%$; [Analysis 8.3](#)). We did not undertake a subgroup analysis by ethos and environment, or partnerships, as only one study did not actively target these components in their intervention.

Socioeconomic status

Ten studies with 2193 participants were categorised as specifically undertaken with low-socioeconomic status children and had a similar pooled effect (MD -0.01 , 95% CI -0.11 to 0.08), compared to seven studies undertaken with high/unclear socioeconomic status groups (MD -0.04 , 95% CI -0.13 to 0.06 ; 2573 children). No subgroup effect was noted ($P = 0.73$, $I^2 = 0\%$; [Analysis 8.4](#)).

Other subgroup analyses

As we did not identify high statistical heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

Absolute weight in kilograms (kg)

Nine studies measured weight and we included them all in the meta-analysis. Pooled analysis on these nine studies found that children who received the healthy eating intervention on average had lower weight by 0.23 kg (95% CI -0.49 to 0.03 ; $P = 0.09$, $I^2 = 0\%$; 2071 children; [Analysis 9.1](#)). We assessed the certainty of evidence as high. We did not conduct a sensitivity analysis by study quality as

only one study was classed as high risk and there were no industry-funded studies.

Subgroup analyses

Health Promoting Schools Framework

We did not undertake any subgroup analysis by the Health Promoting Schools' components as all studies targeted ethos and environment, and partnership as part of their intervention. Only one study did not target the curriculum.

Socioeconomic status

Six studies with 1600 children were categorised as specifically undertaken with low-socioeconomic status children and had a smaller (less favourable) pooled effect (MD -0.22, 95% CI -0.52 to 0.08) on weight compared to three studies undertaken with high/unclear socioeconomic status groups (MD -0.26, 95% CI -0.82 to 0.30; 471 children). No subgroup effect was noted ($P = 0.90$, $I^2 = 0\%$; [Analysis 9.2](#)).

Other subgroup analyses

As we did not identify high heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

Overweight and obesity

Five studies reported on number of children with overweight and obesity and we included them all in the meta-analysis. Pooled analysis of these five studies found that those receiving the healthy eating intervention have a reduced risk ratio of 0.81 (95% CI 0.65 to 1.01; $P = 0.07$, $I^2 = 0\%$; 1070 children) for overweight and obesity (see [Analysis 10.1](#)). We assessed the certainty of evidence as high. This equates to an absolute risk reduction of 19%, however, the 95% CI indicates possible positive and negative effects.

Subgroup analyses

Health Promoting Schools Framework

We did not undertake any subgroup analysis by the Health Promoting Schools' components as all studies targeted partnerships and only one did not target ethos and environment, or the curriculum as part of their intervention.

Socioeconomic status

Two studies with 806 children were categorised as specifically undertaken with low-socioeconomic status children and had a pooled effect of RR 0.86 (95% CI 0.67 to 1.11) on weight compared to three studies undertaken with high/unclear socioeconomic status groups (RR 0.69, 95% CI 0.43 to 1.09; 264 children). No subgroup effect was noted ($P = 0.40$, $I^2 = 0\%$; [Analysis 10.4](#)).

Other subgroup analyses

As we did not identify high heterogeneity in the primary analysis ($I^2 < 75\%$) we did not undertake any further subgroup analyses.

Waist circumference

Three studies reported on the impact of the ECEC-based healthy eating intervention on waist circumference. Pooled analysis on two studies estimated a reduction in waist circumference for those receiving the healthy eating intervention by MD 0.82 cm (95% CI -1.35 to -0.29; $P = 0.002$; $I^2 = 0\%$; 838 children; [Analysis 11.1](#)).

[Peñalvo 2015](#) did not provide a sample and as such could not be included in the meta-analysis. The study authors reported a favourable effect of the intervention on waist circumference.

Subgroup analyses

Due to the small number of studies included in the meta-analysis (fewer than five), we did not undertake any subgroup analyses.

Language and cognitive outcomes

Two studies reported on language and cognitive outcomes. [Ray 2020](#) reported on the effect of vegetable tasting sessions and nutrition games on cognitive self-regulation skills using five items derived from the Child Social Behaviour Questionnaire, rated on a scale of 1 to 3, previously used in the Millennium Cohort Study on three year olds. The study found evidence of a between-group difference (SMD 0.05, 95% -0.14 to 0.24; 432 children).

[Puder 2011](#) found varying evidence of an effect of the intervention on measures of concentration, assessed using a validated measure, Konzentrations-Handlungsverfahren für Vorschulkinder. The study found a reduction in attention measured in minutes (SMD -0.06, 95% CI -0.29 to 0.16; 309 children) and an increase in attention measured by number of correct cards (SMD 0.02, 95% CI -0.17 to 0.21; 434 children), and in spatial working memory (SMD 0.12, 95% CI -0.07 to 0.31; 434 children).

Social/behavioural outcomes

Two studies reported on social and behavioural outcomes. [Fernandez-Jimenez 2019](#) reported on the impact of a multi-component, ECEC-based healthy eating intervention that included education meetings with children and family and 11 activities delivered by ECEC educators. The authors reported on child scores on the Test of Emotion Comprehension questionnaire that was used to assess emotional understanding, and found favourable effects (SMD 0.15, 95% CI -0.09 to 0.40; 282 children).

[Ray 2020](#) reported on the effect of vegetable tasting sessions and nutrition games on emotional self-regulation skills using five items derived from the Child Social Behaviour Questionnaire rated on a scale of 1 to 3, previously used in the Millennium Cohort Study on three year olds. The study found evidence of a between-group difference (SMD 0.08; 95% -0.11 to 0.26; 432 children).

Child quality of life

Three studies comparing an ECEC-based healthy eating intervention with usual practice or no intervention reported on a measure of quality of life. All measures were validated, score-based and continuous, including the Paediatric Quality of Life Inventory (PedsQL) 4.0 ([Kipping 2019](#); [Puder 2011](#)), and parent proxy version of KIDSCREEN-10 ([Yoong 2020a](#)). Pooled analysis of all three studies found no evidence of effect of those receiving the ECEC-based healthy eating intervention on child quality of life (SMD 0.07, 95% CI -0.09 to 0.23; $P = 0.37$, $I^2 = 0\%$; 644 children; [Analysis 12.1](#)).

Subgroup analyses

Due to the small number of studies included in the meta-analysis (fewer than five), we did not undertake any subgroup analyses.

Cost assessments

Six studies presented cost assessments of ECEC-based interventions with varying levels of detail. Only one study undertook a formal economic analysis examining the impact of a web-based menu-planning intervention to improve child dietary intake in ECEC (Yoong 2020a). This was conducted on the primary outcome of menu compliance with dietary guidelines rather than on child diet, and assessed the impact of an online menu planning program together with health promotion practitioner support relative to usual care. The prospective economic evaluation of the intervention versus usual practice was conducted from a modified societal perspective over 12 months. A modified societal perspective allows for the financial implications of various stakeholders to be taken into account. This economic analysis was constrained to those who would be impacted financially by the intervention, and as such included the health services (as the organisation providing implementation support) and ECEC services (as the ones enacting the changes).

At 12-month follow-up, these costs were calculated to be AUD 4634 per centre for intervention services and AUD 7640 per centre for usual practice services. The mean difference in total cost (intervention plus menu planning and review investment) was -AUD 482 (95% uncertainty interval (UI) -AUD 859 to -AUD 56). That is, the average cost per intervention service would be AUD 482 less per year than for usual practice services. The average cost-effectiveness ratio for usual practice was -AUD 2897 and the Relative Vigour Index was calculated to be 1.11 and should be interpreted to mean that the intervention offers better outcomes at an acceptable cost.

Natale 2014b undertook a cost analysis of the Healthy Caregiver-Healthy Children Program (HC2) that was targeted primarily towards low-income, ethnically diverse children in the USA. The HC2 intervention consisted of: implementing daily nutrition- and physical activity-focused curricula for teachers, parents, and separately, for children; providing technical assistance with menu modifications; and the creation of centre policies on dietary requirements for meals and snacks, time spent engaging in physical activity and limited television viewing. This was delivered over 12 months, with booster sessions in years 2 and 3. The total cost of HC2 was valued at USD 206,319 (estimated at a cost of USD 114 per child in year 1, and USD 29 per child in years 2 and 3), totalling USD 172 per child.

Leis 2020 undertook a study to describe the implementation costs of the Saskatchewan/New Brunswick Healthy Start-Départ Santé (HS-DS) intervention that was focused on supporting ECEC services to implement healthy eating and physical activity programmes. The implementation steps included engaging with ECEC directors and educators, training, booster training, provision of materials and ongoing support. All the inputs (including staff time, materials, development cost and support services) into the programme were characterised and then costed to provide an overall cost of implementing a programme. The total overall cost of implementing HS-DS slightly decreased each year from USD 378,753 (year 1), USD 356,861 (year 2) and USD 312,179 (year 3), equating to approximately USD 258 per child.

Three studies captured intervention costs, however, did not do a formal cost analysis. Kipping 2019 captured all intervention costs associated with delivering the NAP SACC UK programme. The total

cost of the workshop delivery in nurseries was GBP 4373 including trainers' time, refreshments, equipment, administration and travel (as a one-off cost). The mean cost incurred by each nursery was GBP 717 (SD GBP 260). The mean cost of health visitor intervention delivery (including workshop delivery) per nursery was GBP 1092 (SD GBP 198). The NAP SACC UK at Home element cost GBP 11,947. Additionally, there was a small increase in self-reported family food expenditure between baseline and follow-up in both the intervention (GBP 17; SD GBP 52) and the control arms (GBP 3; SD GBP 46), and mean spend on physical activity (intervention: GBP 7; SD GBP 113; control: GBP 5; SD GBP 28).

laia 2017 captured the cost associated with intervention delivery (including educator training and parent motivational interviewing) should it be carried out again in the future, however, did not include one-off costs (i.e. project planning, database management). The estimated cost was EUR 6500 for delivery of the training by a psychiatrist, two psychologists and two experts in early childhood physical activity. Additionally, it was estimated that the time for delivering the intervention by all participants and healthcare professionals was a total of 1094 hours, and an additional EUR 4000 was estimated for cost of printing the educational material.

Stookey 2017 estimated that the ECEC-based intervention (including 16 hours of health professional one-on-one support provided to the ECEC educator) was low-cost and required one full-time staff person at the local ECEC agency to co-ordinate processes. Additionally, all operation costs were covered through grant funds of less than USD 100,000 per year. The integration of the Healthy Apple programme with a child health programme required child health staff to spend approximately 16 hours more per ECEC centre than routine services.

All six studies estimated overall implementation cost including cost to both the health service (i.e. healthcare providers) and ECEC service and one included cost to the home (Kipping 2019). The only study that did a formal economic analysis found that the intervention offered a better outcome at an acceptable cost. Two studies reported cost per child and this was USD 172 and USD 258 per child. All other studies described total cost to deliver the intervention with varying detail. The few studies that described relevant economic evaluations indicate that economic evidence regarding ECEC-based healthy eating interventions to improve child diet is currently lacking (Aluko 2022).

Adverse consequences

We undertook an exploratory approach to describe all or any potential adverse effects mentioned in the included studies. Three studies included an explicit measure to assess potential unintended adverse effects of the healthy eating intervention (Kipping 2019; Pearson 2022; Seward 2018).

In the evaluation of NAP SACC UK (Kipping 2019), centre managers and those delivering the intervention (health visitors and trainers) were asked to contact the study team within five working days if any untoward incident or adverse event occurred to a member of staff or child, as a direct result of participation in the study. Study-specific adverse event/incident report forms were made available, and no events were reported.

Seward 2018 reported no evidence of a difference between intervention and control service cooks receiving negative feedback

about the service menu in the past month from educators (intervention 32% (n 7/22 services) versus control 25% (n 4/16 services); $P = 0.62$), children (intervention 32% (n 7/22) versus control 6% (n 1/16); $P = 0.07$) or parents (intervention 9% (n 2/22) versus control 0% (n 0/16); $P = 0.95$). There were also no significant differences, after adjusting for baseline values, observed between groups for the estimated average % of food classified as waste for each meal: morning tea (adjusted difference -0.41 , 95% CI -2.35 to 1.52 ; $P = 0.66$); lunch (adjusted difference 3.31 , 95% CI -2.64 to 9.27 ; $P = 0.26$); and afternoon tea (adjusted difference -1.24 , 95% CI -3.77 to 1.28 ; $P = 0.31$).

Pearson 2022 assessed whether there were increases in frequency of parent complaints or concerns regarding a m-health intervention targeting packing of lunch boxes and introducing a lunchbox policy and found no evidence of differences between intervention and control groups.

None of the three studies reported a higher number of adverse effects from participation in the intervention. Overall, this review identified few studies specifically assessing and describing adverse events, indicating that the evidence surrounding adverse consequences of the delivery of ECEC-based healthy eating interventions is currently lacking.

Studies not reporting on primary or secondary outcomes synthesised in our review

Four studies (Nekitsing 2019a; Reyes-Morales 2016; Yeh 2018; Zeinstra 2018) met our eligibility criteria and were included in this review, however, did not report on any of the primary and secondary outcomes synthesised in our review. This primarily included studies that assessed child consumption of single foods including Nekitsing 2019a, which reported on child consumption of a test vegetable (mooli), Zeinstra 2018, which reported on child consumption of pumpkin, white radish and courgette and Reyes-Morales 2016, which reported on the proportion of children consuming sugary water, plain water, fruit water, soft drink, processed juice, savoury milk, yoghurt, fritters, hamburgers, hotdogs, French fries and pizza separately. Yeh 2018 did not report on child diet and reported on child BMI percentile, which was not included in our synthesis.

DISCUSSION

Summary of main results

Our review found that healthy eating interventions delivered in ECEC settings may improve child diet quality, but the evidence is very uncertain and likely increases fruit consumption (moderate-certainty evidence). There is uncertainty about the effect of ECEC-based healthy eating interventions on vegetable consumption (very low-certainty evidence). The exploratory subgroup analysis found that the effect on vegetable consumption may be higher in high socioeconomic status populations compared to low-socioeconomic status populations ($P = 0.04$). ECEC-based healthy eating interventions likely result in little to no difference in consumption of non-core foods (i.e. less healthy/discretionary) and sugar-sweetened beverages, with moderate-certainty evidence.

In terms of secondary outcomes, healthy eating interventions may have favourable effects on child weight (high-certainty evidence) and risk of being overweight or obese (moderate-

certainty evidence), although they may result in little to no difference in mean BMI (low-certainty evidence) and BMI z-scores (high-certainty evidence). The meta-analyses of two studies suggest some favourable findings of ECEC-based healthy eating interventions on child waist circumference, however, given the small number of studies, the evidence remains highly uncertain. For weight loss interventions, the US Preventive Services Task Force suggests that a BMI z-score reduction of 0.20 to 0.25 may be clinically significant and equivalent to a 5% weight loss (US Preventive Services Task Force 2017). For prevention interventions, however, there is no clear consensus on what constitutes a clinically significant reduction in weight gain for this age group. Other studies have reported that a small energy deficit (~ 400 kJ/day) in children can meaningfully reduce the prevalence of overweight and obesity (Cochrane 2016; Wang 2012). As such, it is likely that an effect of this magnitude for both weight (approximately 230 g) and waist circumference (0.82 cm) if sustained, could be meaningful at a population level.

Three or fewer studies examined child social and emotional outcomes, language and cognitive outcomes and quality of life, suggesting that little is known about the impact of ECEC-based healthy eating interventions on these outcomes. Less than 15% of the included studies assessed cost or cost-effectiveness (providing very low-certainty evidence about whether interventions are cost-effective) and adverse consequences (providing low certainty evidence of little to no adverse consequences).

Overall, findings from our review support existing recommendations for the delivery of ECEC-based healthy eating interventions by providing empirical evidence from RCTs that ECEC-based healthy eating interventions may improve some measures of child diet and child physical outcomes, with little evidence of any adverse consequences. It should be noted, however, that the certainty of this evidence is moderate to very low.

Overall completeness and applicability of evidence

We undertook a comprehensive database search of RCTs using a validated search filter, supplemented by searches of grey literature, trials registries, and protocols, and author contact. As such, it is unlikely that many published studies were missed in this process. However, visual inspection of the forest plots indicated some asymmetry potentially due to publication bias (i.e. studies with null results may have not been published or are delayed in publication). The majority of the studies were conducted in the USA (20 studies), Australia (6 studies) and Israel (4 studies), and no studies were undertaken in low- and low- to middle-income countries. Therefore, findings from studies included in this review are likely applicable to public health and education decision making in high-income countries only and the effectiveness of these interventions in low- and lower-middle-income countries remains unknown. All but one study was undertaken in children aged between two and six years, therefore the impact of the interventions on children aged six months to two years also remains unknown.

The majority of the studies targeted multiple risk factors (primarily physical activity, 35 interventions, (60%)). Therefore, the effects of interventions that target healthy eating in isolation remains unknown. The majority of studies (in 37 interventions, 64%) also targeted all three Health Promoting Schools' components (health curriculum, ethos and environment, and partnership). Although we undertook a number of subgroup analyses to explore potential

differences in effects on dietary outcomes by these components, there was no evidence to suggest any difference by subgroups. As such, we know very little about the specific components of ECEC-based healthy eating interventions that may be associated with improved child dietary outcomes.

We included only RCTs in this review as they are considered the gold standard design for exploring intervention effects. It is possible that inclusion of non-randomised studies may have captured different studies, including those from low-income countries. However, given that the original aim of the review was to establish efficacy of ECEC-based healthy eating interventions and the large number of included studies, it was not feasible for us to include non-randomised evidence in the current review.

Quality of the evidence

Several factors may limit the certainty of the evidence outlined in this review. The most common reason for downgrading was due to studies assessed as high risk of bias overall, inconsistency (as assessed via I^2 statistic values from the meta-analysis) and publication bias (as assessed through visual inspection of the forest plot). The number of studies classified as high risk of bias overall is unsurprising as this is primarily related to blinding of participants and personnel. For dietary outcomes, blinding of participants and personnel, and of outcome assessors, is highly challenging, introducing the potential for performance and detection bias in outcome assessments. Additionally, blinding of participants to intervention allocation is often not possible with the types of interventions assessed in this review. Future studies should better report on blinding of outcome assessors and statistical analyses, particularly for measures such as diet where objective measurement is challenging or high-cost, or both. For diet quality and vegetable consumption, we noted high heterogeneity and publication bias via the visual inspection of forest plots. Some inconsistency in findings was also expected given the differences in target populations, characteristics of the intervention, the ways in which these outcomes were assessed and follow-up periods. Additionally, our subgroup analysis did not find any evidence favouring small studies (< 400 children). It is possible that positive results bias may have been present, however, the included outcomes appear to be well distributed across both positive and negative findings, and there was little indication of selective publishing in our review of trial registry and protocol papers.

Attrition bias also appears prevalent across studies, particularly for measures of dietary intake. Attrition is challenging for interventions delivered in this setting due to families moving or changing services, or children in the older rooms transitioning to schools and leaving ECEC. Some studies have attempted to address this by utilising cross-sectional study designs, where children are resampled at baseline and follow-up. Further reporting of reasons for dropout and comparison of characteristics between those dropping out with those who were retained, will help with future assessments of attrition bias. Lastly, very few studies assessed adverse consequences and cost, and we downgraded evidence for indirectness as many RCTs were not designed to directly answer this question.

In the sensitivity analysis removing studies classed as high overall risk of bias, we noted a reduction in the estimated pooled effect, with evidence no longer supporting a positive effect for diet quality

(SMD 0.34 vs 0.21) and fruit consumption (SMD 0.11 vs. 0.05) suggesting that these findings may need to be interpreted with caution. Baseline imbalance and loss of clusters were the main reasons for this, indicating that attrition bias (particularly at a cluster level) could have resulted in more positive results given the likelihood that those who were not responding to the intervention may be more likely to drop out. However, this could also be attributed to the smaller sample size and number of included studies.

Potential biases in the review process

We attempted to minimise positive results bias in interpreting study results by involving multiple authors in the review and interpretation process and by following publishing guidance when describing study findings (Santesso 2020). Authors did not screen, extract data, or undertake any risk of bias assessments for any studies that they were involved in for this review. As many of the review authors also undertake primary research related to the review topic, it is possible that we have interpreted the results to be more positive. While we attempted to adhere to the methods outlined in the review protocol as closely as possible (Yoong 2021), we included a posthoc decision rule for selecting from multiple dietary and anthropometric outcomes due to the large number of different outcomes measured in these studies. However, the selection of these outcomes was based on a core outcome set for early intervention studies to prevent obesity (Brown 2022), which were most commonly reported in studies, and allowed for comparison with population-level guidelines.

Agreements and disagreements with other studies or reviews

Overall, although no other systematic reviews with a meta-analysis directly addressing the same question exist, our findings are consistent with reviews addressing similar questions more broadly. This includes a living systematic review by Hodder 2020, which included all healthy eating interventions targeting children aged five years and under (ECEC- and non-ECEC-based) that found small effects of multicomponent interventions, child feeding interventions and parent nutrition education interventions on fruit and vegetable consumption. Our effect sizes for fruit and vegetable consumption are comparable to those described in Hodder 2020. A Cochrane Review examining obesity prevention interventions among children aged zero to five years also found a small pooled effect of physical activity and nutrition interventions on child BMI and BMI z-scores (Brown 2019). Similarly, the effect sizes are comparable across our review and in Brown 2019.

Other non-Cochrane reviews that have explored ECEC-based interventions specifically have used narrative or vote-counting approaches, have included non-controlled studies and did not report on the impact of the interventions on specific dietary outcomes (Matwiejczyk 2018; Van de Kolk 2019; Ward 2015; Yoong 2020b; Yuan 2014). Despite these differences, findings from our review are broadly consistent with previous reviews that reported primarily positive effects on dietary outcomes and inconsistent effects on child weight outcomes. Further, previous reviews also described a small-to-moderate effect size, consistent with that identified in our review for a range of dietary outcomes. Our review significantly adds to the evidence base by describing the effects of only RCTs on specific dietary outcomes and examining impact on a broader range of child physical outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

Findings from our review support the likely positive impact of healthy eating interventions delivered in early childhood education and care settings (ECEC) on a number of dietary and anthropometric outcomes, although certainty of evidence was moderate to very low. It highlights the importance of this setting to support the development of healthy eating behaviours in the early years and as a key setting for population-wide obesity prevention efforts.

Most of the interventions delivered in this setting targeted all components of the Health Promoting Schools Framework and also included efforts to promote physical activity. This review provides compelling evidence for ECEC educators and managers to prioritise the delivery of multi-component healthy eating interventions, including those that target the curriculum, ethos and environment, and partnerships with community and parents. Despite the potential benefits, the challenges with implementing multi-component and comprehensive healthy eating programmes in ECEC settings have been well described, with suboptimal implementation documented across many jurisdictions (Grady 2019; Yoong 2016). There is, therefore, a need for government action and investment to support co-ordinated, population-wide implementation on multiple levels, if the benefits of such programmes are to result in larger health gains.

The WHO have released Global Standards for Healthy Eating, Physical Activity and Sedentary Behaviour in the ECEC setting (World Health Organization 2021). This resource provides guidance regarding national and subnational actions that can be taken by policy and decision makers to provide supportive systems to implement these programmes in practice. The key strategies outlined include providing policy leadership, resourcing and financing, building workforce capability, generating evidence-informed standards and establishing partnerships. A Cochrane Review by the authors of this review also describes a number of local-level, evidence-based implementation strategies that can be employed by local health promotion teams or other organisations responsible for supporting obesity prevention efforts in ECEC (Wolfenden 2020). This includes providing educational materials, educational meetings, audit and feedback, opinion leaders, small incentives or grants, educational outreach visits or academic detailing and reminders that can be provided to ECEC services.

Implications for research

Findings from this review highlighted a number of areas where limited evidence exists and future research is likely warranted. Only one randomised controlled trial (RCT) targeted children aged between six months to two years, and found a positive improvement in child vegetable consumption (Blomkvist 2021). Given the increasing number of parents returning to work and accessing ECEC services for their young children, future studies targeting this age group are needed to support the development of healthy infant feeding behaviours. Additionally, we found only two RCTs undertaken in family day care settings, which were both conducted in the USA, consistent with our previous review of controlled trials in this setting (Yoong 2020b). Family day care services are structurally different from centre-based services and provide care to a significant proportion of young children in high-

income countries. Additionally, a number of studies suggest that these services may be accessed by more disadvantaged groups (Benjamin-Neelon 2018; Lindsay 2015; Lum 2021). Therefore, interventions in this setting provide an opportunity to influence the nutrition behaviour of these groups.

Critically, our review found that no studies have been undertaken in low- and lower-middle-income countries. This lack of research focusing on young children's activity and healthy eating in low- and middle-income countries has been previously documented (Kariippanon 2022; Zhou 2014), with much of the existing ECEC-based intervention research primarily focused on child cognitive, educational and developmental outcomes. Such outcomes may be more aligned to the immediate priorities and needs of low- and middle-income countries. It is possible that the delivery and evaluation of ECEC-based healthy eating interventions in these countries may need to be integrated within other programmes focused on child learning and development more broadly. As observational studies have documented associations between improved child nutrition and cognitive and behavioural outcomes (Khalid 2017; O'Neil 2014; Tandon 2016), we sought also to explore the impact of healthy eating interventions on these outcomes. However, we identified few studies that measured these outcomes and of those that did, findings indicate possible positive and negative effects. Lastly, few studies formally reported undertaking a cost evaluation and assessing adverse consequences. Future research should attempt to examine more directly any adverse consequences and undertake formal prespecified cost evaluations in order to provide essential data needed for decision making.

While findings from this review highlight the potential for this setting to deliver effective healthy eating programmes, little is known about the specific characteristics of the intervention that may have influenced child diet and physical outcomes. Given the challenges and additional resourcing needed to implement complex interventions, a better understanding of the discrete components that influence child health outcomes are needed to support prioritising of implementation efforts. We are aware of a number of multi-arm (Grady 2020), or factorial trials (Zarnowiecki 2021), to allow for better understanding of the impact of discrete intervention components. For example, Zarnowiecki 2021 applied the multiphase optimisation strategy (MOST) which is a multiphase experimental design to support optimisation of an ECEC-based healthy eating intervention. This study is currently in progress and utilises a factorial RCT design to describe the impact of different strategies targeting the curriculum, and ethos and environment components of ECEC-based healthy eating interventions. Additionally, the inclusion of comparative effectiveness studies (those that compared two healthy eating interventions) are likely to help with better understanding the effects of different intervention components.

Finally, we identified a large number of dietary outcomes that have been assessed in studies of ECEC-based healthy eating interventions. Despite the large number of studies included overall in the review, the variability in reported outcomes resulted in only small number of studies included for each dietary outcome synthesised in our review. A recent publication outlines the development of a recommended core outcome set, including key dietary and anthropometric measures for early obesity prevention studies (Brown 2022). The reporting of outcomes consistent with that outlined in the recommended core outcomes will reduce

heterogeneity in outcomes and increase the likelihood of new studies being in future meta-analyses.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]

Alkon 2014
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 7 months Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based Operation: not reported Country (region): USA (California, Connecticut, North Carolina) Country income classification: high Low-SES sample: yes

Alkon 2014 (Continued)

Population description: racial/ethnic diversity among the children

Inclusion criteria: included English-speaking director, on-site kitchen, racial/ethnic diversity among the children, participation by at least 60% of families and a population of children in care primarily comprised of low-income children between the ages of 3-5 years

Exclusion criteria: chronic illnesses or conditions that affected nutritional status, severe food allergies, gastrointestinal disorders or mobility impairment

Number of services randomised: 18 (9 intervention, 9 control)

Number of children randomised: 552 (260 intervention, 292 control)

Characteristics

Children

Age:

Intervention: 3 years: 31%; 4 years: 50%; 5 years: 19%
 Control: 3 years: 29%; 4 years: 54%; 5 years: 17%

Gender (% female):

Intervention: 44%
 Control: 48%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity:

Intervention: white: 55%; African American: 17%; Hispanic, Latino: 15%; Asian: 8%; other: 5%
 Control: white: 37%; African American: 16%; Hispanic, Latino: 19%; Asian: 19%; other: 9%

Parent/family SES:

Employment status (primary caregiver):

Intervention: working full time: 74%; working part time: 14%; unemployed: 2%; student: 5%; not working: 5%

Control: working full time: 74%; working part time: 17%; unemployed: 5%; student: 2%; not working: 2%

Parent education (primary caregiver):

Intervention: < high school: 23%; high school and higher: 77%

Control: < high school: 44%; high school and higher: 56%

Method of recruitment: not reported

Missing data/dropout: 1 control centre withdrew and was replaced with a matched centre prior to intervention

Reasons for dropout: the centre was unable to complete the required number of study questionnaires.

Characteristics of dropouts: not reported

 Interventions

Programme name: NAP SACC (The Nutrition And Physical Activity Self-Assessment for Child Care)

Number of conditions: 1 intervention, 1 control

Intervention duration: 7 months

Alkon 2014 (Continued)

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

ECEC staff

Workshops: NAP SACC workshops for ECEC providers and staff included education on childhood obesity, healthy eating for young children, physical activity for young children, personal health and wellness and working with families to promote healthy behaviours.

Support: on-site consultations and additional telephone and email consultations

Resources: written materials around nutrition and physical activity were provided to staff.

Service

Materials: posters displayed in centres and information sheets on nutrition and physical activity

Policy: child-care health consultants worked with centre directors to write and update the centre's nutrition and physical activity policies.

Partnerships

Families

Workshop: services were provided the parent workshop 'raising healthy kids'.

Resources: written materials around nutrition and physical activity were provided to parents.

Healthcare

Delivery: nurse child healthcare consultants delivered the intervention to staff and parents.

Intensity of intervention: 5 x 1-h NAPSACC workshops to ECEC providers and staff (e.g. cooks, administration); 1 x at least monthly consultations; additional phone and email consultations and posters and information sheets distributed (and displayed in the centre and provided to parents)

Intervention delivered by: healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: not reported

Description of control: delayed intervention control

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI z-score, % underweight, % healthy weight, % overweight, % obese

Number of participants analysed:

Intervention baseline: 99

Intervention follow-up: 99

Control baseline: 110

Control follow-up: 110

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Alkon 2014 (Continued)

Outcome relating to adverse consequences: not reported

Notes **Funding source:** grant funded by the US Department of Health and Human Services, health resources and services administration, maternal and child health research program

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were measured by a research assistant blinded to group assignment.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	One cluster withdrew prior to the intervention but after randomisation and was replaced. Study authors stated that "There were 211 children (63% of 336) with measurements at both the pre- and post-intervention periods." Due to the magnitude of missing data, we assessed the risk of bias as high.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol, and trial registration is vague so it was unclear whether there was selective outcome reporting
Recruitment bias	Unclear risk	It is unclear whether allocation occurred before or after baseline data collection. One control cluster was lost and replaced with a matched centre prior to intervention but after randomisation.
Baseline imbalance	Unclear risk	Although centres were matched on size and proportion of children eligible for income subsidies, groups significantly differed in parent ethnicity, parent education, employment status, and household density. Only state, parent education, and family poverty were included in regression analysis. Some known confounders of children's BMI, such as parent BMI and child-level accelerometer and sleep data, were not collected.
Loss of clusters	Low risk	One control cluster lost and replaced with a matched centre prior to intervention
Incorrect analysis	Low risk	Hierarchical linear models were conducted to assess child-level BMI z-score outcomes while accounting for clustering within centres.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Study authors stated that "Third, some centres had more child-level data and some states had more centres contributing to the final analyses. Fourth, some known confounders of children's BMI, such as parent BMI and child-level accelerometer and sleep data were not collected... Lastly, there was a historical cohort effect on both the intervention and control centres given obesity prevention campaigns at the national level (i.e., Let's Move Child Care) and legislation (i.e., Healthy Hunger-Free Kids Act) in the U.S. that promoted healthy nu-

Alkon 2014 (Continued)

trition and physical activity in child care during the study period." There is insufficient information to assess whether an important risk of bias exists.

Başkale 2011
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 4 months (varies with outcomes)</p> <p>Unit of allocation: nursery schools</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (nurseries)</p> <p>Operation: nursery schools connected to the Izmir Provincial Directorate of National Education</p> <p>Country (region): Turkey (Izmir)</p> <p>Country income classification: upper-middle</p> <p>Low-SES sample: no</p> <p>Population description: nursery schools connected to the Izmir Provincial Directorate of National Education. These schools were layered into the 3 socioeconomic levels they represent: low-, middle-, and upper-income brackets. 2 schools from each bracket were included.</p> <p>Inclusion criteria: 12 nursery schools are connected to the Izmir Provincial Directorate of National Education. Children included in the study were 5 years of age. The children in the control group had not received nutrition education but they had received a general programme of education (the nutrition education prescribed by the Ministry of National Education preschool).</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 12 (6 intervention, 6 control)</p> <p>Number of children randomised: 238 (141 intervention, 97 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i></p> <p>Intervention: mother: 33.45; father: 36.96 Control: mother 33.42; father: 36.84</p> <p><i>Gender (% female):</i> both mother and father reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i> low: 16%; medium: 73.1%; upper: 10.9 %</p>

Başkale 2011 (Continued)

Method of recruitment: not reported

Missing data/dropout: 11 children (4.6%) were lost to follow-up.

Reasons for dropout: some sample losses were experienced, often due to illness, moving, and registering for the primary schools' preclasses children would attend the next year.

Characteristics of dropouts: there were no differences between the dropped-out children/parents and the children/parents who remained in the study.

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 weeks

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: game-based nutrition education was delivered to children, guided by a nurse educator, including activities such as playing, painting, colouring and interactive stories.

Partnerships

Healthcare

Delivery: a nurse educator guided the nutrition education.

Intensity of intervention: 20-30-min sessions once a week for 6 weeks (classes were divided into groups and held with 8-15 children). Parent nutrition education sessions were given to both intervention and control (1.5-2 h).

Intervention delivered by: research team, healthcare staff

Modality: face-to-face

Theoretical basis: Piaget's Cognitive Development Theory

Description of control: usual care, plus parents in both groups were provided with the same nutrition education (1.5-2 h) to present them with information on children's nutritional needs and educational booklet

Outcomes

Outcomes relating to child dietary intake:

Weekly frequency of vegetable consumption, weekly frequency of green leafy vegetables, weekly frequency of root vegetables, weekly frequency of cabbage, weekly frequency of citrus, weekly frequency of other fruits

Number of participants analysed

Intervention baseline: 141

Intervention follow-up: 141

Control baseline: 97

Control follow-up: 97

Data collection measure: FFQ

Data collector: parents

Validity of measures used: not reported

Başkale 2011 (Continued)

Outcomes relating to child physical measures:

BMI, mid-upper arm circumference, underweight, healthy weight, overweight or obese, underweight, healthy weight, mid-upper arm circumference ≤ 10 , mid-upper arm circumference > 10 to < 85 , mid-upper arm circumference ≥ 85

Number of participants analysed:

Intervention baseline: 37

Intervention follow-up: 37

Control baseline: 48

Control follow-up: 48

Data collection measure: objectively measured (CDC)

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes **Funding source:** no external or intramural funding was received.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	2 schools from each income bracket (low, middle, and upper) were drawn from a bag, then randomised to intervention and control.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	Blinding not reported, and it is not clear whether parents were aware of allocation as parents in both experimental and control groups were provided the same nutrition education. Parents completed the food frequency form prior to the intervention, following the intervention, and 1 year after the intervention.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Unclear risk	Blinding not reported, and it is not clear whether parents were aware of allocation as parents in both experimental and control groups were provided the same nutrition education. Parents completed the food frequency form prior to the intervention, following the intervention and 1 year after the intervention.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's weight, height, and mid-upper arm circumference were measured and are not likely to be influenced by lack of blinding.

Başkale 2011 (Continued)

Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 139 (99%) students in the intervention group and 88 (91%) students in the control group at post-test 1, and 67 (48%) students in the intervention group and 48 (49%) students in the control group at post-test 2. Post-tests occurred a year apart, and an ITT analysis was conducted. Reasons provided for attrition (i.e. illness, moving, and registering for primary schools) appear reasonable. Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 67 (48%) students in the intervention group and 48 (49%) students in the control group at post-test 2. An ITT analysis was conducted. Reasons provided for attrition (i.e. illness, moving, and registering for primary schools) appear reasonable. Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	There is no information regarding whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	The analysis showed that the groups were not statistically different ($P > 0.05$).
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Unclear risk	Adjusting for clusters was not reported, though some of the sociodemographic characteristics of the families and children in the experimental and control groups were tested for homogeneity to confirm that there were no differences. There is not enough information to assess whether an important risk of bias exists.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	The control group appears ambiguous and it is unclear if nutrition education, which was the intervention, was also delivered at the control schools. There is insufficient information to assess whether an important risk of bias exists.

Blomkvist 2021
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 3 months Unit of allocation: kindergartens Unit of analysis: child
Participants	Service type: kindergarten Operation: public and private Country (region): Norway ((Telemark, Oppland, Sør-Trøndelag and Møre og Romsdal) Country income classification: high Low-SES sample: unclear

Blomkvist 2021 (Continued)

Population description: the 4 counties covered 2 different geographical areas of Norway and included public and private kindergartens located in both rural and urban settings.

Inclusion criteria: having children of the appropriate age (i.e. born in 2016)

Exclusion criteria: kindergartens registered as 'open kindergartens' in which children and their parents attend together (n = 18), kindergartens registered with < 4 children (n = 7) and kindergartens with children from 3-5 years only (n = 12) were not invited.

Number of services randomised: 46 kindergartens (16 intervention 1, 15 intervention 2, 15 control)

Number of children randomised: 267 children (111 intervention 1, 85 intervention 2, 71 control)

Characteristics
Children

Age: 16.7 months (SD 3.0)

Gender (% female): 47.60%

Ethnicity: all children were born in Norway

Parents

Age (years): 30.9 (SD 5.4)

Gender (% female): 88.70%

Ethnicity:

Mother born in Norway: 91.5%

Father born in Norway: 89.5%

Parent/family SES:

Mothers' education, high: 64%

Fathers' education, high: 42.1%

Method of recruitment: the invitations were sent to the kindergarten managers by email and included detailed information about the study and a link to the study registration web page. The kindergarten managers received 1 reminder email after a couple of weeks. As few kindergartens (n = 32) registered for the study initially, a random selection of kindergarten managers (n = 321) was additionally contacted by telephone and asked if they had received the email and further asked if they could be interested in participating in the study. The phone call recruitment lasted until the number of kindergartens registered was assumed to yield the planned study sample size.

Missing data/dropout: total loss to follow-up: 102/246 = 41%

Reasons for dropout: 21 parents registered for the trial but did not complete the baseline questionnaire, leaving 246 children. 3 of the kindergartens (n = 29 children) withdrew consent shortly after randomisation (2 of them due to sick leaves and pregnancies amongst the staff and 1 kindergarten withdrew due to economic issues). 73 parents (34%) did not complete the post-intervention questionnaire, leaving 144 children for the main analysis.

Characteristics of dropouts: mothers without a higher education were more likely to drop out of the study. Amongst the complete cases, there were slightly fewer fathers with a higher education in Intervention 1, and a slightly higher baseline intake of intervention vegetables amongst children in Intervention 2.

Interventions

Programme name: Barns matmot 2.0

Number of conditions: 2 interventions, 1 control

Intervention duration: 12 weeks

Blomkvist 2021 (Continued)**Intervention setting:** ECEC**Intervention strategies:****Intervention 1 (Menu moderation and sensory lessons)****Health curriculum***Children*

Education: kindergarten staff were instructed to implement pedagogical tools including weekly sensory lessons for the participating children.

Ethos and environment*Children*

Exposure: during the sensory lessons, children were introduced to the intervention vegetable of the month, presented in 3 different ways; in the first week, it was presented raw, in the second week, raw with a dip and in the third week, it was presented differently (e.g. baked or otherwise prepared) (3 additional exposures of each food compared to Intervention 2). Children were served a warm lunch meal with alternating vegetables for 3 d/week during the 3-month intervention period.

Role modelling/healthy eating practices: kindergarten staff were given advice on meal practice and feeding practices during mealtime and encouraged to sit down with the children and eat the same food during lunchtime.

Service

Resources: the kindergartens had access to the 3 menus with 9 different recipes in a password-protected website designed specifically for each intervention group. Each of the 3 menus had 1 vegetable in focus: spinach, celeriac and fennel. Recommendations for meal and feeding practices were also presented in short informational videos on the study website. Kindergartens were offered compensation to buy necessary kitchenware, such as a good knife, saucepans or a hand blender.

Support: if the kindergarten personnel had questions during the intervention, they could email or telephone a contact person using information on the website.

Families

Resources: the parents of the registered children were also given access to the website with the 9 recipes; however, the parents had no commitments or tasks regarding introducing the menus at home. Recommendations for meal and feeding practices were also presented in short informational videos on the study website.

Intervention 2 (Menu moderation)**Ethos and environment***Children*

Exposure: children were served a warm lunch meal with alternating vegetables for 3 d/week during the 3-month intervention period.

Service

Resources: the kindergartens had access to the 3 menus with 9 different recipes in a password-protected website designed specifically for each intervention group. Each of the 3 menus had one vegetable in focus: spinach, celeriac and fennel. Kindergartens were offered a compensation to buy necessary kitchenware, such as a good knife, saucepans or a hand blender.

Support: if the kindergarten personnel had questions during the intervention, they could email or telephone a contact person using information on the website.

Families

Blomkvist 2021 (Continued)

Resources: the parents of the registered children were also given access to the website with the 9 recipes; however, the parents had no commitments or tasks regarding introducing the menus at home.

Intensity of intervention:

Intervention 1: children were exposed to 3 d/week for 3 months; staff implemented weekly sensory lessons in the classroom.

Intervention 2: children were exposed to alternating vegetables for 3 d/week for 3 months.

Intervention delivered by:

Intervention 1: ECEC staff

Intervention 2: ECEC staff

Modality:

Intervention 1: face-to-face, online, written

Intervention 2: online, written

Theoretical basis: not reported

Description of control:

Usual care

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, intervention vegetables intake

Number of participants analysed:

Intervention 1 baseline: 103

Intervention 1 follow-up: 63

Intervention 2 baseline: 78

Intervention 2 follow-up: 42

Control baseline: 65

Control follow-up: 39

Data collection measure: selected items from FFQ

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: this research project was funded by the Norwegian Women's Public Health Association, and some projects costs were funded by the University of Agder and the Teacher's Education Unit

Blomkvist 2021 (Continued)

at the University of Agder. Approximately one-fifth of the wages cost for the corresponding author was funded by the Hospital of Southern Norway.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors stated that "The random allocation sequence was generated in SPSS by the last author, who had neither contact with the kindergartens nor access to or information from the completed questionnaires."
Allocation concealment (selection bias)	Low risk	Study authors stated that "The 46 kindergartens included were randomised into one of three groups after the parents had completed the baseline questionnaire, approximately 2 weeks before the start of the intervention."
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Study authors stated that "The first author contacted the kindergarten managers to inform them about which group they were randomised to." Blinding of staff not reported, though staff in the intervention groups had access to resources indicating blinding may have been broken and the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Study authors stated that "The first author contacted the kindergarten managers to inform them about which group they were randomised to." Parents completed the food frequency questionnaire. Blinding of parents not reported, though parents in the intervention groups had access to resources indicating blinding may have been broken. The outcome measurement is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Study authors stated that "In total, 267 children were registered for the study. Twenty-one parents registered for the trial but did not complete the baseline questionnaire, leaving 246 children. Three of the kindergartens (n = 29 children) withdrew consent shortly after randomisation (two of them due to sick leaves and pregnancies amongst the staff and one kindergarten withdrew due to economic issues). Seventy-three parents (34%) did not complete the post-intervention questionnaire, leaving 144 children for the main analysis (total loss to follow-up: 102/246 = 41%)." A full intention-to-treat analysis could not be performed. Due to the magnitude of missing data, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Low risk	Additional measures, including anthropometric data of children, were also collected according to the protocol, however the authors stated that "Only primary outcomes of the intervention are included in the present paper."
Recruitment bias	Low risk	All participants and kindergartens were recruited prior to randomisation.
Baseline imbalance	Low risk	Study authors stated that "The cluster randomisation produced groups that were broadly comparable at baseline." It is reported that there were slightly fewer fathers with a higher education in intervention 1, and a slightly higher baseline intake of intervention vegetables amongst children in intervention 2, based on case completers. The authors used adjusted models to control for these variables.
Loss of clusters	Low risk	Loss of 3 clusters, however reasons were unrelated to the intervention and comprised a small percentage of all clusters. Study authors stated that "Three of the kindergartens (n = 29 children) withdrew consent shortly after randomisation (two of them due to sick leaves and pregnancies amongst the staff and one kindergarten withdrew due to economic issues)."

Blomkvist 2021 (Continued)

Incorrect analysis	Unclear risk	Adjusting for clusters was not reported, however the authors stated that "To address any imbalances that may have resulted from the cluster design and losses to follow-up, we also present a set of adjusted effect estimates, controlling for the baseline values of each outcome, and maternal and paternal education." There is not enough information to assess whether an important risk of bias exists.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Céspedes 2013
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: preschool</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: not reported</p> <p>Country (region): Colombia (Usaquén, Bogota)</p> <p>Country income classification: upper-middle</p> <p>Low-SES sample: yes</p> <p>Population description: Usaquén represents the different SES levels seen in Colombia and includes an underprivileged community with a high migration rate.</p> <p>Inclusion criteria: all children 3–5 years of age at baseline and their parents and teachers were eligible.</p> <p>Exclusion criteria: children, parents or teachers who had received formal training in healthy habits, nutrition or physical activity in the 6 months before the study and children whose parents did not consent</p> <p>Number of services randomised: 14 (7 intervention, 7 control)</p> <p>Number of children randomised: 1216 children (622 intervention, 594 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention: 3 years: 55%; 4 years: 43.4%; 5 years: 1.6% Control: 3 years: 52%; 4 years: 44.8%; 5 years: 3.2%</p> <p><i>Gender (% female):</i></p> <p>Intervention: 47.6% Control: 46.3%</p> <p><i>Ethnicity:</i> not reported</p>

Céspedes 2013 (Continued)

Parents
Age (years):

Intervention: 31.25 (SD 8.1)

Control: 29.94 (SD 6.8)

Gender (% female):

Intervention: 83.6%

Control: 85.8%

Ethnicity: not reported

Parent/family SES: not reported

ECEC staff
Age (years):

Intervention: 39.04 (SD 10.6)

Control: 35.05 (SD 8.9)

Gender (% female):

Intervention: 100%

Control: 98.5%

Ethnicity: not reported

Service/ECEC staff SES:

SES of the neighbourhood where the preschool facility is located:

Intervention: low: 57.1%; high: 42.9%

Control: low: 71.4%; high: 28.6%

Method of recruitment: not reported

Missing data/dropout: all ECEC services were retained. 91.8% of children retained; 93.7% of parents retained; 88.9% of teachers retained

Reasons for dropout: attrition was mainly due to school change or migration associated with factors such as local violence or changing jobs.

Characteristics of dropouts: there were no significant differences associated with sex or weighted score change observed after the initial 5-month period between those lost to follow-up and those remaining in the study. In both cohorts, children lost to follow-up were older (3.7 and 3.3 years, $P < 0.01$; and 3.8 and 3.1 years, $P < 0.01$, respectively).

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 5 months

Intervention setting: ECEC

Intervention strategies:
Health curriculum
Children

Education: educational and playful activities including Sesame Workshop Healthy Habits story books, posters, videos, games and songs.

Workshops: a "healthy family day" workshop with families

Ethos and environment

Céspedes 2013 (Continued)

Children

Resources: weekly health notes

ECEC staff

Training: 3 x centralised training sessions, plus personalised sessions with a research supervisor

Resources: teachers' guide

Partnerships
Families

Meeting: 1 x 1-h presentation of the intervention

Workshops: 3 x workshops

Resources: weekly notes containing positive health messages about nutrition and active lifestyles to share with children

Intensity of intervention: 1 h/d of Sesame Workshop Healthy Habits story-books, posters, videos, games and songs for children; 1 x 1-h "healthy family day" workshop; weekly health notes for children; 3 x parent workshops and weekly health notes; 3 x centralised teacher training sessions, plus personalised working sessions with research supervisor (2 h every 15 d)

Intervention delivered by: research team

Modality: face-to-face, written

Theoretical basis: Social Cognitive Theory and the Transtheoretical Model

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI, eutrophic, risk of undernourished, undernourished, overweight, obese

Number of participants analysed:

Intervention baseline: 488

Intervention follow-up: 433

Control baseline: 476

Control follow-up: 425

Data collection measure: objectively measured (CDC)

Data collector: nutritionist

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The Santo Domingo Foundation

Risk of bias

Céspedes 2013 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A blinded randomisation assignment schedule was used to allocate to treatment groups. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Low risk	The blinded randomisation assignment schedule was concealed until treatments had been allocated.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by nutritionists using standard techniques and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	100 (8.2%) children were lost to follow-up, with similar numbers of attrition in both groups (51/622 = 8.2% intervention, 49/594 = 8.2% control). Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Low risk	Per the PRISMA diagram, full recruitment occurred before randomisation
Baseline imbalance	Low risk	There were no significant differences between groups with respect to baseline characteristics except for modest differences in teachers' educational level, age of parents and teachers, and children's weight. The researchers ran additional models simultaneously, adjusting by the effect of parents' and teachers' age, and children's weight.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Changes between baseline and end-of study scores were modelled as the outcome, randomisation assignment as the independent predictor variable of interest, and subject's preschool facilities as the clustering variable."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Davis 2016
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 7 months Unit of allocation: Head Start centres Unit of analysis: child
Participants	Service type: centre-based (Head Start)

Davis 2016 (Continued)

Operation: Head Start centres

Country (region): USA (New Mexico)

Country income classification: high

Low-SES sample: yes

Population description: a primarily Hispanic or American Indian student population and a location in a nonmetropolitan community within 150 miles (240 km) of the research centre.

Inclusion criteria: Head Start centres were eligible for the study if they had at least 2 classrooms, ≥ 15 3-year-old children enrolled, a retention rate of at least 80% over 2 school years, a primarily Hispanic or American Indian student population and a location in a nonmetropolitan community within 150 miles (240 km) of the research centre.

Exclusion criteria: Head Start centres housing other prekindergarten programs were excluded.

Number of services randomised: 16 centres (8 intervention, 8 control)

Number of children randomised: 1898 (945 intervention, 871 control)

Characteristics

Children

Age: 2 years: 1.6%; 3 years: 41.1%; 4 years: 55.4%; 5 years: 1.8%

Gender (% female): 47.4%

Ethnicity: Hispanic: 57.2%; non-Hispanic: 42.8%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: centre race/ethnicity: American Indian: 40.6%; Hispanic: 59.4%

Parent/family SES: not reported

Method of recruitment: Head Start centres were recruited by a community engagement specialist on the research team.

Missing data/dropout: all ECEC services were retained. 74% of eligible population consented to participate. 99% of consenting participants provided data.

Reasons for dropout: graduation or transfer to prekindergarten classes, the difficulty in instituting environmental and policy changes and the large effect size required by the small number of study sites.

Characteristics of dropouts: not reported

Interventions

Programme name: CHILE: Child Health Initiative for Lifelong Eating and Exercise

Number of conditions: 1 intervention, 1 control

Intervention duration: 2 years

Intervention setting: ECEC, home and local community

Intervention strategies:

Health curriculum

Children

Davis 2016 (Continued)

Education: a nutrition and physical activity curriculum for the Head Start centres provided to children. Each lesson incorporates child's development Head Start domains such as emotional/social, literacy and mathematics.

Ethos and environment

Children

Exposure: children were provided opportunities to try new fruits and vegetables and to participate in physical activity during daily class activities.

Menu modification: as new fruits and vegetables were introduced to children, they were incorporated in the school menu.

ECEC staff

Training: quarterly professional development for Head Start teachers and food service staff. Hands-on sessions provide staff with information about physical activity and nutrition and technical assistance for implementing the intervention.

Service

Policy: policy changes were made for the food service to switch to healthier food products.

Partnerships

Families

Resources: take-home materials about nutrition and physical activity were provided to families.

Events: 2 family events reinforcing these messages during the school year.

Community

Access: increasing availability and visibility of healthier food options in local grocery stores and providing recipes and nutrition-related information to families while shopping.

Healthcare

Engagement: local healthcare providers were asked to emphasise healthy eating and physical activity during routine patient visits and health professionals were invited to attend family events to show support for the intervention.

Intensity of intervention: nutrition curriculum to be incorporated into Head Start learning domains including literacy, maths or science; addition of 30 min of physical activity to daily class activities; quarterly professional development (8 sessions) for ECEC staff; in-class nutrition lessons provide children multiple exposures to each novel fruit or vegetable; take home materials for families 2 times/year

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: Socioecological approach

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

Underweight, healthy weight, overweight, obese, adjusted BMI z-score

Number of participants analysed

Intervention baseline: 210

Intervention follow-up: 157

Control baseline: 226

Control follow-up: 174

Data collection measure: objectively measured (CDC)

Data collector: researcher

Davis 2016 (Continued)

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The National Institute of Diabetes and Digestive and Kidney Diseases (Grant R01 DK72958)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Head Start centres were stratified by race/ethnicity and average BMI. A random uniform variable was generated for each centre. Centres with smaller values within each stratum were assigned to the intervention group until desired sample sizes were achieved.
Allocation concealment (selection bias)	Low risk	Before allocation, centres were stratified according to the race/ethnicity and average BMI of the centres' population. Randomisation occurred after all centres were recruited.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were assessed at the centres and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	Data were available for 157 (75%) participants in the intervention group and 174 (77%) participants in the control group. Study authors stated that "Limitations of the CHILE study included the drop out of students due to graduation or transfer to prekindergarten classes." Due to the magnitude of missing data over the short-term and long-term follow-up, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	Outcomes are not clearly reported in the trial registration or trial protocol, so it was unclear whether there was selective outcome reporting.
Recruitment bias	Low risk	Individual recruitment occurred prior to cluster randomisation.
Baseline imbalance	Low risk	The intervention and comparison groups did not differ significantly at baseline.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Analyses accounted for repeated measurements for Head Start centers and children by including random effects for each center and child."
Contamination	Unclear risk	No evidence to make assessment

Davis 2016 (Continued)

Other bias	Unclear risk	Study authors stated that "The large effect size required by the small number of study sites, which may have resulted in the study being underpowered." There is insufficient information to assess whether an important risk of bias exists.
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De Bock 2011
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: preschool</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschools)</p> <p>Operation: not reported</p> <p>Country (region): Germany (Baden-Württemberg)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: the study was set in Baden-Württemberg, a federal state (population nearly 11 million) in south-west Germany with an extensive network of urban and rural preschools</p> <p>Inclusion criteria: preschools were eligible to participate in the study if they were located in 1 of 3 pre-defined regions and had applied to participate in the nutritional intervention module of a state-sponsored health promotion programme 'Komm mit in das gesunde Boot' ('Come aboard the healthy boat') with at least 15 children participating.</p> <p>Exclusion criteria: sites were excluded if they had < 15 children participating in the state-sponsored programme or if there was no external physical activity teacher available in the area.</p> <p>Number of services randomised: 18 preschools (10 intervention, 8 control)</p> <p>Number of children randomised: 377 (194 intervention, 183 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 3 years: 16%; 4 years: 45.6%; 5 years: 33.6%; 6 years: 4.6%</p> <p><i>Gender (% female):</i> 46.8%</p> <p><i>Ethnicity:</i> without migrant background: 65.5%; with migrant background: 32.4%; missing: 2%</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i></p>

De Bock 2011 (Continued)

Maternal education level: low: 16.3%; middle: 55.7%; high: 21.2%; missing: 6.6%

Method of recruitment: a 2-level sampling strategy involving both preschools from 3 geographic regions that had formally applied for participation in the state-sponsored programme and the parents of children enrolled at these sites

Missing data/dropout: of the 348 preschool children providing data, 29.6% (n = 103) participated in measurements at all 3 time points, 51.4% (n = 179) children participated twice and 19.0% (n = 66) at 1 measurement point, with 58.0% of the children (n = 202) providing both pre and post-intervention measurements.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: 'Komm mit in das gesunde Boot' ('Come aboard the healthy boat') (nutrition module)

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: external nutrition experts delivered 15 x standardised 2-h nutrition sessions, mostly during preschool hours, conducted once weekly over a 6-month period.

Ethos and environment

Children

Exposure: children were offered weekly healthy snacks like fruit and vegetables and water. Intervention activities included familiarising children with different food types and preparation methods and cooking and eating meals in groups of children, teachers and parents.

ECEC staff

Training: preschool group teachers assisted the nutrition expert during sessions, to enable them to sustain intervention-related activities after the study.

Partnerships

Families

Education: 5 of the 15 sessions actively involved parents by targeting them alone (discussions on parents' modelling role and nutritional needs of children) or together with their children.

Healthcare

Delivery: external experts delivered nutrition sessions.

Intensity of intervention: external nutrition experts were trained to deliver the intervention in intensive 4-d training sessions. The experts delivered 15 standardised 2-h nutrition sessions (during preschool hours), conducted once weekly over a 6-month period, with 5 of these sessions actively involving parents (alone and with their children).

Intervention delivered by: research team, healthcare staff

Modality: face-to-face

Theoretical basis: The Theory of Social Learning and Zajonc's Exposure Effect

Description of control: wait-list control

De Bock 2011 (Continued)

Outcomes

Outcomes relating to child dietary intake:

Fruit intake, vegetable intake, water intake, sugared drink intake

Number of participants analysed: not reported

Data collection measure: parent survey

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, waist circumference, skinfold sum

Number of participants analysed: not reported

Data collection measure: objectively measured

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: the study was funded by a grant from the Baden-Württemberg Stiftung. Authors were funded by European Social Fund and by the Ministry of Science, Research and the Arts Baden-Württemberg.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	Assignment of preschools was blinded through the use of sequentially numbered, sealed envelopes. However, there is no mention as to whether envelopes were opaque.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Teachers and children were not blind to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Teachers and children were not blind to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents completed the eating behaviour questionnaire. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.

De Bock 2011 (Continued)

Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height, weight, waist circumference, and skinfold thickness were measured by study personnel who were blinded to group assignment.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	There was substantial dropout, whereby only 58% of the children provided both pre- and post-intervention measurements. It is unclear if the dropout is evenly distributed across arms, and no information is provided as to reasons for missing data/dropout. Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	There was substantial dropout, whereby only 58% of the children provided both pre- and post-intervention measurements. It is unclear if the dropout is evenly distributed across arms, and no information is provided as to reasons for missing data/dropout. Due to the magnitude of missing data, the risk of bias was assessed as high.
Selective reporting (reporting bias)	High risk	Anthropometric outcomes of BMI, weight-to-height ratio, and skinfold sum are specified in the protocol and study methods, however are reported incompletely. Study authors stated that "We also found no significant intervention effect on BMI, waist-to-height ratio, or skinfold sum," though no data are provided. Further, secondary dietary outcomes of water intake and consumption of high-energy drinks are specified in the protocol and study methods, however are reported incompletely. Study authors stated that "The intervention did not have significant effects on daily water intake or the consumption of high-energy drinks (data not presented)."
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of centres.
Baseline imbalance	Unclear risk	Study authors state that "We stratified the recruited pre-schools before randomisation to balance aggregate pre-school social background and immigrant proportion." Analysis adjusted for confounding factors, including child's age, gender, SES, and immigrant background. However, no baseline data are provided to compare randomised groups.
Loss of clusters	High risk	One cluster lost
Incorrect analysis	Low risk	Study authors stated that "As our data stemmed from natural pre-school-bound clusters of children, we first determined the extent of clustering. Intra-class correlation coefficients (ICC) on the level of pre-schools were 0.016 and 0.014 for the primary outcomes of fruit intake and vegetable intake, respectively. With an average cluster size of 19.5 children per pre-school, the design effect ($d = 1 + (\text{average cluster size} - 1) \times \text{ICC}$) did not exceed 2, allowing us to ignore the issue of clustering in our analyses."
Contamination	Unclear risk	No evidence to make assessment.
Other bias	Unclear risk	Study authors stated that "First, children were sampled from pre-schools that applied for a nutritional intervention, possibly resulting in limited generalizability" and "Third, despite the calculation of a minimal sample size of 332, we only had 202 children providing both pre- and post-intervention measurements. Our analysis thus may have been underpowered for detecting changes in anthropometric outcomes or water and sugar-sweetened drinks consumption." There is insufficient information to assess whether an important risk of bias exists.

De Coen 2012

Study characteristics

Methods

Study design: cluster-RCT

Length of follow-up from baseline: 2 years

Unit of allocation: communities (a local authority - town or municipality)

Unit of analysis: child

Participants

Service type: centre-based (pre-primary school)

Operation: not reported

Country (region): Belgium (Flanders)

Country income classification: high

Low-SES sample: no

Population description: the 6 communities were selected from the research regions in Flanders, Belgium disposed by the Flemish Policy Research Centre for Welfare, Health and Family, which commissioned the research project. The selection of these 6 communities out of the research regions was based on 5 socioeconomic characteristics: (i) the number of births in underprivileged families; (ii) the proportion of pupils in primary school with a school delay; (iii) the rate of unemployment; (iv) the number of people on welfare support; and (v) the number of underprivileged foreigners. High scores on these parameters are indicators of a lower socioeconomic profile.

Inclusion criteria: the selection of these 6 communities out of the research regions was based on 5 socioeconomic characteristics: (i) the number of births in underprivileged families; (ii) the proportion of pupils in primary school with a school delay; (iii) the rate of unemployment; (iv) the number of people on welfare support; and (v) the number of underprivileged foreigners. High scores on these parameters are indicators of a lower SES profile. If a community scored higher than the Flemish mean on 3-5 of the abovementioned characteristics, it was labelled as 'low SES'; communities with 1 or 2 scores higher than the Flemish mean were labelled as 'medium SES'; and communities with no scores higher than the mean were labelled as 'high SES'. 2 communities had a high, 2 had a medium and 2 had a low-SES profile.

Exclusion criteria: not reported

Number of services randomised: 6 communities (18/32 schools participated in intervention, 13/17 schools participated in control)

Number of children randomised: 1589 participated

Characteristics
Children

Age: 4.95 years (SD 1.31)

Gender (% female): 50%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

De Coen 2012 (Continued)

Method of recruitment: recruitment of the participants took place in pre-primary and primary schools.

Missing data/dropout: 46% dropout: 586 children dropped out for the questionnaire; 178 BMI values could not be attained at follow-up

Reasons for dropout: for BMI only: due to absence on the day of the measurement or change of school

Characteristics of dropouts: the baseline BMI z-scores were not significantly different between the communities. There were no other significant differences between intervention and control regions. Over the conditions, participants with a low SES dropped out significantly more at the follow-up measurement ($\text{Chi}^2 = 10.03$, $P = 0.001$).

Interventions

Programme name: the POP (Prevention of Overweight among Pre-school and school children)

Number of conditions: 1 intervention, 1 control

Intervention duration: 2 school years

Intervention setting: ECEC and wider community

Intervention strategies:

Health curriculum

Children

Education: schools were requested to implement 5 x Healthy Weeks per intervention year (1 for each cluster of topics) with a minimum 1 h of classroom time dedicated to the topic together with extracurricular activities.

Ethos and environment

ECEC staff

Resources: schools received guidelines and a manual describing the modules/objectives, tasks and responsibilities, including theory-based methods and practical strategies. These 7 modules were: the organisation of the POP project at school level; the organisation of classroom activities (Healthy Weeks), including suggested dose and content; development of an active playground; implementation of health-related physical education; environmental and policy changes to increase the availability of water at school (e.g. water fountains); environmental and policy changes to increase to availability of vegetables and fruits at school; and, educational strategies for parents on all topics.

Meetings: 4 x meetings with the teachers. An implementation plan and problem solving was discussed.

Financial support: teachers received EUR 250 to buy materials or finance environmental changes.

Service

Policy: schools were requested to evaluate and improve their playground and snack and beverage policy.

Partnerships

Families

Resources: parents received a poster, 5 letters and a website link to resources, distributed by the school.

Communication: schools were requested to communicate with the parents on the programme and distribute materials to the parents.

Community

Meetings: 2 x meetings were held in each intervention community with the researchers, community organisations and stakeholders regarding local social and health problems.

Engagement: community organisations, members of the city council, aldermen and local non-profit organisations working with children or health topics were approached to support the intervention at community level, to raise awareness and give greater publicity to the project.

Resources: each intervention year, information brochures and posters regarding the 5 topics of the project were distributed through general practitioners, pharmacists, social services and at relevant community events by the regional health boards and the research team.

De Coen 2012 (Continued)

Healthcare

Support: regional health boards supported schools and communities to implement the project (making contact with services at least twice/year). Regional health boards received EUR 500.

Intensity of intervention: 2 x community meetings to support the development of the intervention; yearly dissemination of information brochures and posters regarding the 5 intervention topics; 5 x Healthy Weeks per intervention year with a minimum of 1 h classroom time dedicated to the topic with extracurricular activities; 4 x teacher meetings; regional health boards contacted services at least twice yearly; parents received a poster, 5 letters and a website link.

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: Socio-Ecological Model in health promotion programmes

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Fruit intake, vegetable intake, milk intake, water intake, soft drink intake, sweet or savoury snack intake

Number of participants analysed:

Intervention baseline: 1032

Intervention follow-up: 396

Control baseline: 557

Control follow-up: 398

Data collection measure: 24-item semi-quantitative FFQ

Data collector: parent

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI z-score

Number of participants analysed

Intervention baseline: 1032

Intervention follow-up: 670

Control baseline: 557

Control follow-up: 442

Data collection measure: objectively measured (Flemish reference data using the LMS (curve-L, mean-M and coefficient of variation-S))

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

De Coen 2012 (Continued)

Outcome relating to adverse consequences: not reported

Notes

Funding source: commissioned, financed and steered by the Ministry of the Flemish Community (Department of Economics, science and Innovation; Department of Welfare, Public Health and Family).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	High risk	Study authors stated that "Schools were aware of the fact that they were in an intervention community or in a control community."
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents completed the semi-quantitative FFQ. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by the research team and are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data were available for 694 (54%) of sample at follow-up. Study authors stated that "selective drop-out may have influenced the outcomes. Although this was not particular for one condition, the low-SES participants dropped out significantly more." Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	Data were available for 1112 (70%) of sample at follow-up, and a higher percentage of the intervention group was lost to follow-up compared to the control group (35% vs 21%). Of the 477 dropouts, 178 (37%) were due to absence on the day of the measurement or change of school. Study authors stated that "selective drop-out may have influenced the outcomes. Although this was not particular for one condition, the low-SES participants dropped out significantly more." Due to the magnitude of missing data and difference in the proportions of participants followed up between groups, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	High risk	Individuals and schools were recruited after randomisation of clusters.
Baseline imbalance	Low risk	The baseline BMI z-scores were not significantly different between the communities. There were no other significant differences between intervention and control regions.

De Coen 2012 (Continued)

Loss of clusters	Low risk	No apparent loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Children were clustered in thirty-one schools (nesting variable)." and "the community was entered as a possible moderating factor by investigating the interaction between condition and community."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Study authors stated that "In some schools, parents experiencing language or other problems filling in the questionnaire were assisted by an intercultural worker or interpreter." However, it is not mentioned that the parental intervention itself was offered in multiple languages, introducing possible bias, especially if language barriers were higher in one group versus another. There is insufficient information to assess whether an important risk of bias exists.

Eliakim 2007
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 14 weeks</p> <p>Unit of allocation: preschool class</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschool)</p> <p>Operation: not reported</p> <p>Country (region): Israel (Oranit)</p> <p>Country income classification: high</p> <p>Low-SES sample: no</p> <p>Population description: an upper-middle SES community</p> <p>Inclusion criteria: the study included all 4 preschool classes in the community of Oranit, Israel. Children were included after their parents signed an informed consent form.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 4 (2 interventions, 2 control)</p> <p>Number of children randomised: 118</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention: 66 months (SD 0.6) Control: 67 months (SD 0.7)</p> <p><i>Gender (% female):</i></p> <p>Intervention: 39% Control: 47%</p>

Eliakim 2007 (Continued)

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: no dropout during the intervention period

Reasons for dropout: not applicable

Characteristics of dropouts: not applicable

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 14 weeks (4 months)

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: integrating nutritional topics, such as basic knowledge about major food groups and the food pyramid, vitamins, food choices, food preparation and cooking methods, fast food vs home cooking, and drinking and eating habits into the current curriculum. Topics were taught through short lectures/talks, games and book reading. Children were encouraged to reduce sedentary activities and increase after-school activity.

Ethos and environment

Children

Exposure: children participated in 45 min/d exercise training (6 d/week), primarily in the form of games.

Resources: children received dietary information using work sheets/flyers.

ECEC staff

Training: the intervention group preschool teachers were instructed so that all the nutritional aspects of the intervention and the majority of exercise classes were performed by the preschool staff.

Partnerships

Healthcare

Delivery: twice a week, physical activity training was directed by a professional youth coach.

Intensity of intervention: preschool teachers instructed so they could deliver the intervention; 2 x parent orientation lectures; nutrition education (intensity not reported); exercise training 45 min/d, 6 d/week

Intervention delivered by: research team, ECEC staff, healthcare

Modality: face-to-face, written

Theoretical basis: not reported

Eliakim 2007 (Continued)

Description of control: usual care, plus parents were invited for 2 orientation lectures (childhood obesity and beneficial effects of exercise in children) during the first 2 months of the programme

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

Weight, BMI, BMI percentile, body fat percentage, obese, overweight, overweight or obese

Number of participants analysed:

Intervention baseline: 54

Intervention follow-up: 54

Control baseline: 47

Control follow-up: 47

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive: not reported

Outcome relating to child social/emotional measures performance: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Study authors state only, "No adverse events were reported"

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Notes

Funding source: grant from the Israel Heart Fund, and the Carlos Lindenberg Memorial Fund of the Jewish Community of San Diego, USA

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Teachers appear to have been involved in intervention design and delivery so we assumed they were not blind to the study allocation. However the outcome is not likely to be influenced by lack of blinding.

Eliakim 2007 (Continued)

Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height, weight, and skinfold thickness were measured by the same trained individual and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Study authors stated that "54 children from the intervention group and 47 children from the control group started the program. No dropouts occurred during the intervention period." Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	No significant differences in age, gender, body weight and height, BMI, BMI percentiles, body fat, and fitness were found between groups prior to intervention.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	High risk	Classes were randomised, however there was no accounting for clustering of children within classes.
Contamination	Unclear risk	All 4 preschool classes were from the same community, however there is not enough information provided to assess whether contamination exists.
Other bias	Unclear risk	No conflict of interest statement was reported.

Fernandez-Jimenez 2019
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 5 months Unit of allocation: school Unit of analysis: child
Participants	Service type: centre-based (Head Start) Operation: public Country (region): USA (Harlem, New York City) Country income classification: high Low-SES sample: yes Population description: minority community (underserved, urban, multi-ethnic). Harlem is predominantly a mix of immigrant Hispanic and African-American populations. Inclusion criteria: the preschools must be located in Harlem, New York; public; have children between ages 3 and 5 years of age; provide meals for the children; and, must make available use of their applicable programme operation space. Preschools were also asked to commit to not to participate in any other major structured health intervention programme aside from the usual curriculum during the study.

Fernandez-Jimenez 2019 (Continued)

Exclusion criteria: not reported

Number of services randomised:

Number of children randomised: 585 (413 intervention, 172 control)

Characteristics

Children

Age: 4.1 years (SD 0.6)

Gender (% female): 51.10%

Ethnicity: non-Hispanic black: 37.4%; Hispanic/Latino: 53.9%; other/multiracial: 8.7%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: approximately 20% of children were lost to follow-up or had incomplete data. No school withdrew from the study.

Reasons for dropout: mainly because preschoolers aged out and moved to other schools and/or residences

Characteristics of dropouts: not reported

Interventions

Programme name: the FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) trial

Number of conditions: 1 intervention, 1 control

Intervention duration: 4 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: 37 h of educational programme over 4 months

Partnerships

Families

Education: invitations to informational and educational meetings, called FAMILIA days, and a minimum of 11 family health activities (12 h) that the teacher regularly provided to parents during the duration of the child educational intervention

Resources: teachers regularly sent educational material with the students to work on with their families at home.

Intensity of intervention: 37-h educational programme for children over 4 months; 12 h of educational meetings for parents/caregivers

Intervention delivered by: research team, ECEC staff

Modality: face-to-face

Fernandez-Jimenez 2019 (Continued)

Theoretical basis: not reported

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI z-score

Number of participants analysed:

Intervention baseline: 304

Intervention follow-up: 304

Control baseline: 144

Control follow-up: 144

Data collection measure: objectively measured (CDC)

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: emotional comprehension score

Number of participants analysed:

Intervention baseline: 304

Intervention follow-up: 304

Control baseline: 144

Control follow-up: 144

Data collection measure: Test of Emotion Comprehension (TEC) questionnaire

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Study authors state only, "No adverse events were reported"

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Notes

Funding source: American Heart Association under grant No. 14SFRN20490315

Risk of bias

Fernandez-Jimenez 2019 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Social/emotional outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured and were not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Social/emotional outcomes	Unclear risk	No information provided on whether the individuals conducting the Test of Emotion Comprehension were blind to group allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Study authors stated that "After a median follow-up of 5.4 months, ~20% of children were lost to follow-up or had incomplete data; therefore, 448 children (304 in the intervention group and 144 in the control group) were included in the main analysis (complete-case intention-to-treat analysis) of the primary outcome of the study." Similar reasons for loss to follow-up were noted between groups (i.e. unable to contact, unable to schedule, moved, withdrew consent). Study authors stated that "The primary analysis was supplemented by sensitivity analyses conducted using multiple imputation procedures, which explored different assumptions for the distribution of the missing data. Similar results were obtained across these sensitivity analyses. Therefore, we might reasonably assume that the missing data did not significantly affect the validity of our findings." Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Social/emotional outcomes	Low risk	Study authors stated that "After a median follow-up of 5.4 months, ~20% of children were lost to follow-up or had incomplete data; therefore, 448 children (304 in the intervention group and 144 in the control group) were included in the main analysis (complete-case intention-to-treat analysis) of the primary outcome of the study." Similar reasons for loss to follow-up were noted between groups (i.e. unable to contact, unable to schedule, moved, withdrew consent). Study authors stated that "The primary analysis was supplemented by sensitivity analyses conducted using multiple imputation procedures, which explored different assumptions for the distribution of the missing data. Similar results were obtained across these sensitivity analyses. Therefore, we might reasonably assume that the missing data did not significantly affect the validity of our findings." Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were pre-specified in the protocol paper.

Fernandez-Jimenez 2019 (Continued)

Recruitment bias	High risk	Individual recruitment occurred after randomisation of clusters.
Baseline imbalance	Low risk	No significant differences were found between groups at baseline, except that there was a greater proportion of Hispanic/Latino compared with non-Hispanic Black children in the intervention group as compared with the control group. Study authors state that "Interaction models were also fitted to identify possible baseline score-, age-, sex-, race/ ethnicity-, and socioeconomic-by-treatment effects for the main outcome variable."
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Multilevel linear mixed-effects models that account for the hierarchical cluster randomized design were used to test for the adjusted intervention effect."
Contamination	Unclear risk	All schools were from the same community, however there is not enough information provided to assess whether contamination exists.
Other bias	Unclear risk	Protocol states that school recruitment would occur in a 2:1 ratio (intervention: control), however the study states that recruitment occurred in a 3:2 ratio. No explanation provided for deviation from protocol. There is insufficient information to assess whether an important risk of bias exists.

Fitzgibbon 2005
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 14 weeks Unit of allocation: school Unit of analysis: child
Participants	Service type: centre-based (Head Start) Operation: not reported Country (region): USA (Chicago) Country income classification: high Low-SES sample: yes Population description: primarily black Inclusion criteria: all children at the sites were eligible to participate. Exclusion criteria: not reported Number of services randomised: 12 (6 intervention, 6 control) Number of children randomised: 409 (197 intervention, 212 control) Characteristics Children Age:

Fitzgibbon 2005 (Continued)

Intervention: 48.6 months (SD 7.6)
Control: 50.8 months (SD 6.4)

Gender (% female):

Intervention: 49.7%
Control: 50.5%

Ethnicity:

Intervention: black: 99%; Latino: 0%; multiracial/other: 1%
Control: black: 80.7%; Latino: 12.7%; multiracial/other: 6.6%

Parents

Parent/caregiver age (years):

Intervention: 30.0 (SD 9.7)
Control: 30.8 (SD 9.5)

Parents gender (% female): 100%

Parent/Caregiver Ethnicity: not reported

Parent/family SES:

Female parent years of education
Intervention: 12.4 (SD 1.8)
Control: 12.7 (SD 1.7)

Method of recruitment: not reported

Missing data/dropout: 89% retention for BMI and 78% for dietary outcomes

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Hip-Hop to Health Jr

Number of conditions: 1 intervention, 1 control

Intervention duration: 14 weeks

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: healthy eating and exercise intervention covered health topics. Sessions included a 20-min lesson that introduced a healthy eating or exercise concept with an activity. The lessons and activities often involved colourful, friendly, handheld puppets that represent the 7 foods of the food pyramid.

Ethos and environment

Children

Exposure: sessions also incorporated 20 min of teacher-led, ongoing physical activity with a 5-min warm-up, 10 min of aerobic activity, and a 5-min cool-down.

Partnerships

Families

Resources: parents received weekly newsletters with information that mirrored the children's curriculum and included a homework assignment to reinforce concepts.

Fitzgibbon 2005 (Continued)

Incentive: parents received USD 5 grocery store coupon for each homework assignment completed.

Intensity of intervention: 40-min lessons, 3 times a week for children for 14 weeks; weekly newsletters and weekly homework assignment (approximately 15 min activity) for parents

Intervention delivered by: ECEC staff

Modality: face-to-face, written

Theoretical basis: Social Learning theory, Self-Determination Theory and the Transtheoretical Model that incorporates stages of change

Description of control: alternative intervention control (covered general health concepts such as dental health, immunization, seat belt safety, and 911 procedures).

Outcomes

Outcomes relating to child dietary intake:

Total fat intake, saturated fatty acids, dietary fibre

Number of participants analysed:

Intervention baseline: 175

Intervention follow-up: 133

Control baseline: 183

Control follow-up: 147

Data collection measure: partial or full recall by parent

Data collector: researcher (parents provided information to researcher)

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, BMI z-score, weight

Number of participants analysed:

Intervention baseline: 197

Intervention follow-up: 179

Control baseline: 212

Control follow-up: 183

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Study authors state only, "No adverse events were reported for any participants"

Fitzgibbon 2005 (Continued)

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Notes **Funding source:** supported by a grant from the National Heart, Lung, and Blood Institute (Grant HL58871).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Dietary intake data were obtained from the parent by a trained and certified registered dietitian who was blinded to treatment group.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data were available for 133 (68%) participants in the intervention group and 147 (69%) students in the control group at post-intervention. Due to the magnitude of missing data at follow-up, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 179 (96%) participants in the intervention group and 183 (86%) students in the control group at post-intervention. Due to the relatively small (< 20%) proportion of missing data across both groups, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	Only 24-h recall results were published in study, yet prior publication mentions diet observation and FFQ, as well.
Recruitment bias	Unclear risk	It is unclear whether allocation occurred before or after baseline data collection.
Baseline imbalance	Unclear risk	Groups were comparable at baseline for all but age, race, exercise frequency, height, and weight, though height and weight differences were no longer significant when adjusted for age.
Loss of clusters	Low risk	No apparent loss of clusters

Fitzgibbon 2005 (Continued)

Incorrect analysis	Low risk	Dietary measures, BMI and BMI z-score are adjusted for Head Start site
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	No conflict of interest statement was reported.

Fitzgibbon 2006
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 14 weeks</p> <p>Unit of allocation: school</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (Head Start)</p> <p>Operation: not reported</p> <p>Country (region): USA (Chicago)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: predominantly Latino centres</p> <p>Inclusion criteria: all children were eligible to participate in the intervention.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 12 (6 intervention, 6 control)</p> <p>Number of children randomised: 401 (202 intervention, 199 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention: 50.8 months (SD 7.3) Control: 51.0 months (SD 7.0)</p> <p><i>Gender (% female):</i></p> <p>Intervention: 47.5% Control: 51.3%</p> <p><i>Ethnicity:</i></p> <p>Intervention: black: 15.8%; Latino: 73.3%; multiracial/other: 10.9% Control: black: 6.5%; Latino: 89.4%; multiracial/other: 4%</p> <p>Parents</p> <p><i>Age (years):</i></p> <p>Intervention: 31.5 (SD 8.6)</p>

Fitzgibbon 2006 (Continued)

Control: 30.7 (SD 7.2)

Gender (% female): 100%

Ethnicity: not reported

Parent/family SES:

Female parent years of education

Intervention: 11.3 (SD 3.6)

Control: 10.6 (SD 3.7)

Method of recruitment: not reported

Missing data/dropout: retention rate at post-intervention was 97%

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Hip-Hop to Health Jr

Number of conditions: 1 intervention, 1 control

Intervention duration: 14 weeks

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: a diet/physical activity curriculum delivered by trained ECEC educators 3 x/week. Each session included 20 min of nutrition activity based on hand puppets that reflected the food pyramid.

Ethos and environment

Children

Exposure: 20 min of aerobic activity led by trained ECEC educators 3 x/week

All participants

Cultural: the programme was culturally proficient, tailored to a Latinx population and delivered in both Spanish and English.

Partnerships

Families

Resources: parents received weekly newsletters and accompanying homework assignments designed to be an interactive activity between parents and children.

Incentive: a small monetary incentive was provided for completed homework.

Intensity of intervention: 40-min lessons, 3 times/week for children for 14 weeks; 12 x weekly newsletters, weekly homework assignments for parents

Intervention delivered by: ECEC staff

Modality: face-to-face, written

Theoretical basis: Social Cognitive Theory and Self-Determination Theory

Description of control: alternative intervention control (covered general health concepts such as seat belt safety, immunisation, and dental health)

Outcomes

Outcomes relating to child dietary intake:

Fitzgibbon 2006 (Continued)

Total fat, saturated fatty acids, fibre

Number of participants analysed:

Intervention baseline: 188

Intervention follow-up: 178

Control baseline: 174

Control follow-up: 156

Data collection measure: partial or full recall by parent

Data collector: researcher (parent provided information to researcher)

Validity of measures used: not reported

Outcomes relating to child physical measures:

Weight, BMI, BMI z-score

Number of participants analysed:

Intervention baseline: 202

Intervention follow-up: 196

Control baseline: 199

Control follow-up: 187

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Study authors state only, "No adverse events reported during the trial for any participants"

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Notes

Funding source: National Heart, Lung, and Blood Institute (Grant HL 58871)

Risk of bias

Bias

Authors' judgement

Support for judgement

Random sequence generation (selection bias)

Unclear risk

The random sequence generation procedure was not described.

Fitzgibbon 2006 (Continued)

Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data were available for 178 (88%) participants in the intervention group and 156 (78%) students in the control group at post-intervention. Due to the magnitude of missing data and difference in the proportions of participants followed up between groups, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 196 (97%) participants in the intervention group and 187 (94%) students in the control group at post-intervention. There were no significant differences in retention rates between intervention and control groups. Study authors stated that "The primary analytic approach was ITT, with all participants completing follow-ups included in the condition to which they were assigned." Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	Only 24-h recall results were published in the study, yet prior publication mentions diet observation and FFQ
Recruitment bias	Unclear risk	Baseline data collection occurred after randomisation of schools, however it is unclear whether individual recruitment occurred before or after randomisation.
Baseline imbalance	High risk	Study authors report baseline imbalance that is not accounted for in the analysis
Loss of clusters	Low risk	No apparent loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Proc Mixed was used, with the individual school as the unit of randomization, yielding a test statistic with 10 df for 12 schools."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Fitzgibbon 2011
Study characteristics

Fitzgibbon 2011 (Continued)

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 14 weeks (varies with outcomes)</p> <p>Unit of allocation: school</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (Head Start)</p> <p>Operation: public</p> <p>Country (region): USA (Chicago)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: not reported</p> <p>Inclusion criteria: up to 2 children/family were eligible to participate.</p> <p>Exclusion criteria: not reported (exclusions appear to occur after baseline)</p> <p>Number of services randomised: 18 (9 intervention, 9 control)</p> <p>Number of children randomised: 729 (376 intervention, 353 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 51.3 months (SD 6.6)</p> <p><i>Gender (% female):</i> 53%</p> <p><i>Ethnicity:</i> black: 94%; Latino: 3%; multiracial/other: 3%</p> <p>Parents</p> <p><i>Age (years):</i> 30.9 (SD 8.6)</p> <p><i>Gender (% female):</i> 90%</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i></p> <p>Income, USD, median: 15,000 Education, years: 12.3 (SD 1.7)</p> <p>Method of recruitment: not reported</p> <p>Missing data/dropout: baseline data were collected for the 669 children (92%) however, 50 of these children were excluded.</p> <p>Reasons for dropout: transferred out of the participating schools before the intervention began, and 1 child was excluded because he was the 3rd child in a participating family.</p> <p>Characteristics of dropouts: not reported</p>
Interventions	<p>Programme name: teacher-delivered Hip-Hop to Health Jr</p> <p>Number of conditions: 1 intervention, 1 control</p> <p>Intervention duration: 14 weeks</p>

Fitzgibbon 2011 (Continued)

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: teachers taught 2 sessions/week, with the option of including a 3rd session. Each week focused on a theme with a specific objective. Each session included a 20-min lesson related to healthy eating and exercise. Lessons featured colourful "pyramid puppets" to represent the 7 food groups of the food pyramid. Intervention incorporated songs and raps on a CD.

Ethos and environment

Children

Exposure: each session also incorporated 20 min of physical activity. Intervention CD included 2 fully scripted exercise routines.

ECEC staff

Training: teachers attended training sessions. Following the first formal session, the intervention co-ordinator conducted 3 in-school training sessions and met with teachers on an individual basis weekly.

All participants

Cultural: cultural considerations for black children were incorporated in the intervention.

Partnerships

Families

Resources: parents received weekly newsletters that paralleled the children's curriculum in content and included a homework assignment. Parents also received the CD to reinforce nutrition and physical activity concepts at home.

Incentive: parent received USD 5 for each homework assignment completed and returned.

Intensity of intervention: 1 x 3 h initial staff training, plus 3 x in-school staff training sessions; intervention co-ordinator met with teachers weekly to support intervention delivery; 40-min lessons, 2 sessions/week (teacher could opt for 3rd); weekly parent newsletters that included homework

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, written

Theoretical basis: Social Cognitive Theory and Self Determination Theory

Description of control: alternative intervention control (covered health concepts including care seats, seat belt safety, immunisation, dental health and calling 911)

Outcomes

Outcomes relating to child dietary intake:

Energy, total fat, fibre, fruit, 100% fruit juice, vegetables, diet quality (total, total fruit, whole fruit, saturated fat, whole grains, total vegetables, solid fats and added sugars)

Number of participants analysed:

Intervention baseline: 278

Intervention follow-up: 196-238

Control baseline: 230

Control follow-up: 160-202

Data collection measure: 24-h diet record (combination of in-school observations and food records or recalls completed by parent)

Data collector: parent and researcher

Fitzgibbon 2011 (Continued)

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, BMI z-score, weight

Number of participants analysed:

Intervention baseline: 325

Intervention follow-up: 309

Control baseline: 293

Control follow-up: 280

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: supported by the National Heart, Lung and Blood Institute (HL081645)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was unclear.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Due to the nature of the study design, both parents and interviewers were aware of group assignments. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Due to the nature of the study design, both parents and interviewers were aware of group assignments. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Dietary intake was reported by parents and observed by research staff. There was no blinding of outcome assessors, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were measured by interviewers aware of group assignments, however the outcome measurements are not likely to be influenced by lack of blinding.

Fitzgibbon 2011 (Continued)

Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Only 86% of intervention and 79% of control had baseline diet data, and follow-up loss was 14% of intervention children with baseline diet data (27% loss from all children in intervention group) and 12% of control children with baseline diet data (31% loss from all children in control group). Study authors stated that "The proportion of children with valid records differed by school (highest = 94%, lowest = 55%, $p < 0.001$) but not by intervention group ($P = 0.24$). The 440 children who had valid diet records at both visits did not differ significantly from the other 178 children in gender, race, age, BMI, BMI z-score, weight or height. There was also no significant difference in parents' gender, age, education, median income, marital status, full-time employment, BMI, height, or weight." Study authors stated that "Only children with valid data for the relevant variables at baseline and postintervention were included in analyses (BMI change, physical activity, screen time, and diet)." Therefore, risk of attrition bias was considered low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	All children enrolled in the study (minus those who were excluded prior to intervention) were measured at baseline. Follow-up data were available for 309 (95%) children in the intervention group and 280 (96%) children in the control group. No information regarding missing data provided. Study authors stated that "Only children with valid data for the relevant variables at baseline and postintervention were included in analyses (BMI change, physical activity, screen time, and diet)." Therefore, risk of attrition bias was considered low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	Recruitment of preschools occurred before randomisation, however it is not clear whether recruitment of children came before or after randomisation of preschools.
Baseline imbalance	High risk	Groups differed at baseline by total screen time/d, energy intake, and fibre intake, however the model only adjusted for baseline BMI and BMI z-score, age, preschool, and classroom.
Loss of clusters	Unclear risk	One cluster did not have diet observation data because school personnel felt the in-school diet observations would be disruptive. It is unclear whether other clusters were lost due to insufficient reporting.
Incorrect analysis	Low risk	Study authors stated that "To test for differences between groups in BMI and BMI Z score change at postintervention, we used both mixed-model analysis of variance, controlling for school and classroom nested within school, and mixed model analysis of covariance, controlling for school, classroom nested within school, the baseline value, and baseline age."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Fitzgibbon 2013
Study characteristics

Methods	Study design: cluster-RCT
	Length of follow-up from baseline: 14 weeks
	Unit of allocation: preschool

Fitzgibbon 2013 (Continued)

Unit of analysis: child

Participants

Service type: centre-based (Head Start)

Operation: public

Country (region): USA (Chicago)

Country income classification: high

Low-SES sample: yes

Population description: Hispanic children and their parents

Inclusion criteria: a parent-child dyad was eligible if the parent gave informed consent for herself and the child, the child's height and weight were measured at baseline, and the child was still enrolled in a participating classroom when the intervention began. Up to 2 children per family were eligible to participate.

Exclusion criteria: not reported

Number of services randomised: 4 (2 interventions, 2 control)

Number of children randomised: 157 (78 intervention, 79 control)

Characteristics
Children
Age: 54.2 months (SD 5.0)

Gender (% female): 50%

Ethnicity: Latino: 94%; black: 2%; multiracial/other: 4%

Parents
Age (years): 32.8 (SD 6.0)

Gender (% female): 89%

Ethnicity: unclear

Parent/family SES:

Income (USD median: 15,000

Parent education (years): 11.2 (SD 2.2)

Method of recruitment: not reported

Missing data/dropout: all clusters retained, however 1 intervention and 2 control participants were missing from follow-up.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Family-Based Hip-Hop to Health

Number of conditions: 1 intervention, 1 control

Intervention duration: 14 weeks

Intervention setting: ECEC and home

Intervention strategies:

Fitzgibbon 2013 (Continued)

Health curriculum

Children

Education: a nutrition and physical activity curriculum (3 x/week) was provided to children, led by bilingual/bicultural educator and supplemented by a Spanish language CD. The nutrition instructions included activities led by puppets representing food groups. The nutrition and physical activity components designed to target specific child behaviours (e.g. increase consumption of fruits and vegetables, reduce television viewing, and increase duration of daily physical activity).

Ethos and Environment

Children

Exposure: each session also included 20 min of aerobic activity.

All participants

Cultural: the intervention was tailored to cultural and developmental needs of the population (lower-income, Hispanic populations).

Partnerships

Parents

Education: parents encouraged to attend 6 weekly 90-min classes that included 60 min of interactive curriculum (healthy eating and exercise for weight management), supplemented with the Spanish language CD.

Exposure: the remaining 30 min involved moderate physical activity (e.g. salsa aerobics, walking group).

Resources: parents received weekly newsletters with programme information. Each family received a copy of the Spanish language CD to reinforce the classroom material at home.

Intensity of intervention: 40-min nutrition education sessions/week for children; 6 x 90-min education sessions for parents; weekly newsletters for parents

Intervention delivered by: ECEC staff

Modality: face-to-face, written

Theoretical basis: Social Cognitive Theory, the Health Belief Model and Self-Determination Theory

Description of control: alternative intervention control (covered health concepts including seat belt safety, immunisation, dental health and calling 911)

Outcomes

Outcomes relating to child dietary intake:

Energy, total fat, fibre, fruit, 100% fruit juice, vegetables

Number of participants analysed:

Intervention baseline: 55

Intervention follow-up: 50

Control baseline: 58

Control follow-up: 56

Data collection measure: 24-h diet record (combination of in-care observations and parent records for all foods consumed outside of care)

Data collector: parent-reported and researcher observations

Validity of measures used: not reported

Outcomes relating to child physical measures:

Fitzgibbon 2013 (Continued)

BMI, BMI z-score, weight

Number of participants analysed:

Intervention baseline: 72

Intervention follow-up: 71

Control baseline: 74

Control follow-up: 72

Data collection measure: objectively measured (CDC)

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: National Cancer Institute (CA121423), R25CA057699, and the Consortium to Lower Obesity in Chicago Children (CLOCC)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Dietary intake was reported by parents and observed by research staff. There was no blinding of outcome assessors, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were measured by interviewers aware of group assignments, however the outcome measurements are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Only 76% of intervention and 78% of control had baseline diet data, and follow-up loss was 9% of intervention children with baseline diet data (31% loss from all children in intervention group) and 3% of control children with baseline diet data (24% loss from all children in control group). Study authors stat-

Fitzgibbon 2013 (Continued)

ed that "Only participants with height and weight measurements, valid accelerometer records, complete screen time data, or valid diet data at baseline and follow-up were included in the relevant follow-up analyses." No information provided regarding reasons for missing data at follow-up. Due to the magnitude of missing data, the risk of bias was assessed as high.

Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 71 (99%) participants in the intervention group and 72 (97%) students in the control group at post-intervention. Study authors stated that "Only participants with height and weight measurements, valid accelerometer records, complete screen time data, or valid diet data at baseline and follow-up were included in the relevant follow-up analyses." Reason for missing data was similar across groups (i.e. missed visit). Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Unclear risk	Per the PRISMA diagram, individual recruitment occurred after randomisation of preschools. However, it is unclear if parents were aware of allocation at recruitment.
Baseline imbalance	Unclear risk	Baseline analysis was conducted but results were not provided.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "We used a mixed model analysis of covariance to test for differences between groups in physical activity at post-intervention and in screen time and diet at post-intervention and follow-up, controlling for school, classroom nested within school, and the baseline value." and "To test for differences between groups in BMI and BMI z-score change at post-intervention and 1-year follow-up, we used a mixed model ANOVA, controlling for school and classroom nested within school, as well as a mixed model analysis of covariance, controlling for school, classroom nested within school, the BMI percentile at baseline (< 85th or > 85th), baseline age, and time between visits."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Gans 2022
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 8 months Unit of allocation: family child-care homes (i.e. family day care) Unit of analysis: child
Participants	Service type: family child-care homes Operation: not reported Country (region): USA (Rhode Island and Massachusetts)

Gans 2022 (Continued)

Country income classification: high

Low-SES sample: yes

Population description: Rhode Island (RI) is a state where approximately 16% of the population identifies as Hispanic or Latinx, at least 40% of family child-care providers are Spanish speaking.

Inclusion criteria: family child-care providers had to meet the following criteria: have a family day care within 60 miles of Providence, Rhode Island in operation for at least 6 months; be able to read and speak Spanish or English; have a working phone; care for at least 1 unrelated 2–5 year-old child for 10 h or more/week who ate at least 1 meal and snack/d at the family child-care home and, family child-care providers could not plan to close their service for > 3 consecutive weeks during the year following their enrolment in the study.

Exclusion criteria: not reported

Number of services randomised: unclear

Number of children randomised: 119 (60 intervention, 59 control)

Characteristics

Children

Age: 41.7 months (SD 12.0)

Gender (% female): 50%

Ethnicity:

Ethnicity: Latinx: 55%, non-Latinx: 43, missing: 2%

Race: white: 46%, black: 10%, Asian: 1%, American Indian: 1%, Native Hawaiian: 1%, other/> 1 race: 39%, missing: 3%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

ECEC staff

Age (years): 48.86 (SD 8.96)

Gender (% female): 100%

Ethnicity:

Ethnicity: Hispanic: 67.2%; non-Hispanic: 32.8%

Race: white: 2.6%; NA/NA/NP/PI (not defined): 19%; mixed race: 24.1%; declined or missing: 54.3%

Service/ECEC staff SES: household income < USD 25,000: 12.6%; USD 25,001-USD 50,000: 47.9%, USD 50,001-USD 75,000: 20.2%; USD 75,001-USD 100,000: 10.1%; ≥ USD 100,001: 5.9%; missing: 3.4%

Method of recruitment: recruitment, enrolment and baseline assessment was conducted on a rolling basis from 2015-2018. A variety of recruitment strategies were used including: (1) information sessions at community organisations that provide training and support for family child-care providers. These organisations also offered recruitment flyers and brochures to family child-care providers; (2) meetings with the co-ordinators of family child-care provider systems who then emailed study information to family child-care providers in their systems; (3) presentations at local family child-care providers' conferences; (4) direct mailings followed by staff phone calls to licensed family child-care providers whose contact information was publicly available through state databases in Rhode Island, and Mass-

Gans 2022 (Continued)

achusetts; and (5) word of mouth referrals from family child-care providers already participating in the study.

Missing data/dropout: 168 family child-care providers completed the baseline survey, 126 completed the in-person survey/baseline visit and consented to enrol, and 120 completed the 2-d baseline observations. Of those, 1 family child-care provider withdrew after baseline measurement but before randomisation. A total of 423 parents of eligible children consented for their children to be observed and/or measured; 377 of those children had at least 1 measurement; 370 children had their meals observed; 349 had accelerometer measurement, and 327 had anthropometric measurements.

Reasons for dropout: reasons for dropout included: did not have kids 2-5 in home to observe at follow-up, did not want home observation, withdrew from study and loss of contact.

Characteristics of dropouts: not reported

Interventions

Programme name: Healthy Start-Comienzos Sanos

Number of conditions: 1 intervention, 1 control

Intervention duration: 8 months

Intervention setting: family child-care home

Intervention strategies:

Ethos and environment

ECEC staff

Resources: monthly materials (a report, newsletters and videos (via DVD or emailed video link) in English or Spanish) tailored to the topic chosen by the family child-care provider

Feedback and support: monthly support from a support coach trained in brief motivational interviewing. First, the coach reviewed with the family child-care provider in person, an individually tailored written feedback report that indicated whether the provider met or did not meet best practices for nutrition, physical activity and screen-time topics (based on baseline data).

Motivational interviewing: the coach then conducted brief motivational interview with the family child-care provider. At the end of the session, the family child-care provider selected 1 topic to work on. Monthly calls using motivational interviewing were completed following this.

Meetings: in-person group meetings led by the support coach were also held every 6 weeks in a central public location (e.g. library or church). All participating family child-care providers were invited to attend these meetings to support one another, discuss challenges and successes, learn a new activity, and share a meal.

Service

Resources: a set of active toys (e.g. hula hoops, tunnel, bean bags, soft balls) with accompanying activity cards and video clips with ideas for using the toys.

Partnerships

External provider

Delivery: a support coach delivered the intervention.

Intensity of intervention: 8 x monthly staff meetings; 8 x monthly staff resources; staff group meetings every 6 weeks

Intervention delivered by: healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: Social ecological framework, Social Cognitive Theory, Self Determination Theory

Gans 2022 (Continued)

Description of control: alternative intervention (covered reading readiness and early literacy skills)

Outcomes

Outcomes relating to child dietary intake:

Diet quality (total fruit, whole fruit, total vegetable, greens and beans, whole grains, total dairy, total protein, seafood and plant protein, fatty acids, refined grains, sodium, added sugar, saturated fats)

Number of participants analysed:

Intervention baseline: 187

Intervention follow-up: 187

Control baseline: 190

Control follow-up: 190

Data collection measure: Dietary Observation in Child Care

Data collector: researchers

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: this project was funded by the National Heart Lung and Blood Institute, Grant # NIH - R01HL123016. The funding body had no role in the design of the study and collection, analysis, and interpretation of data nor in writing the manuscript.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors state that services were "randomized into either the intervention or comparison group in matched pairs based on primary language spoken and number of age eligible children in their family childcare homes using a Microsoft Excel randomization function."
Allocation concealment (selection bias)	Low risk	Study authors state "Once family childcare home providers completed all baseline measures, they were randomized into either the intervention or comparison group in matched pairs".
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Study authors state that "Because the days of observation were announced, it is possible that family child care providers changed their behavior on the occasions of having observers in their home, although this would likely have affected both experimental groups." However, providers were informed of their study allocation by the project co-ordinator. The outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Evaluation staff were not informed of the intervention group assignment. Study authors state that "we did not measure whether blinding of observers was successfully achieved. However, the field staff were not told the experimental group of family child care provider they observed. Toys that were provided did not have any project identifying information on them, so should not

Gans 2022 (Continued)

		have unblinded experimental group status. In addition, the observers were trained not to have conversations with providers except to clarify information about recipes or ingredients."
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Data were available for 370/423 (87%) of children overall, 42/60 (70%) services in the intervention group, and 47/59 (80%) services in the control group. Study authors state that "Family child care providers and children who completed follow-up were similar to those who were lost to follow-up, suggesting that attrition did not overly bias the sample." Reasons for service dropout were provided, however it is unclear whether missing outcome data were related to the true outcome.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	Low risk	Individual recruitment occurred prior to service randomisation
Baseline imbalance	Low risk	Baseline analysis was conducted and there were no significant differences between groups for age, sex, race, ethnicity, or other demographic variables for children or family child-care provider.
Loss of clusters	Unclear risk	30% of clusters were lost in the intervention group and 20% of clusters lost in the control group. Study authors state that "there was no differential dropout between experimental groups, therefore we did not include imputation of missing values in the analyses." It is unclear whether this loss of clusters introduced bias.
Incorrect analysis	Low risk	Study authors state that "Generalized Estimating Equations (GEE) with robust standard errors were used to model HEI [Healthy Eating Index] scores and physical activity over time. A working independence correlation structure was used to correct for dependency of observations within family child care providers."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Grummon 2019
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 12 weeks Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based Operation: public (combination of full-time and part-time programmes) Country (region): USA (San Mateo County, California) Country income classification: high Low-SES sample: yes

Grummon 2019 (Continued)

Population description: primarily English- or Spanish-speaking families and low income

Inclusion criteria: centres were eligible if they were in San Mateo County, California; were licensed; had enrolled at least 10 children aged 2–5 years; had English- or Spanish-speaking staff; served primarily English- or Spanish-speaking families; and participated in the Child and Adult Care Food Program (a federal nutrition assistance programme providing funding for meals and snacks, and a marker for centres that serve lower-income children). At each centre, all eligible children and their parents were invited to participate. Children were eligible if they were 2–5 years old. Their parents were eligible if they spoke English or Spanish.

Exclusion criteria: not reported

Number of services randomised: 4 (2 intervention, 2 control)

Number of children randomised: 164 (87 intervention, 77 control)

Characteristics

Children

Age:

Intervention: 4.1 years (SD 0.59)

Control: 4.32 years (SD 0.44)

Gender (% female): 56%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity:

Intervention: Hispanic ethnicity: 98%

Control: Hispanic ethnicity: 82%

Parent/family SES:

Annual household income ≤ USD 30,000:

Intervention: 67%

Control: 67%

Education of high school degree or less:

Intervention: 66%

Control: 54%

Method of recruitment:

not reported

Missing data/dropout: of the 161 children measured at baseline, 7 (4%) were lost to follow-up.

Reasons for dropout: child no longer enrolled at child care

Characteristics of dropouts: not reported

 Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 weeks

Intervention setting: ECEC and home

Grummon 2019 (Continued)

Intervention strategies:

Health curriculum

Children

Education: children participated in activities while at child care, including singing along to the 'Drink More Water' children's song, and reading the children's book *Potter the Otter: A Tale About Water* (facilitated by child-care teachers or research assistants).

Ethos and environment

Children

Exposure: providers served children water at meals and snacks. Children sampled water infused with fruit or herbs.

Materials: children received a CD with the 'Drink More Water' song, a copy of the Potter the Otter book and stickers promoting water consumption.

Service

Environment: classrooms provided with child-sized pitchers, cups and water bottles

Policy: implementation of rules and policies. The study principal investigator met with centre directors and head teachers to explain the Healthy Beverages policy and asked that centres comply with standards. Centre directors incorporated rules about beverages into staff handbooks or policies using language provided by the research team.

Partnerships

Families

Workshop: parents invited to attend in-person training (study staff described how to determine the amount of added sugar in beverages)

Resources: parents received written 'behavioural contracts' listing rules about beverages they might consider adopting.

Educational activities: parents received personalised report cards with their child's weight and beverage consumption, handouts (e.g. recipes for spa water) and interactive family activities (e.g. a worksheet for finding free water sources at the park).

Community

Engagement: community advisory board (representatives from county public health, local child-care organisations, child-care providers and parents) provided regular feedback.

Intensity of intervention: frequency and duration of strategies were not reported

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, written

Theoretical basis: The Social Ecological Framework

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

All less healthy beverage intake, all healthier beverage intake, 100% juice intake, total sugar-sweetened beverage intake (excluding sweetened milk), unsweetened high-fat milk (2% or whole) intake, sweetened milk intake, total water intake, tap water intake, bottled water intake, unsweetened low-fat or non-fat milk intake

Number of participants analysed:

Intervention baseline: 80

Intervention follow-up: 80

Control baseline: 74

Grummon 2019 (Continued)

Control follow-up: 74

Data collection measure: parent-reported questionnaire

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI percentile, BMI, overweight or obese

Number of participants analysed:

Intervention baseline: 80

Intervention follow-up: 80

Control baseline: 74

Control follow-up: 74

Data collection measure: objectively measured (CDC)

Data collector: trained research assistants

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: National Institutes of Health (grant number K23 HD067305 to A.I.P.). Carolina Population Center (grant numbers P2C HD050924 and T32 HD007168). Johns Hopkins Center for a Livable Future – Lerner Fellowship. Maternal and Child Health Bureau, Health Resources and Services Administration, US Department of Health and Human Services (grant numbers U45MC27709 and UA6MC27378)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.

Grummon 2019 (Continued)

Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's at-home beverage consumption. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by a trained research assistant and the outcome measurements are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 80 (94%) children in the intervention group and 74 (97%) children in the control group. Reasons for loss to follow-up similar between groups (i.e. child no longer enrolled at child-care facility). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 80 (94%) children in the intervention group and 74 (97%) children in the control group. Reasons for loss to follow-up similar between groups (i.e. child no longer enrolled at child-care facility). Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Low risk	The reported outcomes aligned with those outlined in the trial registration.
Recruitment bias	High risk	Individual recruitment occurred after randomisation of clusters.
Baseline imbalance	Unclear risk	Study authors state that "Analytic models controlled for child's age and sex and parent/household demographic characteristics," though differences in these variables were not reported.
Loss of clusters	Low risk	No apparent loss of clusters
Incorrect analysis	Low risk	Study authors stated that "To account for clustering, models clustered SE within children and included a set of indicator variables (i.e. fixed effects) for child-care classrooms. Inclusion of classroom fixed effects also accommodated and corrected for any potential pair effects resulting from having conducted randomization within cities."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Hodgkinson 2019
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 6 months Unit of allocation: centre Unit of analysis: centre
Participants	Service type: centre-based (Sure Start Early Years) Operation: not reported Country (region): UK (Lancashire)

Hodgkinson 2019 (Continued)

Country income classification: high

Low-SES sample: yes

Population description: Sure Start Early Years' Centres focus on the 20% most disadvantaged families.

Inclusion criteria: inclusion criteria were (1) located in one of the 12 district authorities of Lancashire, UK, (2) located in an area of deprivation, (3) high levels of overweight/obese reception class children (4-5 years) in the neighbouring primary school, (4) not previously taken part in the intervention and (5) has a matched Centre in the geographical locality.

Exclusion criteria: centres were excluded if they had previously accessed any part of the intervention being evaluated.

Number of services randomised: 10 (5 intervention, 5 control)

Number of children randomised: 87 (48 intervention, 39 control)

Characteristics

Children

Age:

Intervention: 51% 24-25 months; 51%; 26-27 months: 15%; 28-29 months: 11%; 30+ months: 23%
Control: 24-25 months: 44%; 26-27 months: 9%; 28-29 months: 12%; 30+ months: 35%

Gender (% female): 49%

Ethnicity: not reported

Parents

Age (years):

Intervention: 19-29 years: 40%; 30-34 years 36%; 235-41 years: 3%
Control: 19-29 years: 47%; 30-34 years: 27%; 35-41 years: 27%

Gender (% female): 99%

Ethnicity:

Intervention: Asian: 13% ; white: 87%; black: 0%; other: 0%
Control: Asian: 12%; black: 6%; white: 76%; other: 6%

Parent/family SES:

Paid employment:

Intervention: none: 51%; part time: 40%; full time: 9%;
Control: none: 47%; part time: 44%; full time: 9%

Socioeconomic group

Intervention: professional/managerial/technical: 13%; skilled/partially skilled/unskilled: 87%
Control: professional/managerial/technical: 18%; skilled/partially skilled/unskilled: 82%

Method of recruitment: Early Years' Centres sent out recruitment letters to 160 (10%) parents with a 2-year old child on their registers. Only 1 parent responded. Therefore, with the assistance of the centre staff, 1 of the authors spent time at each centre, recruiting parents with a 2-year-old child into the study.

Missing data/dropout: 1 control centre withdrew, so the matched intervention centre needed to withdraw (6 families lost to follow-up).

Reasons for dropout: 1 pair of centres was withdrawn because the control centre refused to allow families to be recruited to the study

Hodgkinson 2019 (Continued)

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC and home

Intervention strategies:
Ethos and environment
Children

Exposure: trained ECEC centre staff delivered healthy cooking courses and active play sessions to children families, in groups or one-to-one.

ECEC staff

Training: educators were trained to educate families about healthy eating and being active (2-3 staff from each intervention centre were trained for 2 h). 1-2 were educators trained to deliver group or one-on-one sessions with parent-child dyads. Training covered centre policies for food, drink and physical activity, provision of snack/meals service, cooking, good growing and active play, practice breastfeeding; and health promotion in the form of leaflets, displays, advice on nutrition and physical activity.

Service

Resources: centre received curriculum pack called Healthy Heroes – 4 bright coloured characters who lead healthy lifestyles.

Partnerships
Families

Resources: families received the Healthy Heroes Activity Pack including activity cards (e.g. eating at the table), stickers, songs, puppets, national campaign materials (Change4Life), and activity cards for families to use at home

Exposure: trained ECEC centre staff delivered healthy cooking courses and active play sessions to families, in groups or one-to-one.

Healthcare

Engagement: Lancashire County Council's Children and Young People's Team, National Health Service (NHS) Public Health personnel and NHS Early Years Health Practitioners trained the educators.

Intensity of intervention: 2-3 staff from each service provided training for 2 h; 1-2 staff from each service trained to provide parent-child dyad sessions over 2 d; parent child-dyads attended sessions over 6 months (duration and frequency not reported)

Intervention delivered by: ECEC staff, healthcare

Modality: face-to-face, written

Theoretical basis: Social Learning Theory

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI z-score

Number of participants analysed:

Intervention baseline: 46

Hodgkinson 2019 (Continued)

Intervention follow-up: 46

Control baseline: 34

Control follow-up: 34

Data collection measure: objectively measured (WHO)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: Alison Hodgkinson was sponsored by her employer NHS North Lancashire and Lancashire County Council.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centres were matched in pairs by disadvantaged geographical area. Matched centres were randomly allocated to intervention or control by picking their name from a hat.
Allocation concealment (selection bias)	Low risk	Study authors stated that "Ten centres were recruited in five matched pairs and all centres had agreed to be allocated to either the intervention or control arm of the study."
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, child-care service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	No blinding of outcome assessors, however children's height and weight were measured and are unlikely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	Attrition was not reported for the time point extracted (6 months), so risk of attrition bias is unclear.
Selective reporting (reporting bias)	Low risk	The reported outcomes aligned with those outlined in the trial registration.
Recruitment bias	High risk	Individual recruitment occurred after randomisation of clusters. Study authors state that "This lack of balance is common in cluster trials where randomisation is not at the individual level but at the cluster level and is likely a result of recruitment bias by children centre staff, subconsciously selecting those they thought could benefit most."
Baseline imbalance	Low risk	Baseline imbalance was reported for the number of Centre visits per week, children > 98th percentile BMI-for-age, and mother's smoking. Only imbalance

Hodgkinson 2019 (Continued)

		of BMI was accounted for in analysis, though BMI is the only one likely to impact the outcome.
Loss of clusters	High risk	One control cluster lost, and the matched intervention cluster was removed from analysis
Incorrect analysis	Low risk	Study authors stated that "Finally, two multilevel models were fitted, allowing the variance between centres and between children within centres to be jointly estimated together with the effect of the intervention versus control, and thus allowed for non-ignorable intraclass correlation."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Hu 2009
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 1 year Unit of allocation: kindergartens Unit of analysis: child
Participants	Service type: centre-based (kindergartens) Operation: not reported Country (region): China (Anhui Province) Country income classification: upper-middle Low-SES sample: unclear Population description: this study was performed in Hefei, the capital city of Anhui Province, eastern China. The city is divided into 3 administrative districts: east urban, central urban and west urban, which have been built around 17 kindergartens (totaling 8752 children). Inclusion criteria: not reported Exclusion criteria: not reported Number of services randomised: 7 (4 intervention, 3 control) Number of children randomised: 2102 (1252 intervention, 850 control) Characteristics Children <i>Age:</i> 4.6 years (SD 0.6) <i>Gender (% female):</i> Intervention: 47.7% Control: 44.04% <i>Ethnicity:</i> not reported

Hu 2009 (Continued)

Parents

Age (years):

Intervention: mother: 31.5 (SD 2.6); father: 33.6 (SD 2.9)
Control group: mother: 31.4 (SD 2.1); father: 33.3 (SD 2.3).

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Family income per capita (RMB/month):

Intervention < 400: 13.99%; 400-800: 57.48%; > 800: 28.54%

Control: < 400: 14.56%; 400-800: 61.13%; > 800: 24.31%

Mothers' education:

Intervention: elementary: 1.21%; junior middle: 22.23%; senior middle: 38.80%; college: 27.41%; graduate: 10.35%

Control: elementary: 1.56%; junior middle: 19.98%; senior middle: 38.03%; college: 29.96%; graduate: 10.47%

Fathers' education:

Intervention: elementary school: 0.49%; junior middle: 14.31%; senior middle: 32.34%; college: 31.93%; graduate: 20.94

Control: elementary school: 0.84%; junior middle: 15.40%; senior middle: 34.66%; college: 29.72%; graduate: 19.37%

Method of recruitment: not reported

Missing data/dropout: 87.95% retained at mid-term follow-up and 84.86% retained at post-intervention follow-up

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 months (including 2 months of summer and winter vacation)

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: monthly nutrition education sessions with a flexible curriculum delivered by trained graduate students and research assistants. The programme was developed by nutrition professionals and included basic nutrition information, skills for food preparation and cooking and benefits of physical activity.

Ethos and environment

Children

Resources: teachers distributed an illustrated book to children about nutritional themes.

Service

Resources: 2 promotional pictures depicting common unhealthy dietary behaviours and good lifestyle behaviours were displayed in the kindergartens.

Partnerships

Families

Hu 2009 (Continued)

Education: a flexible curriculum for in-kindergarten education delivered monthly to children and parents by trained nutrition graduate students and research assistants. Parents were informed of the events by their children's teachers and training took place within the kindergartens. At least 8 lectures or activities were implemented in each kindergarten during the 1-year intervention period.

Resources: pamphlets, which included nutritional information and described healthy lifestyle behaviours were distributed to parents.

Activities: parents were instructed to read the pamphlet and were periodically checked by research assistants. The nutritional prejudices of the parents were addressed directly in a series of activities.

Intensity of intervention: at least 8 lectures or activities were implemented in each intervention kindergarten; 1 x illustrated book was distributed to children; pamphlets delivered to parents; 2 series of promotion pictures displayed in intervention kindergartens

Intervention delivered by: research team

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: usual care, plus children in the control group received a book with general picture stories

Outcomes

Outcomes relating to child dietary intake:

Unhealthy snacks intake, Western-style high-energy foods intake, preference for salty foods, monophagia, eating candy before meal, eating candy before going to bed, eating breakfast, eating a fixed quantity at a particular time

Number of participants analysed:

Intervention baseline: 1237

Intervention follow-up: 1042

Control baseline: 831

Control follow-up: 713

Data collection measure: parent questionnaire

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

Weight, weight-for-age z-score

Number of participants analysed:

Intervention baseline: 1237

Intervention follow-up: 1042

Control baseline: 831

Control follow-up: 713

Data collection measure: objectively measured (WHO)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Hu 2009 (Continued)

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

 Notes **Funding source:** Nutrition Educational Project of the Chinese Academy of Preventive Medicine (No. 200106)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was stratified by administrative district in order to achieve heterogeneity in location. Kindergartens were then randomised to either an intervention or control group using computer-generated numbers within each district.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No clear blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary behaviours. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by trained graduate student research assistants using a standard technique and the outcome measurements are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 1092 (88%) pairs in the intervention group and 727 (87%) pairs in the control group at follow-up. Loss to follow-up is reasonable and similar across both groups, though no reasons are given for missing data. Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 1092 (88%) pairs in the intervention group and 727 (87%) pairs in the control group at midterm, and 1042 (84%) pairs in the intervention group and 713 (86%) pairs in the control group at post-test. Loss to follow-up is reasonable and similar across both groups, though no reasons are given for missing data. Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.

Hu 2009 (Continued)

Baseline imbalance	Low risk	There were no significant differences in age, gender, parents' education, or family income between groups. Randomisation was stratified by administrative district.
Loss of clusters	Unclear risk	Not sufficiently reported
Incorrect analysis	High risk	Kindergartens were randomised, however there was no accounting for clustering of children within kindergartens.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

laia 2017
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 1 year Unit of allocation: child-care centre Unit of analysis: child
Participants	Service type: centre-based Operation: public Country (region): Italy (Cesena, Forlì-Cesena) Country income classification: high Low-SES sample: unclear Population description: not reported Inclusion criteria: each cluster aimed to include at least 15 3-year-old children to be eligible for the trial. Eligibility criteria for participants were: no chronic medical condition precluding them from study participation; being Italian or Italian-speaking non-Italian families. Exclusion criteria: not reported Number of services randomised: 16 (8 intervention, 8 control) Number of children randomised: 425 children (199 intervention, 226 control) Characteristics Children <i>Age:</i> 3.41 (SE 0.09) <i>Gender (% female):</i> 48% <i>Ethnicity:</i> Italian: 91.2%; non-Italian: 8.8% Parents <i>Age (years):</i> not reported

laia 2017 (Continued)

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Mothers' employment status: working full time: 44.9%; working part time: 31.7%; unemployed: 23.3%

Fathers' employment status: working full time: 92.1%; working part time: 5.1%; unemployed: 2.8%

Mothers' level of education: none: 1.3%; primary school: 0.8%; secondary school: 17.6%; high school: 51.1%; graduation: 29.2%;

Fathers' level of education: none: 1.4%; primary school: 0.9%; secondary school: 33.1%; high school: 43.7%; graduation: 21%

Method of recruitment: "we informed all childcare centre directors about our study procedures. They all agreed to take part in it without knowing the random allocation of their centres."

Missing data/dropout: intervention: 23/199 (11.6%); control: 16/226 (7.1%)

Reasons for dropout: intervention: 8 children changing ECEC centre; data collection problems (15 incomplete diaries and 8 diaries missing; 8 children without weight/height measurements). Control: 6 children changing ECEC centre; data collection problems (10 incomplete diaries and 6 diaries missing; 6 children without weight/height measurements)

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC and local health centres

Intervention strategies:

Health curriculum

Children

Education: children and teachers engaged in learning experiences (~1 h/d) to achieve 3 behaviour goals: increasing fruit and vegetable intake (e.g. via encouragement to eat vegetables first at lunch, tending vegetable gardens, inventing and playing stories with fruit and vegetable characters, making creative experiences with fruit and vegetables and peer-to-peer role modelling); reducing time spent watching television; and, limiting sugar-sweetened beverage intake.

Ethos and environment

Children

Exposure: children were exposed to new fruit and vegetables.

Peer modelling: teachers repeatedly allocated 'good fruit and vegetable eaters' to different tables so as to raise the fruit and vegetable intake among 'bad' fruit and vegetable eaters.

ECEC staff

Training: teachers received 10 h of training to promote more active play at ECEC centres and inserted this subject into their annual educational timetables.

Resources: information manual

Service

Environment: water is the only beverage at special events, such as birthdays or parties

Partnerships

laia 2017 (Continued)

Families

Education: parents received 2 x face-to-face motivational interviews to help families to increasingly adopt healthy lifestyles, the first was conducted by trained paediatric nurses, the second by trained primary care paediatricians.

Resources: an information leaflet and manual

Activities: teachers launched a book-lending initiative among parents.

Community

Environment: a poster highlighting 4 key behaviours was displayed in waiting rooms of paediatric clinics and in child-care centre halls.

Healthcare

Delivery: trained primary care paediatricians delivered education.

Intensity of intervention: 2 x 20-min face-to-face parent motivational interviews; information tools; 10 h-long teacher training; teachers engaged children in learning experiences for 1 h/d

Intervention delivered by: research team, ECEC staff, healthcare

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: usual care and parents were offered routine healthcare advice during child health visits.

Outcomes

Outcomes relating to child dietary intake:

Fruit and vegetable intake, sugar-sweetened beverages intake

Number of participants analysed:

Intervention baseline: 185

Intervention follow-up: 162

Control baseline: 178

Control follow-up: 162

Data collection measure: parent diary

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, BMI z-score

Number of participants analysed:

Intervention baseline: 184

Intervention follow-up: 176

Control baseline: 191

Control follow-up: 185

Data collection measure: objectively measured (CDC)

Data collector: researchers

Iaia 2017 (Continued)

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost:

Training, time for carrying out the intervention study, cost of materials

Number of participants analysed (intervention group only):

Services: 8

Children: 199

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: in September 2012, OROGEL S.p.A., a company based in via Dismano 2600, I-47522, Cesena, Forlì Cesena, Italy, granted EUR 10 000 in support of the educational intervention. "This sponsor had no role in designing and conducting our study; collecting, managing, analysing and interpreting its data; and preparing, reviewing and approving the paper."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors stated that "A person not involved in the study used a computer to create an allocation table to randomly allocate 8 clusters to the intervention group and 8 clusters to the control group."
Allocation concealment (selection bias)	Unclear risk	Study authors stated that "We informed all childcare centre directors about our study procedures. They all agreed to take part in it without knowing the random allocation of their centres. We did not provide parents with any information about their children's allocation before we achieved their parental consent." However, it is possible that centres shared allocation with parents due to randomisation occurring prior to recruitment.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, childcare service staff and parents were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, childcare service staff and parents were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Cost	Unclear risk	We assumed that due to the nature of the intervention, child-care service staff and parents were not blind to the study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias)	High risk	Parents reported children's dietary intake. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.

laia 2017 (Continued)

Diet outcomes

Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by trained nurses and were not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Cost	Unclear risk	Blinding not reported. It is unclear if this outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 162 (88%) participants in the intervention group and 162 (91%) participants in the control group at follow-up. Further, ITT analyses were used. Study authors stated that "We suffered a significant loss of the data at follow-up. Nevertheless, the ITT approach is likely to have successfully accounted for potential attrition bias." Reasons for missing data were similar across groups (i.e. changing child-care centre, data collection problems). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 176 (96%) participants in the intervention group and 185 (97%) participants in the control group at follow-up. Further, ITT analyses were used. Study authors stated that "We suffered a significant loss of the data at follow-up. Nevertheless, the ITT approach is likely to have successfully accounted for potential attrition bias." Reasons for missing data were similar across groups (i.e. changing child-care centre, data collection problems). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Cost	Low risk	Data was available for all participants in the intervention arm (no data was collected for the control arm given the outcome).
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	Individual recruitment occurred after randomisation of clusters. Study authors stated that "We did not provide parents with any information about their children's allocation before we achieved their parental consent." It is unclear whether this blinding could have been broken.
Baseline imbalance	Low risk	Study authors states that there were "no differences between the groups in the children's baseline characteristics. There was a higher percentage of overweight and obese fathers (IOTF cutoffs) in the intervention group compared with the control group: 55 vs 36.4% overweight and 7.7 vs 4.1% obese ($\chi^2 = 7.34$; $P = 0.025$)." Analyses did not account for this difference, however this is unlikely to influence the outcome.
Loss of clusters	Low risk	No clusters were lost at follow-up. Study authors stated that "All the randomized childcare centres completed our study protocol."
Incorrect analysis	Low risk	Study authors stated that "To examine the hierarchical data structure (children's measurements, child, childcare centres), we applied a three-level linear model, though preferring a two-level model that used children as random effect because of a school random effect near to 0. We provided both multilevel models: a random intercept model and a random intercept and slope model. We chose the first model in order to apply a principle of parsimony."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	The intervention received financial support from a commercial organisation. Study authors state that this company had no operational role.

Jones 2015

Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 12 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschools and long-day care)</p> <p>Operation: were not 100% government-funded services. 90%-98% of services operated 5 d/week</p> <p>Country (region): Australia (Hunter region, New South Wales)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: the study took place in the Hunter region of New South Wales, Australia. The region encompasses non-metropolitan 'major cities' and 'inner regional' areas as described by the Australian Statistical Geography Standard. There are 586,000 people residing in the area, of whom 23,000 are children aged 3–5 years. Approximately 3% of residents are of Aboriginal or Torres Strait Islander origin and 4% speak languages other than English. The Hunter region has lower indices of SES than the New South Wales state average.</p> <p>Inclusion criteria: not reported</p> <p>Exclusion criteria: services in the region were ineligible if they: catered exclusively for children requiring specialist care (< 1 % of services), provided all on-site meals to children (approximately 30% of services) or were fully government-funded (approximately 3 % of services), as the ethical clearance and intervention design were not appropriate for such services.</p> <p>Number of services randomised: 128 (64 intervention, 64 control)</p> <p>Number of children randomised: not reported (3 children from each service randomly selected for dietary outcome assessment)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i> not reported</p> <p>Service</p> <p><i>Ethnicity:</i></p>

Jones 2015 (Continued)

Children of Aboriginal or Torres Strait Islander background enrolled:

Intervention: 68%

Control: 78%

Service socioeconomic area:

Top 50% of New South Wales:

Intervention: 30%

Control: 27%

Method of recruitment:

Phone and mail

Missing data/dropout: 6 child-care services with baseline data declined to participate in the trial. 62 services were retained in the intervention group, and 60 in the control. But observational data were collected from 17 intervention centres and 19 control centres.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 months

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

Children

Exposure: provision of adult-guided fundamental movement skills for at least 75% of children daily. Restriction of sedentary screen time to less than weekly.

Role modelling: staff role modelling of physical activity and healthy eating to children

Prompts and feedback: staff provision of prompts and positive feedback to encourage child healthy eating

ECEC staff

Training: a series of 3 x 1-h training workshops which focused on policy and practice implementation.

Support: following each staff training workshop, implementation support staff facilitated a discussion with nominated supervisors and ECEC service staff to reach group agreement regarding an implementation strategy for the targeted policies and practices.

Engagement: nominated supervisors were asked to lead the development and implementation of nutrition and physical activity policies, co-facilitate training workshops with implementation support staff and communicate expectations regarding the implementation of policies and practices to ECEC service staff during staff meetings.

Service

Policy: development and implementation of written nutrition and physical activity policies

Jones 2015 (Continued)

Monitoring: daily staff monitoring of children's lunch boxes against written nutritional guidelines and provision of feedback to parents when a non-compliant food was packed. Provision of water or reduced-fat milk only.

Resources: all services received an electronic and hardcopy package of tools and resources to support ECEC service staff to implement the healthy eating and physical activity policies and practices. Services received hard copy and electronic bimonthly newsletters, which communicated key messages relating to the healthy eating and physical activity policies and practices. Services that implemented all policies and practices received a certificate of recognition, were acknowledged in newsletters and were used as case-study examples.

Feedback: verbal and written feedback describing service progress toward implementation of the targeted policies and practices was delivered at 6 intervals throughout the 12-month intervention.

Partnerships

Healthcare

Support: health promotion officers provided each service with a support staff member who provided ongoing implementation support and positive reinforcement via in-person visits, telephone and email contact.

Intensity of intervention: 3 x 1-h staff training workshops; bimonthly newsletters. The frequency and duration of the following strategies were not reported: ongoing implementation support; face-to-face meetings; telephone and email contact; executive support; consensus process with staff; academic detailing visits; provision of tools and resources; performance monitoring and feedback.

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: Damschroder's Consolidated Framework for Implementation Research

Description of control: usual care, plus services received 3 newsletters at the commencement, mid-point and conclusion of the 12-month intervention. The newsletters were provided in hard copy and electronic formats and contained information on healthy eating and physical activity unrelated to the specific policies and practices targeted by the intervention.

Outcomes

Outcomes relating to child dietary intake:

Fruit intake, vegetable intake, grains (breads and cereals) intake, meat and meat alternatives intake, milk/yoghurt/cheese intake, discretionary food intake

Number of participants analysed:

Intervention baseline: not reported

Intervention follow-up: 41

Control baseline: not reported

Control follow-up: 49

Data collection measure: in-care observations

Data collector: trained research observers

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Jones 2015 (Continued)

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Increased occurrence of injury among staff or children

Number of participants analysed: not reported

Data collection measure: nominated supervisors were asked to report on the number of staff and children involved in adverse events in their service

Data collector: nominated supervisors

Validity of measures used: not reported

Notes

Funding source: Australian National Preventive Health Agency (reference 95WOL2011), Hunter New England Population Health and Hunter Medical Research Institute.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	After the completion of baseline data collection, ECEC services were randomly allocated to either the intervention or control condition by a research assistant using a random number function in a 1:1 (intervention:control) ratio.
Allocation concealment (selection bias)	Low risk	After baseline data were collected, a statistician not involved in the trial allocated the services to groups using a random number function.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Services were not blind to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Adverse consequences	Unclear risk	Services were not blind to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Children's dietary intake was observed by a trained observer who did not participate in the intervention delivery and who was blind to service group allocation.
Blinding of outcome assessment (detection bias) Adverse consequences	Unclear risk	Services were not blind to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Data analysed for 17/62 (27%) of intervention services and 19/60 (32%) of control services. Dietary observations were conducted in a random subsample of intervention and control services at follow-up, however there is no information on how the random sample was determined or if there was loss to follow-up in the random subsample. Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Adverse consequences	Unclear risk	The number of services that reported on this outcome at follow-up is unclear.
Selective reporting (reporting bias)	High risk	Observation data and adverse events, the data of interest for the review, are not mentioned in the available protocol. These outcomes appear to have been added in post-hoc with no reasoning provided.

Jones 2015 (Continued)

Recruitment bias	Low risk	ECEC services were recruited prior to randomisation, and no ECEC services were recruited after randomisation.
Baseline imbalance	Unclear risk	No information provided on individual participants. Data only provided at the service level
Loss of clusters	Low risk	2 of the 64 intervention clusters and 4 of the 64 control clusters were lost. However, this is a small percentage (< 5%) of the overall sample. Study authors stated that "There were no differences between the characteristics of services that provided follow-up data and those that did not (p = 0.22-1.00)."
Incorrect analysis	Low risk	Study authors stated that "The model was adjusted for potential clustering effect."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Intervention and control groups showed baseline imbalance in terms of extra-neous training. Study authors stated that "Project records show that 80% of intervention group services and 12% of control group services attended training in healthy eating and physical activity provided by the 'Munch & Move' program during the study period." and "Project records provided by the program show 45% of intervention group services and 52% of control group services attended training in healthy eating and physical activity provided by the 'Good for Kids. Good for Life' program during the period from 2006 to 2011." There were also baseline differences in the implementation of policies and practices between groups. Study authors stated that "However, five of the seven policies and practices were being implemented by 80% or more of intervention group services at baseline, limiting scope for further improvements. Second, the trial did not exclude services who were already implementing all policies and practices at baseline (24% of intervention services)." Children who were randomly selected for observation were chosen based on their birth date. There is insufficient information to assess whether an important risk of bias exists.

Kipping 2019
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 8-10 months Unit of allocation: nurseries Unit of analysis: child
Participants	Service type: centre-based (preschools, day nurseries and centre nurseries) Operation: combination of community and private Country (region): UK (North Somerset and Gloucestershire) Country income classification: high Low-SES sample: no Population description: the study took place in nurseries in 2 areas of England (North Somerset and Gloucestershire) and in the homes of children recruited to the study. North Somerset is a rural area ad-

Kipping 2019 (Continued)

acent to Bristol, with 14.1% of children living in poverty (percent of children aged < 16 years in families receiving means-tested benefits and low income in 2012). Gloucestershire is a large rural county to the north of Bristol. The health of people in Gloucestershire is generally better than the England average; however, 13.8% of children live in poverty.

Inclusion criteria: child-care providers must be a day nursery, private nursery school, maintained nursery school, children's centre with nursery, or preschool, in North Somerset or Gloucestershire. Settings were eligible if they had a minimum of 20 children aged 2–4 years who attend the child-care providers for at least 12 h/week over 50 weeks of the year, or 15 h/week in term time.

Exclusion criteria: excluded child-care settings were child minders, crèches, playgroups, primary school reception classes (where schools operate an early-admission policy to admit children aged 4 years) and au pairs.

Number of services randomised: 12 (6 intervention, 6 control)

Number of children randomised: 476 (86 participated intervention, 91 participated control)

Characteristics
Children

Age: 2-4 year olds

Gender (% female): not reported

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: ECEC providers were sent a letter from the Council, project information sheet, reply envelope and form indicating if they wished to participate and reason for their response. Non-responders were followed up with a reminder and then a telephone call. All interested ECEC providers were contacted by telephone to discuss the study following which, if the provider was still interested, they were offered a visit to discuss the intervention and study in more detail. A GBP 200 incentive was provided to all participating nurseries at the end of the study.

Missing data/dropout: at the follow-up data collection, 147 (87.5%) out of 168 children at baseline participated in data collection. Out of the 476 potentially eligible children at baseline, 147 (30.9%) children provided data at baseline and follow-up.

Reasons for dropout: 2 (1.2%) children had consent withdrawn, 2 (1.2%) refused to participate in measurements and their parents did not return follow-up questionnaires, 8 (4.8%) moved nursery and 9 (5.4%) moved to primary school and did not take up the offer to continue participation.

Characteristics of dropouts: not reported

 Interventions

Programme name: NAP SACC UK ((The Nutrition And Physical Activity Self-Assessment for Child Care UK)

Number of conditions: 1 intervention, 1 control

Intervention duration: 5 months

Intervention setting: ECEC and home

Intervention strategies:

Kipping 2019 (Continued)

Ethos and environment

ECEC staff

Workshop: specialised staff delivered 2 workshops to the nursery staff on nutrition, oral health and physical activity.

Action planning: the NAP SACC UK partners worked with the nursery manager to set out an action plan, listing 8 goals for improvement. These were 3 nutrition goals, 3 physical activity goals and 2 further goals of their choice. The NAP SACC partner helped the nursery manager agree how and when these goals will be reached.

Support: intervention partners continued regular contact with nursery (via telephone, email or in person), providing support and advice to help the nursery meet their goals.

Self-monitoring: 'Review and reflect' process of self-assessment to see where improvements were made. Where improvements were not made, reasons why were discussed to help overcome barriers. Action plans were revised to set new goals.

Service

Policy: nursery staff were supported to review the nutrition, oral health, physical activity and screen time environment, policies and practices against best practice and national guidelines.

Partnerships

Families

Resources: parents were given access to the NAP SACC at home website to complete healthy habits forms and set goals. As an incentive, the first 50 parents to register received a swimming voucher to the local pool.

Support: parents received tailored texts/emails giving them suggestions or areas to set goals.

Partners

Workshop: a 2-2.5 h training session was delivered to partners.

Support: intervention partners provided support and advice to help the nursery meet their goals.

Intensity of intervention: initial staff meetings lasted for > 2 h (between the health visitor and nursery manager); average number of advice/support opportunities was 2.2 face-to-face meetings, 1.8 telephone calls and 2.8 emails.

2 x workshops delivered to nursery staff by local experts in nutrition (3 h) and physical activity (2.5 h); a home component (website, short message service and emails) was developed to support parents in setting goal, they could assess this as often as they liked (tailored text messages or emails were sent to parents on a fortnightly basis).

Intervention delivered by: research team

Modality: face-to-face, telephone, online, written

Theoretical basis: Social Cognitive Theory and the Socioeconomic Framework

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Types of fruit and vegetable intake; meat, fish, eggs, beans and other non-dairy sources of protein intake; desserts, puddings and cakes intake; beverages intake; starchy food intake

Number of participants analysed:

Intervention baseline: 13-30

Intervention follow-up: 13-30

Control baseline: 12-27

Control follow-up: 12-27

Kipping 2019 (Continued)

Data collection measure: child and Diet Evaluation Tool (CADET)

Data collector: trained observer

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI z-score, weight, overweight or obese, obese

Number of participants analysed:

Intervention baseline: 30-58

Intervention follow-up: 30-58

Control baseline: 18-76

Control follow-up: 18-76

Data collection measure: objectively measured (UK, 1990 age and gender growth reference charts and International Obesity Task Force (IOTF) reference points)

Data collector: trained field workers

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life:

Quality of life (total, physical function, emotional function, social function, nursery function)

Number of participants analysed:

Intervention baseline: 32

Intervention follow-up: 32

Control baseline: 45

Control follow-up: 45

Data collection measure: Paediatric Quality of Life Inventory (PedsQL) 4.0

Data collector: parent

Validity of measures used: validated

Outcome relating to cost:

Average cost of health visitor intervention delivery per nursery (including workshop), average cost of intervention to nursery, parental weekly food spend

Number of participants analysed: not reported

Data collection measure: nursery logs and parent-completed questionnaire

Data collector: unclear and parent

Validity of measures used: not reported

Outcome relating to adverse consequences:

Incident or adverse event

Number of participants analysed: not reported

Kipping 2019 (Continued)

Data collection measure: nursery managers and those delivering the intervention were asked to contact the study team within 5 working days if any untoward incident or adverse event occurred to a member of staff or child as a result of the intervention

Data collector: nursery managers and those delivering the intervention

Validity of measures used: not reported

Notes

Funding source: North Somerset Council and Gloucestershire Council. Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer). Elizabeth Blackwell Institute (University of Bristol) and the Wellcome Trust. Medical Research Council (MRC) and from the Scottish Government Chief Scientist Office

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	ECEC providers were stratified by geographic area, deprivation of location, and size of provider and randomised to the control or intervention groups. Allocation was conducted by an independent statistician at the Bristol Randomised Trials Collaboration, blind to the identity of the ECEC providers.
Allocation concealment (selection bias)	Low risk	Allocation was conducted by an independent statistician who was blind to the identity of the ECEC providers.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No clear blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Quality of life outcomes	High risk	No clear blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Cost	Unclear risk	No clear blinding of participants and personnel to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Adverse consequences	Unclear risk	No clear blinding of participants and personnel to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Dietary intake data were reported by researcher observers and parents using the Child and Diet Evaluation Tool (CADET). Blinding of parents and researchers not reported, and the outcome measurement is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by trained field workers with a member of nursery staff present and the outcome measurements are not likely to be influenced by lack of blinding.

Kipping 2019 (Continued)

Blinding of outcome assessment (detection bias) Quality of life outcomes	High risk	Parents reported children's functioning using the Paediatric Quality of Life Inventory 4.0. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Cost	Unclear risk	No clear blinding of participants and personnel to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Adverse consequences	Unclear risk	No clear blinding of participants and personnel to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	CADET nursery data are available for 130 (85%) children at follow-up, while CADET home data are available for 79 (57%) children at follow-up. Due to the magnitude of missing data and difference in the proportions of participants followed up between groups, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	In the intervention group, 81 children were analysed at baseline, however only 41 (51%) had BMI z-score data at follow-up. In the control group, 86 children were analysed at baseline, however only 56 (65%) had BMI z-score data at follow-up. Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Quality of life outcomes	High risk	Study authors stated that "A total of 124 parents (72.1%) completed the questionnaire about the child's quality of life, expenditure on food and physical activity and child health-care use at baseline. A total of 86 parents (50%) completed the questionnaire at follow-up. The complete case for HRQoL [health-related quality of life] analysis was 77 (44.8%)." Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Cost	High risk	Data were available for 86 (51.8%) of parents at follow-up and 12 services did not take part in the whole intervention, indicating high attrition.
Incomplete outcome data (attrition bias) Adverse consequences	Unclear risk	The number of services and participants that reported on this outcome at follow-up is unclear.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	High risk	Centres were allocated prior to individual recruitment, and thus an individual knew if the school was receiving the intervention or control prior to signing up.
Baseline imbalance	Unclear risk	Baseline differences are noted, although it is unclear if these differences are statistically significant. Study authors state that "Stratified randomisation was used to ensure balance for (1) deprivation... (2) size of child-care provider...and (3) location."
Loss of clusters	High risk	One cluster did not fully implement the intervention, and it is unclear what happened with these data and the children from this centre. All analyses are descriptive.
Incorrect analysis	High risk	There was no accounting for clustering of children within nurseries.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Kobel 2019
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 1 year</p> <p>Unit of allocation: kindergartens</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (kindergartens)</p> <p>Operation: not reported</p> <p>Country (region): Germany (South-West Germany)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: not reported</p> <p>Inclusion criteria: only kindergartens that had not previously taken part in the programme were included in the study. Children within the recruited kindergartens were eligible if they were between 3 and 5 years old at the time of baseline measurements and their parents provided a signed consent form.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 57 (30 intervention, 27 control)</p> <p>Number of children randomised: 973 (318 participated intervention, 240 participated control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 3.6 years (SD 0.6)</p> <p><i>Gender (% female):</i> 47.7%</p> <p><i>Ethnicity:</i> migration background: 33.4%</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i> not reported</p> <p>Method of recruitment: participating kindergartens were recruited from all kindergartens in south-west Germany, which had received written information about programme and study, asking interested kindergarten teachers to participate.</p> <p>Missing data/dropout: 57% dropout</p> <p>Reasons for dropout: not reported</p> <p>Characteristics of dropouts: not reported</p>

Kobel 2019 (Continued)

Interventions

Programme name: Join the Healthy Boat

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 months

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: the intervention materials consisted of 20 exercise and games lessons and 30 ready-to-use ideas, action alternatives and lessons promoting increased physical activity, reduced screen media consumption, and a more healthy diet, including the reduction of sweetened drinks and an increased fruit and vegetable intake.

Ethos and environment

Children

Exposure: short activity games (exercises of 5–7 min each, which also promote children's motor skills) were used twice daily.

ECEC staff

Training: kindergarten teachers were trained twice in 16 h of peer-to-peer training courses.

Resources: kindergarten teachers received instructional and behavioural educational resources.

Partnerships

Families

Resources: family homework, materials for parents' nights and parental letters were provided in 3 languages.

Intensity of intervention: 2 x 16 h of peer-to-peer training (by teachers); all intervention materials are integrated into the everyday life of kindergartens so no external staff or extra time was required; 20 exercise and games lessons and 30 ready to use ideas, action alternatives and lessons for children

Intervention delivered by: ECEC staff

Modality: face-to-face, written

Theoretical basis: Bandura's Socio-Cognitive Theory and Socio-Ecological approach

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Fruit and vegetable intake, sugar sweetened beverage intake

Number of participants analysed:

Intervention baseline: 318

Intervention follow-up: 318

Control baseline: 240

Control follow-up: 240

Data collection measure: parent questionnaire

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

Kobel 2019 (Continued)

BMI percentile

Number of participants analysed:

Intervention baseline: 538

Intervention follow-up: 318

Control baseline: 435

Control follow-up: 240

Data collection measure: objectively measured (German reference data)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: the kindergarten-based health promotion programme “Join the Healthy Boat” and its evaluation study was financed by the BadenWürttemberg Foundation (grant number BWS_1.479.00_2009).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No clear blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported dietary patterns via questionnaire. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by trained technicians and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Follow-up data are available for 558 (57%) of the children who were assessed at baseline. At baseline, 18% of dietary data were missing, while 30% of dietary data were missing at follow-up. Reasons for missing data are unclear,

Kobel 2019 (Continued)

		and the distribution of loss between groups is not noted. Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	Follow-up data are available for 558 (57%) of the children who were assessed at baseline. At baseline, 14% of BMI percentile data were missing, while 14% of BMI percentile data were missing at follow-up. Reasons for missing data are unclear, and the distribution of loss between groups is not noted. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	Protocol states variables for nutrition include consumption of sugar-sweetened beverages, fruit, vegetables, and high-calorie foods. Data on consumption of high-calorie foods are not reported in the study. Further, the protocol states variables for anthropometric parameters include waist circumference, waist-to-height ratio, BMI, and subcutaneous fat. Only BMI percentile outcomes are reported in the study.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	No baseline differences were noted between groups for any relevant variables except for gender. The researchers controlled for gender in the analysis.
Loss of clusters	High risk	After randomisation, 4 kindergartens with 22 kindergarten teachers dropped out, mainly due to personnel and organisation issues, resulting in 376 participating kindergarten teachers and 62 heads of kindergartens. It is not stated which group these clusters were randomised to.
Incorrect analysis	High risk	There was no accounting for clustering of children within kindergartens.
Contamination	Unclear risk	Study authors state that "Even though, a major strength of this study is its randomised controlled design with a control group, the kindergarten teachers in that group were also very health conscious and have not been "inactive", which might have led to a strong contamination with other efforts to promote children's health in the control group." There is not enough information provided to assess whether contamination exists.
Other bias	Unclear risk	Study authors stated that "The minimum assumed number was therefore 880 children, the maximum 1120 children. The overall significance level is set to 0.05 (2-sided). Depending on the number of kindergartens, a small effect size of 0.288 to 0.325 could be achieved for a power of 0.80 for the metric targets." With 558 children at baseline, this study does not appear to be adequately powered. There is insufficient information to assess whether an important risk of bias exists. No conflict of interest statement was reported.

Kornilaki 2021
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 3 months Unit of allocation: nursery schools Unit of analysis: child
Participants	Service type: centre-based (nursery schools)

Kornilaki 2021 (Continued)

Operation: not reported

Country (region): Greece (Heraklion region of Crete)

Country income classification: high

Low-SES sample: unclear

Population description: not reported

Inclusion criteria: parents were eligible if they were Greek speakers (for questionnaire purposes only).

Exclusion criteria: not reported

Number of services randomised: 15 (groups not reported)

Number of children randomised: 329 (184 intervention, 145 control)

Characteristics

Children

Age:

Intervention: 5.03 years (SD 0.54)

Control: 5.05 years (SD 0.54)

Gender (% female):

Intervention: 50%

Control: 54.5%

Ethnicity: not reported

Parents

Age (years):

Intervention: mother: 37.69 (SD 6.2); father: 40.83 (SD 5.4)

Control: mother 37.28 (SD 4.96); father: 40.66 (SD 6.08)

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Family income

Intervention: up to EUR 14,999, 37.61%; EUR 15,000-29,999, 47.86%; EUR 30,000-49,999, 10.26%; > 50,000 euros, 4.27%

Control: up to EUR 14,999, 46.66%; EUR 15,000-29,999, 48%; EUR 30,000-49,999, 2.67%; > EUR 50,000, 2.67%

Mothers' education

Intervention: compulsory: 4.24%; high school: 27.12%; technical/vocational: 33.05%; university: 35.59%

Control: compulsory: 7.79%; high school: 28.57%; technical/vocational: 28.87%; university: 33.77%

Fathers' education

Intervention: compulsory: 11.86%; high school: 34.74%; technical/vocational: 23.74%; university: 29.66%

Control: compulsory: 16.88%; high school: 32.87%; technical/vocational: 28.18%; university: 22.07%

Method of recruitment: all nursery schools in the Heraklion area were invited to participate in the study through phone and email. After organisational approval was given, all educators in each nursery school were verbally invited to the research project and informed consent was obtained. All eligible parents of children in the nursery school were invited to participate through information provided by the educators received directly from the researcher.

Kornilaki 2021 (Continued)

Missing data/dropout: 26 of 329 did not return the eating and physical activity questionnaire at any time point and were withdrawn from the sample. All 3 time points were returned by 137 parents, 113 parents returned 2 questionnaires and 53 parents returned only 1.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 4-6 weeks

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: educators delivered the curriculum they had developed (tailored to each class) following training.

Ethos and environment

ECEC staff

Training: 2 x 2-h professional learning sessions were delivered by trained researchers to the nursery school educators to build the educator's capacity to develop age-appropriate educational curriculum activities that increased young children's healthy eating habits, raised children's environmental consciousness and provided physical activity opportunities, while engaging their popular culture interests. Educators were encouraged to follow 4 best practice principles when delivering the curriculum: implementing the curriculum experiences in the morning when most cognitively alert; using a combination of 3 identified play types; conducting the curriculum activities 2-3 times/week for between 4 and 6 weeks; and, using a range of real-life props as resources. Support: researcher support via telephone and email was provided.

Intensity of intervention: 2 x 2-h professional learning sessions were delivered to staff; delivery of curriculum activities 2-3 times/week by educators

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, telephone, online, written

Theoretical basis: Funds of Knowledge

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Fruit and vegetables intake, unhealthy food (packaged snacks, chocolates and confectionary, flavoured milk, cakes and sweet biscuits) intake, sugar sweetened beverages intake, unsweetened beverages (unflavoured milk and water) intake, fruit intake, vegetable intake

Number of participants analysed:

Intervention baseline: 107-150

Intervention follow-up: 115-119

Control baseline: 86-114

Control follow-up: 70-77

Data collection measure: eating and physical activity questionnaire (EPAQ)

Data collector: parents

Kornilaki 2021 (Continued)

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI

Number of participants analysed: not reported

Data collection measure: objectively measured (IOTF)

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes **Funding source:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Nursery schools were randomly allocated to the intervention and control groups through a computer-generated random number allocation.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents completed the Eating and Physical Activity Questionnaire to report children's dietary intake. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured and were not likely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Data from the Eating and Physical Activity Questionnaire for at least 2 time points are available for 142 (77%) children in the intervention group and 108 (74%) of the control group. However, it is not known whether those who only submitted 2 questionnaires had completed the baseline questionnaire. Reasons for missing data not provided. Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias)	Low risk	Data were available for 177 (96%) participants in the intervention group and 138 (95%) students in the control group at immediate post-intervention, and

Kornilaki 2021 (Continued)

Physical outcomes

167 (91%) students in the intervention group and 133 (92%) students in the control group at 3-month follow-up. Loss to follow-up is similar across both groups and within reason (< 10%). Therefore, risk of attrition bias was considered to be low.

Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	No significant differences in demographic characteristics were noted between trial groups, except for father's height. However, demographic data weren't obtained until 3 months post-intervention. Study authors also state that "Finally, no data were collected about the demographics of each classroom (for example, educator/child ratios) or their educators (years of experience)."
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	High risk	There was no accounting for clustering of children within schools.
Contamination	Unclear risk	No evidence to make assessment
Other bias	High risk	No funding statement was provided.

Kristiansen 2019
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 1 year (varies with outcomes)</p> <p>Unit of allocation: kindergartens</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (kindergarten)</p> <p>Operation: public (control 42.5% vs intervention 57.5%) or private (control 57.5% vs intervention 42.5%)</p> <p>Country (region): Norway (Vestfold and Buskerud)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: not reported</p> <p>Inclusion criteria: the target group for the current study was preschool children with year of birth 2010 and 2011, attending public or private kindergartens in the counties of Vestfold and Buskerud, Norway.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 73 (37 intervention, 36 control)</p> <p>Number of children randomised: 633 (313 intervention, 320 control)</p> <p>Characteristics</p>

Kristiansen 2019 (Continued)

Children

Age: 3-5 year-olds

Gender (% female):

Intervention: 51.1%

Control: 51.9%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Maternal education:

Intervention: low (\leq upper secondary): 32.9%; high (college/university): 67.1%

Control: low: 29.9%; high (college/university): 70.1%

Method of recruitment: all regular kindergartens (n = 479) in the 2 counties were invited by letter followed-up by a phone call to inform about the study and to motivate for participation

Missing data/dropout: from baseline to follow-up 1, 16 children (5%) were lost to follow-up in the control group and 20 children (6%) were lost to follow-up in the intervention group.

Reasons for dropout: the main reason for this loss was children moving to other kindergartens.

Characteristics of dropouts: dropout analysis showed no differences in background characteristics between participating children (n = 633) and those lost to follow-up (n = 66), except that significantly more children were lost in the intervention group compared to the control group (P = 0.02)

Interventions

Programme name: BRA-study (an acronym for the Norwegian words “Barnehage” (kindergarten), “gRønnsaker” (vegetables) and “fAmilie” (family))

Number of conditions: 1 intervention, 1 control

Intervention duration: 5 months

Intervention setting: ECEC and home

Intervention strategies:

Ethos and environment
ECEC staff

Training: kindergarten staff received a 1-d inspirational course (cooking, taste testing, theoretical sessions, action plans). Attendees were instructed to train/inform the relevant staff in their kindergarten. The theoretical sessions covered availability, accessibility, encouragement and role modelling.

Service

Resources: each kindergarten received 4 aprons, a vegetable memory game, booklets, 1 hand blender, 6 posters and brochures. They were also given access to a website with all materials and additional information about vegetables and 4 determinants and invited to a closed Facebook group.

Booster: booster activities were provided at 3 months and 6 months and included booklets with recipes; a vegetable card/poster to register when and which vegetables were served for 3 d with potential for winning a gift card; and suggestions of tasting games to play with the children.

Partnerships
Families

Kristiansen 2019 (Continued)

Resources: kindergarten staff provided families with a 'welcome package' including a cover letter explaining the rationale and the purpose of the intervention, a brochure with vegetable recipe ideas, a stack of post-its with prompts to buy fruit and vegetables and a booklet to read to children. They were also given access to a website with all materials and additional information about vegetables and 4 determinants and invited to a closed Facebook group.

Booster: booster activities were provided at 3 months and 6 months and included booklets with recipes; a vegetable card/poster to register when and which vegetables were served for 3 d with potential for winning a gift card; and suggestions of tasting games to play with the children.

Intensity of intervention: 1 x inspirational training day; 1 x resource pack to staff; 1 x resource pack to parents, 1 x website materials to parents and staff (each), 1 x Facebook page for parents and staff (each), 2 x staff booster training; 2 x parent booster training/activity

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, online, written

Theoretical basis: not reported

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, variety in vegetable intake

Number of participants analysed:

Intervention baseline: 129-222

Intervention follow-up: 137-218

Control baseline: 142-206

Control follow-up: 160-229

Data collection measure: parent questionnaire, direct observation and combination of parent questionnaire and direct observation

Data collector: parents and researchers

Validity of measures used: not reported

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The Research Council of Norway (project number 228452) with supplementary funds from the Throne Holst Nutrition Research Foundation, University of Oslo

Risk of bias

Bias

Authors' judgement

Support for judgement

Random sequence generation (selection bias)

Unclear risk

An external statistician conducted a stratified block randomisation. The randomisation ensured an equal distribution of kindergartens within ownership (public and private) in the 2 groups and total number of participating children

Kristiansen 2019 (Continued)

in each group. However, the study authors state that the subsample of children who were observed for diet outcomes were "preferably, children of mothers with a low educational level...and otherwise children were chosen for observation at random." The random sequence generation procedure for this subsample was not described.

Allocation concealment (selection bias)	Low risk	Allocation was conducted after baseline data collection, however this was done by an independent statistician to ensure even groups.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Kindergarten employees were not blind to study allocation as they received kitchen education. Families were not blind as they received take-home packages and website log-ons. The outcome is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Diet outcomes	Unclear risk	Study authors state that "Researchers were not blinded to intervention group during data collection at follow-up 1. However, as there occasionally were options for the researchers to observe the same child/children during the direct observation of vegetable intake, intraclass correlation (ICC) as an estimate of inter-rater reliability between pairs of observers was calculated. The level of agreement between pairs of observers at follow-up 1 was 0.99 for the 37 children that were observed by two researchers. This agreement did not change when split into intervention (n 24, ICC = 0.99) and control groups (n 13, ICC = 0.98). This corresponds to the ICC found in the baseline data collection. Hence, this might indicate an unbiased observed vegetable intake." Study authors also state "Parents reported children's dietary intake and knew the aims of the intervention." As dietary outcomes were assessed by 2 methods (observation and parent-reported data), risk of bias is unclear.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Follow-up data from observation are available for 311 (76%) of the 411 children who were observed at baseline. Follow-up data from the questionnaire were available for 311 (71%) of the 439 children with baseline data, and follow-up data from the 24-h recall are available from 295 (63%) of the 470 children with baseline data. Reasons for missing data not provided. Due to the magnitude of missing data, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	Trial registration states the following primary outcome measures: "Frequency and variation of vegetable intake in children is measured by internet-based questionnaires completed by parents at baseline (Spring 2015), year 1 (Spring 2016), and year 2 (Spring 2017)," and "Amount of vegetables consumed by children is measured using an internet-based 24 hour recall where parents report the amounts of vegetables that the child ate the day before at baseline (Spring 2015), year 1 (Spring 2016), and year 2 (Spring 2017)." However, the study combines the internet-based 24-h recall with the direct observation to determine baseline total vegetable amount rather than reporting the outcomes of the internet-based 24-h recall alone.
Recruitment bias	Low risk	Individual recruitment occurred before randomisation of clusters.
Baseline imbalance	Low risk	At baseline, groups differed by percent of children attending a public kindergarten, and in children's frequency and variety of vegetable intake. Statistical models adjusted for baseline intake and kindergarten ownership (private or public).
Loss of clusters	Unclear risk	No loss of cluster reported, however some kindergartens had 0-22 students.
Incorrect analysis	Low risk	Study authors stated that "Kindergarten was used as a random effect to account for random inhomogeneity between kindergartens."
Contamination	Unclear risk	No evidence to make assessment

Kristiansen 2019 (Continued)

Other bias	Low risk	No clear other source of bias
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Leis 2020
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 9 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (licensed child-care centres or preschools)</p> <p>Operation: not reported</p> <p>Country (region): Canada (Saskatchewan and New Brunswick)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: given the large area Saskatchewan represents (652 000 km²), it was decided to carry the study with selected early child-care centres in the central region in year 1, and in the South and central-North in years 2 and 3.</p> <p>Inclusion criteria: to be included in the study, an ECEC centre had to prepare and provide meals for lunch. This is required for assessing the quality of foods being served and for measuring nutritional intake.</p> <p>Exclusion criteria: centres with < 20 children between the ages of 3 and 5 were excluded.</p> <p>Number of services randomised: 61 (31 intervention, 30 control)</p> <p>Number of children randomised: 897 (464 intervention, 433 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 4.1 years (SD 0.8)</p> <p><i>Gender (% female):</i></p> <p>Intervention: 49%</p> <p>Control: 46%</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i></p> <p>Median household income:</p>

Leis 2020 (Continued)

Intervention: CAD 54,769 (SD 11,067)
Control: CAD 54,773 (SD 10,790)

Method of recruitment: selected ECEC centres were contacted, provided with information, and invited to participate in the project. Subsequently, ECEC centre directors were telephoned to answer their questions and to confirm their participation while securing the parents' board support.

Missing data/dropout: 1/61 centres dropped out (intervention); participants lost to follow-up: 117

Reasons for dropout: change in centre management

Characteristics of dropouts: no differences in baseline outcome food intake

Interventions

Programme name: Healthy Start-Départ Santé (HSDS)

Number of conditions: 1 intervention, 1 control

Intervention duration: 6-8 months

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

ECEC staff

Training: staff received 1 x 3-h on-site training sessions and were also offered a tailored 90-min booster session at the midway point of the intervention period. The training session covered best practices in physical activity and healthy eating in early childhood, including topics such as the importance of physical activity and healthy eating for preschoolers, how to easily integrate physical activity and healthy eating in the ECEC's daily routine, how to introduce and encourage children to try new and healthy foods, and how to help children develop their fundamental movement skills.

Service

Resources: services received an implementation manual, physical activity and healthy eating manuals, an active play equipment kit and other complementary resources for child-care staff and families. Monthly newsletters were also sent to services, which included tips on how to get children moving or on how to improve healthy eating. Services were encouraged to share these newsletters with parents.

Champion: services encouraged to identify a 'Healthy Star' – a staff member who was a champion for physical activity and healthy eating, and the point of contact for the programme co-ordinators.

Support: ongoing online and telephone support and monitoring.

Partnerships

Healthcare

Delivery: training was delivered by specialists (dietitians, kinesiologists or other experts in the fields of nutrition and physical activity).

Intensity of intervention: 3-h training, ongoing online and telephone support and monitoring and 9-min booster session.

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: not reported

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Fibre intake, fruit and vegetable intake, sodium intake

Leis 2020 (Continued)

Number of participants analysed:

Intervention baseline: 356

Intervention follow-up: 356

Control baseline: 314

Control follow-up: 314

Data collection measure: weighed plate waste enhanced with digital photography

Data collector: not reported

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost:

Average cost of training, total intervention implementation cost

Number of participants analysed:

ECEC staff: 893

Trainers: 92

Data collection measure: intervention database and semi-structured interviews with intervention staff

Data collector: researchers

Validity of measures used: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: a grant from the Public Health Agency of Canada (# 6282-15-2010/3381056-RSFS), a research grant from the Consortium National de Formation en Santé (# 2014-CFMF-01), and a grant from the Heart and Stroke Foundation of Canada (# 2015-PLNI). AFC was funded through a postdoctoral fellowship from the Saskatchewan Health Research Foundation and SW was funded through a Canadian Institutes of Health Research Charles Best Canada Graduate Scholarships Doctoral Award and a Gérard-Eugène-Plante Doctoral Scholarship from the Faculty of Medicine and Health Sciences at the Université de Sherbrooke.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomisation was used to allocate ECEC centres to either the intervention or control group with a 1:1 ratio.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	While blinding was not possible for the ECEC centres, parents and children were not informed about group assignment. Research assistants responsible for collecting data were not told about the ECEC centre's group allocation. It is unclear whether lack of blinding would affect the outcome. For example,

Leis 2020 (Continued)

		teachers could have encouraged children to eat more healthy foods on the days of observation, though this is unknown.
Blinding of participants and personnel (performance bias) Cost	Unclear risk	Blinding was not possible for the ECEC centres. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Children's dietary intake was measured using weighed plate waste enhanced with digital photography. Research assistants responsible for collecting data were not told of the centre's group allocation.
Blinding of outcome assessment (detection bias) Cost	Unclear risk	Blinding was not possible for the ECEC centres. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data were available for 356 (85%) children in the intervention group and 314 (85%) children in the control group at follow-up. Study authors stated that "We used complete case analysis, such that only participants with complete outcome data were included. This represents a deviation from our original protocol, which planned for analyses to be pursued according to the intention-to-treat principle. This modification was necessary as the issue of missing data largely affected outcome variables, and it is generally the norm not to use imputation for missing data among outcome variables, especially when the proportion of missing data is large." Authors also stated that "Although not as susceptible to bias as a per-protocol analysis, the complete case analyses used are associated with a higher risk that the study groups being compared differ in terms of potentially confounding variables that if the intention-to-treat principle were used." As a result, the risk of attrition bias is considered high.
Incomplete outcome data (attrition bias) Cost	Unclear risk	The number of participants or services which did not complete outcome follow-up data for this outcome is unclear.
Selective reporting (reporting bias)	High risk	Dietary outcomes were reported for fibre (g), fruit and vegetable servings, and sodium (mg). Registration notes calories, macronutrients, and micronutrients. Anthropometric data not reported here
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	Children in both groups were similar on all baseline characteristics.
Loss of clusters	Low risk	One cluster lost 9 children, but loss was a small percentage (< 5%) of the overall sample.
Incorrect analysis	Low risk	Study authors stated that "To account for clustering related to repeated measures and due to the sampling of participants in early childcare centres, variables representing participants and early childcare centres were included as random effects in all models."
Contamination	Low risk	Contamination unlikely. Study authors stated that "Following recruitment of one of the childcare centres in the usual practice arm, it was found that it had the same director and shared staff with a nearby early childcare centre which had been recruited in the intervention arm. Given the risk of contamination quasi certain it was decided to amalgamate the 2 centres as one intervention centre."

Leis 2020 (Continued)

Other bias	Unclear risk	Deviations from protocol noted. Study authors stated that "The study protocol was implemented as planned; however, as detailed in the analysis section, the amount of missing data for the outcomes forced us to modify the analysis plan from an intention-to-treat to a complete-cases analysis approach." There is insufficient information to assess whether an important risk of bias exists.
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Lerner-Geva 2014
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 4 months</p> <p>Unit of allocation: kindergartens</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (kindergartens)</p> <p>Operation: not reported</p> <p>Country (region): Israel (Ra'anaana)</p> <p>Country income classification: high</p> <p>Low-SES sample: no</p> <p>Population description: Ra'anaana is placed in the second highest rank of socioeconomic clusters of the population.</p> <p>Inclusion criteria: the study population comprised children aged 4–6 years attending full-day kindergartens in the city of Ra'anaana. Kindergartens considered for inclusion were those that ran a full-day programme until 16:00 h, which all received lunch from the same catering service and had the same standard of physical exercise of 1 h/week.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 6 (2 Intervention 1; 2 Intervention 2; 2 control)</p> <p>Number of children randomised: 204 (69 Intervention 1; 67 Intervention 2; 68 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention 1: ≤ 4 years, 31.9%; 5-6 years, 43.5%; ≥ 6 years, 24.6% Intervention 2: ≤ 4 years, 23.9%; 5-6 years, 43.3%; ≥ 6 years, 32.8% Control: ≤ 4 years, 10.3%; 5-6 years, 61.8%; ≥ 6 years, 27.9%</p> <p><i>Gender (% female):</i></p> <p>Intervention 1: 46.4% Intervention 2: 55.2% Control: 45.5%</p> <p><i>Ethnicity:</i></p> <p>Intervention 1: birthplace - Israel: 91.3%; other: 8.7% Intervention 2: birthplace - Israel: 98.5%; other: 1.5%</p>

Lerner-Geva 2014 (Continued)

Control: birthplace - Israel: 95.4%; other: 4.6%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity:

Intervention 1: both parents born in Israel, 60.3%; 1 parent born in Israel, 26.5%; both parents born overseas, 13.2%

Intervention 2: both parents born in Israel, 73.4%; 1 parent born in Israel, 17.2%; both parents born overseas, 9.4%

Control: both parents born in Israel, 64.2%; 1 parent born in Israel, 23.9%; both parents born overseas, 11.0%

Parent/family SES:

Parent education: intervention 1: both ≥ 13 years, 74.6%; 1 ≥ 13 years, 12.7%; both < 13 years, 12.7%

Intervention 2: both ≥ 13 years, 62.7%; 1 ≥ 13 years, 20.3%; both < 13 years, 17.0%

Control: both ≥ 13 years, 89.1%; 1 ≥ 13 years, 24.7%; both < 13 years, 6.2%

Method of recruitment: 6 kindergartens were randomly approached to participate in the programme.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: It Fits Me: adapted for kindergarten children

Number of conditions: 2 interventions, 1 control

Intervention duration: intervention 1: 4 months; Intervention 2: 10 weeks

Intervention setting: ECEC

Intervention strategies:

Intervention 1: full intervention
Health curriculum

Children

Education: 10 lessons on healthy eating delivered by teachers

Ethos and environment

Children

Exposure: a daily exercise programme (5 d/week) for 30 min in the morning, delivered by a teacher of physical education who had undergone training.

ECEC staff

Training: teachers were given training by attending lectures where they were familiarised with the materials, in order to facilitate their ability to perform the lessons in their classes.

Resources: supporting materials included posters, worksheets, games, colouring-in sheets and instruction materials for teachers.

Families

Resources: a summary for parents about each nutrition lesson was provided to reinforce messages.

Intervention 2: partial intervention
Health curriculum

Children

Education: 10 lessons on healthy eating delivered by teachers

Lerner-Geva 2014 (Continued)

Ethos and environment

ECEC staff

Training: teachers were given training by attending lectures where they were familiarised with the materials, in order to facilitate their ability to perform the lessons in their classes.

Resources: supporting materials included posters, worksheets, games, colouring-in sheets and instruction materials for teachers.

Families

Resources: a summary for parents about each nutrition lesson was provided to reinforce messages.

Intensity of intervention:

Intervention 1: 1 x healthy eating lesson/week for 10 weeks; 30-min physical activity class daily from March-June; teachers attended training lecture (frequency and duration not reported)

Intervention 2: 1 x healthy eating lesson/week for 10 weeks; teachers attended training lecture (frequency and duration not reported)

Intervention delivered by:

Intervention 1: research team, ECEC staff

Intervention 2: research team, ECEC staff

Modality:

Intervention 1: face-to-face, written

Intervention 2: face-to-face, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Daily energy intake

Number of participants analysed:

Intervention 1 baseline: 69

Intervention 1 follow-up: 69

Intervention 2 baseline: 67

Intervention 2 follow-up: 67

Control baseline: 68

Control follow-up: 68

Data collection measure: FFQ and 24-h recall questionnaire

Data collector: parents

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI z-score

Number of participants analysed:

Intervention 1 baseline: 69

Intervention 1 follow-up: 69

Lerner-Geva 2014 (Continued)

Intervention 2 baseline: 67

Intervention 2 follow-up: 67

Control baseline: 68

Control follow-up: 68

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: this research received no specific grant from any funding agency in the public, commercial or not-for-profit sector.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No clear blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake via a quantified FFQ outside of school, and a helper completed a structured form to document children's intake during school. Blinding of parents and helpers not reported, and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by a single investigator and the outcome measurements were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	The number of students available at follow-up is not reported, so risk of attrition bias is unclear.
Incomplete outcome data (attrition bias)	Unclear risk	The number of students available at follow-up is not reported, so risk of attrition bias is unclear.

Lerner-Geva 2014 (Continued)

Physical outcomes

Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Low risk	Parental consent was obtained at the beginning of the programme. All parents were invited to an information evening at the beginning of the programme, where they received an explanation of the research without knowing to which group their child would be allocated.
Baseline imbalance	Low risk	Baseline differences between groups were found for age of children, parents' education, and religious level. Analysis accounted for these differences
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "Each model included fixed effects: baseline measures, age, parents' education, religious status, study group and random effect of kindergarten and child."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Lumeng 2017
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: classrooms</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (Head Start)</p> <p>Operation: federally-funded</p> <p>Country (region): USA (Michigan)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: urban and rural</p> <p>Inclusion criteria: inclusion criteria are that the child is aged 3 or 4 years at study enrolment.</p> <p>Exclusion criteria: exclusions were significant developmental disabilities that would preclude participation, child is a foster child, or parent is non-English speaking.</p> <p>Number of services randomised: 3 Head Start agencies, 18 classrooms (6 Intervention 1; 6 Intervention 2; 6 control)</p> <p>Number of children randomised: 697 (224 Intervention 1; 255 Intervention 2; 218 control)</p> <p>Characteristics</p> <p>Children</p>

Lumeng 2017 (Continued)

Age:

Intervention 1: 4.10 years (SD 0.52)
 Intervention 2: 4.12 years (SD 0.52)
 Control: 4.12 (SD 0.53)

Gender (% female):

Intervention 1: 49.1%
 Intervention 2: 51.4%
 Control: 53.7%;

Ethnicity:

Intervention 1: white, non-Hispanic: 35.9%; African American, non-Hispanic: 39%; Hispanic/other: 25.1%
 Intervention 2: white, non-Hispanic: 56.4%; African American, non-Hispanic: 27%; Hispanic/other: 16.7%
 Control: white, non-Hispanic: 52.1%; Hispanic/other: 24.9%

Parents
Age (years):

Intervention 1: 29.8 (SD 6.8)
 Intervention 2: 29.6 (SD 6.7)
 Control: 29.2 (SD 12.2)

Gender (% female): not reported

Ethnicity:

Intervention 1: white: 46%; African American, non-Hispanic: 38.7%; Hispanic or other: 15.3%
 Intervention 2: white: 63.1%; African American, non-Hispanic: 26.7%; Hispanic or other: 10.2%
 Control: white: 63.6%; African American, non-Hispanic: 23%; Hispanic or other: 13.4%

Parent/family SES:

Family income-to-needs ratio

Intervention 1: 0.84 (SD 0.53)
 Intervention 2: 0.84 (SD 0.56)
 Control: 0.88 (SD 0.53)

Caregiver education

Intervention 1: < high school: 17.1%; high school diploma or GED: 32.4%; some college courses but no degree: 40.1%; 2-year college degree: 6.3%; ≥ 4-year college degree: 4.1%
 Intervention 2: < high school: 14.7%; high school diploma or GED: 31%; some college courses but no degree: 39.3%; 2-year college degree: 11.1%; ≥ 4-year college degree: 4%
 Control: < high school: 14.3%; high school diploma or GED: 35.5%; some college courses but no degree: 33.6%; 2-year college degree: 12.9%; ≥ 4-year college degree: 3.7%

Method of recruitment: families were told about the study during classroom open houses and through flyers in children's backpacks, and compensated for returning an initial enrolment packet, including a signed written informed consent form. They were then contacted by telephone to review eligibility criteria that they reported in the enrolment packet and to confirm complete understanding of the study and validate informed consent.

Missing data/dropout: Intervention 1: 21 lost to follow-up, 2 discontinued intervention; Intervention 2: 18 lost to follow-up, 2 discontinued intervention, 1 no longer eligible; Control: 11 lost to follow-up, 3 discontinued intervention, 1 was no longer eligible

Reasons for dropout: Intervention 1: 21 lost to follow-up, 2 discontinued intervention; Intervention 2: 18 lost to follow-up, 2 discontinued intervention, 1 no longer eligible; Control: 11 lost to follow-up, 3 discontinued intervention, 1 was no longer eligible

Lumeng 2017 (Continued)

Characteristics of dropouts: not reported

Interventions

1 Programme name: The Growing Healthy Study

Number of conditions: 2 interventions, 1 control

Intervention duration: 4 x 1 school year

Intervention setting: ECEC and home

Intervention strategies:

Intervention 1: Preschool Obesity Prevention Series (POPS)

Health curriculum

Children

Education: 6 lessons delivered over 12 weeks by the Head Start teacher and Extension Educators (trained master's level nutrition educator), using children's stories with embedded obesity prevention themes related to behavioural goals (e.g. more fruit and vegetable consumption; less screen time)

Ethos and environment

Children

Exposure: activities include classroom cooking experiences, games/activities associated with story themes, and goal setting.

ECEC staff

Training: training for Head Start. Training covers curriculum specifics as well as strategies for promoting parent self-efficacy for behaviour change and importance of fidelity.

Booster: booster training was provided each year.

Support: phone support from trainers was available as needed.

Partnerships

Families

Education: 8 x 75-min lessons to develop and practice skills and a discussion of strategies to overcome challenges and problem-solving techniques, with an emphasis on building knowledge and self-efficacy about preventing childhood obesity. Recipes are included in each lesson.

Exposure: hands-on activities are included in each lesson.

Support: reinforcing telephone contacts after every other lesson. 'Family Links' and 'Parent Pages' are sent home to reinforce content from school to home. Transportation and child care provided for parents to attend activities, as needed.

Healthcare

Delivery: a trained Master's-level nutrition educator delivered parent education.

Training: nutrition educators received 2-d training (with booster sessions each year).

Support: phone support from trainers was also available as needed.

Intervention 2: POPS + Incredible Years Series (IYS)

Health curriculum

Children

Education: 6 lessons delivered over 12 weeks by the Head Start teacher and Extension Educators, using children's stories with embedded obesity prevention themes related to behavioural goals (e.g. more fruit and vegetable consumption; less screen time). 60 x 15–20 min lessons delivered throughout the year during "Circle Time" in Head Start classrooms, followed by small group activities. Lessons address self-regulation skills, problem solving strategies, and prosocial behaviour, and use child-size puppets to teach skills and engage children. IYS child lessons were delivered by Master's-level mental health specialists, and Head Start teachers direct small group activities after each lesson.

Ethos and environment

Lumeng 2017 (Continued)*Children*

Exposure: activities include classroom cooking experiences, games/activities associated with story themes, and goal setting.

ECEC staff

Training: training for Head Start. Training covers curriculum specifics as well as strategies for promoting parent self-efficacy for behaviour change and importance of fidelity. Teachers also received training in classroom management strategies (e.g. handling transitions effectively) and were mentored by Master's-level mental health specialists in delivering IYS-Child, so that delivery can slowly progress from delivery by mental health specialist, to co-delivery by mental health specialist and teacher, to sole delivery by the teacher over time.

Booster: booster training was provided each year.

Support: phone support from trainers was also available as needed.

Partnerships*Families*

Education: 8 x 75-min lessons to develop and practice skills and a discussion of strategies to overcome challenges and problem-solving techniques, with an emphasis on building knowledge and self-efficacy about preventing childhood obesity. Recipes are included in each lesson. 12–14 x 2-h lessons focusing on parenting skills such as using effective praise, incentives, limit-setting, and handling misbehaviour. Concepts are discussed using video vignettes about parenting challenges.

Exposure: hands-on activities are included in each lesson.

Materials: homework

Support: follow-up phone calls. "Family Links" and "Parent Pages" are sent home to reinforce content from school to home. Transportation and child care provided for parents to attend activities, as needed.

Healthcare

Delivery: a trained Master's-level nutrition educator delivered parent education.

Training: nutrition educators received 2-d training. The Master's-level trained mental health specialists received training in classroom management strategies (e.g. handling transitions effectively).

Booster: booster training was provided each year.

Support: phone support from trainers was also available as needed. Master's level trained mental health specialists communicated extensively to share ideas and co-ordinate efforts across sites, and received monthly supervision from IYS trainers about their delivery of IYS components, and consultation as needed. Master's-trained mental health specialists also worked with teachers within their own site to develop lesson plans and small group activities.

Intensity of intervention:

Intervention 1: 8 x 75-min weekly parent lessons with telephone follow-ups every other lesson; 6 lessons for children over 12 weeks; 2 h of training for Head Start teachers; phone support as needed; 2 d of training for Extension educator

Intervention 2: 8 x 75-min weekly parents lessons with telephone follow-ups every other lesson; 6 x 15-20-min lessons for children followed by small group activities; 2 h of training for Head Start teachers and phone support as needed; 2 h/week parent lessons with homework and follow-up calls; 2 d of training for Extension educator

Intervention delivered by:

Intervention 1: research team, ECEC staff, healthcare staff

Intervention 2: research team, ECEC staff, healthcare staff

Modality:

Lumeng 2017 (Continued)

Intervention 1: face-to-face, telephone, written

Intervention 2: face-to-face, telephone, written

Theoretical basis: POPS is based on social cognitive theory

Description of control: usual Head Start curriculum and support

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, 100% fruit juice intake, sugar-sweetened beverages intake, whole fruit intake

Number of participants analysed:

Intervention 1 baseline: 224

Intervention 1 follow-up: 224

Intervention 2 baseline: 255

Intervention 2 follow-up: 255

Control baseline: 218

Control follow-up: 218

Data collection measure: 24 h diet recalls and observation

Data collector: parent and researcher

Validity of measures used: not reported

Outcomes relating to child physical measures:

Overweight, obese, normal weight, underweight, BMI z-score

Number of participants analysed:

Intervention 1 baseline: 84-220

Intervention 1 follow-up: 82-195

Intervention 2 baseline: 82-250

Intervention 2 follow-up: 82-230

Control baseline: 68-213

Control follow-up: 68-200

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: USDA/National Institute of Food and Agriculture/Agriculture and Food Research Initiative grant 2011-68001-30089

Lumeng 2017 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors stated that "The 6 teaching teams (hereafter referred to as "classrooms") within each agency were randomly assigned by using an automated system overseen by the study statistician to 1 of 3 study arms, with the limitation that each agency have 2 classrooms allocated per study arm and that the classrooms were located in different communities to prevent cross contamination."
Allocation concealment (selection bias)	Unclear risk	Centres appear to be randomised prior to data collection, however it is unclear if families could potentially know allocation prior to recruitment. Study authors stated that "Families were assigned to a study arm as a function of their classroom assignment, which was based on the location geographically closest to their home address."
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were aware of their study allocation (intervention or control). However, the protocol states that "Only one classroom participates per physical school site to prevent cross-contamination across study arms and ensure that participants are blind to group assignments." It is unclear whether the blinding of participants could have been broken or whether the lack of blinding would affect the outcome.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Although protocol states that "Only one classroom participates per physical school site to prevent cross-contamination across study arms and ensure that participants are blind to group assignments," we assumed that due to the nature of the intervention, ECEC service staff, study personnel delivering the intervention, and parents were aware of their study allocation (intervention or control). However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Unclear risk	Parents reported children's dietary intake via multiple 24-h recalls conducted by trained dietitians who were blinded to study arm. Although protocol states that "Only one classroom participates per physical school site to prevent cross-contamination across study arms and ensure that participants are blind to group assignments," due to the nature of the intervention, parents may have been aware that they were assigned to an intervention. The outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Study authors stated that "Data collectors and interventionists did not interact, and data collectors were blinded to study arm."
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Follow-up data were available for 201 (90%) children in the Head Start (HS) + POPS group, 234 (92%) children in the HS + POPS + IYS group, and 203 (93%) children in the HS only (control) group. < 20% of participants dropped out with similar numbers across groups. ITT analyses were also used also. Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Follow-up data were available for 201 (90%) children in the HS + POPS group, 234 (92%) children in the HS + POPS + IYS group, and 203 (93%) children in the HS only (control) group. < 20% of participants dropped out with similar numbers across groups. ITT analyses were also used also. Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	Study authors stated that "research staff trained in dietary recall methods observed each meal and snack at school and recorded each child's intake;

Lumeng 2017 (Continued)

		these data were incorporated into the recall." However, this procedure was not specified in the protocol.
Recruitment bias	Low risk	Individuals were recruited and enrolled prior to cluster randomisation.
Baseline imbalance	Low risk	Participant characteristics at the time of allocation were similar except for child race/ethnicity. This was accounted for in the analyses.
Loss of clusters	Low risk	No reported loss of clusters, with small numbers of children lost to follow-up.
Incorrect analysis	Low risk	Study authors stated that "Mixed models were used to account for having repeated measures (pre and post) as well as for clustering of children within a classroom."
Contamination	Low risk	Study authors stated that "The 6 teaching teams (hereafter referred to as "classrooms") within each agency were randomly assigned by using an automated system overseen by the study statistician to 1 of 3 study arms, with the limitation that each agency have 2 classrooms allocated per study arm and that the classrooms were located in different communities to prevent cross-contamination."
Other bias	Low risk	No clear other source of bias

Morris 2018
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 3 months Unit of allocation: kindergartens Unit of analysis: child
Participants	Service type: centre-based (Early Childhood Management Services-run kindergartens) Operation: not reported Country (region): Australia (Melbourne) Country income classification: high Low-SES sample: no Population description: not reported Inclusion criteria: sessional kindergartens Exclusion criteria: not reported Number of services randomised: 25 teachers (14 intervention, 11 control) Number of children randomised: 300 (168 intervention, 132 control) Characteristics Children <i>Age:</i>

Morris 2018 (Continued)

Intervention: 4.76 years (SD: 0.36)
Control: 4.68 years (SD: 0.37)

Gender (% female): not reported

Ethnicity:

Intervention: born in Australia: 90.6%; not born in Australia: 9.4%
Control: born in Australia: 94.6%; not born in Australia: 5.4%

Parents

Age (years):

Intervention: mother: 35.15 (SD 4.92); father: 38.32 (SD 5.69)
Control: 35.32 (SD 4.93); fathers: 37.29 (5.31)

Gender (% female): not reported

Ethnicity:

Mothers:

Intervention: born in Australia: 72.4% (intervention); not born in Australia: 27.6%
Control: born in Australia: 70.3%; not born in Australia: 29.7%

Fathers:

Intervention: born in Australia: 74.8%; not born in Australia: 24.4%
Control: born in Australia: 61.8%; not born in Australia: 36.4%

Parent/family SES:

Combined family income

Intervention: low < AUD 25,000-65,000: 28.1%; medium AUD 65,001-105,000: 31.4%; ; high AUD 105,001-145,000: 40.5%

Control: low < AUD 25,000-65,000: 27.4%; medium AUD 65,001-105,000: 29.2%; high AUD 105,001-145,000: 43.4%

Mothers' education

Intervention: high school only: intervention 29.5%; vocation/technical: intervention 13.1%; all university: 49.2%

Control: high school only: 33.7%; vocation/technical: 5.8%; all university: 51.9%

Fathers' education

Intervention: high school only: 35.5%; vocation/technical: 21.5%; all university: 37.2%

Control: high school only: 40.6%; vocation/technical: 20.8%; all university: 34.6%

Method of recruitment: all eligible parents of children were personally invited to participate by the researchers at the kindergarten service. Parents initiated their child's participation.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 8 weeks

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Morris 2018 (Continued)

Education: teachers implemented their planned play-based learning experiences over a period of 8 weeks.

Ethos and environment

ECEC staff

Training: session 1 - All teachers (intervention and control) attended a professional learning session (delivered by research group) to explain the project. They also considered a case study detailing a preschool-aged child's interest in digital media and popular culture characters. Waitlist control teachers then departed the session. The remaining intervention group teachers brainstormed a series of play-based learning experiences, connecting well-being and sustainability knowledge to the case study-child's interests. Session 2 - Intervention teachers only attended a second professional learning session. The session started with a seminar detailing content knowledge about well-being and sustainability appropriate for young children (topics were physical activity, healthy eating, healthy lifestyles, and natural environments). This was followed by a discussion and workshop of teacher's play-based learning experience.

Resources: teachers were provided with: professional learning materials, namely a Pedagogical Communication Strategy and details of different play types (e.g. open-ended, modelled and purposefully framed play) used to build children's knowledge about well-being and sustainability; a visual-arts diary to record their planned play-based learning experiences and observation/assessment of the implemented experiences using their normal methods; and, a book detailing the use of the 3 play-types in the provision of early childhood environmental education. Teachers had access to a purpose-designed website containing copies of all project materials.

Support: teachers were provided with an implementation protocol and the phone and email contact details of researchers.

Intensity of intervention: 2 x professional learning sessions; at least 2 x play based learning experiences implemented each week for children

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, online, written

Theoretical basis: Funds of Knowledge

Description of control: wait-list control, plus teachers attended 1 professional learning session

Outcomes

Outcomes relating to child dietary intake:

Total unhealthy food (e.g. packaged snack foods, confectionary and cakes) intake, fruit and vegetable intake, unsweetened drinks intake, sweetened drink intake, vegetable intake, usual vegetables intake, fruit intake, packaged snacks intake

Number of participants analysed:

Intervention baseline: 89-102

Intervention follow-up: 89-102

Control baseline: 81-101

Control follow-up: 81-101

Data collection measure: Eating and Physical Activity questionnaire (EPAQ)

Data collector: parent

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Morris 2018 (Continued)

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An uninvolved researcher used a computer algorithm to complete random permutations of 1 for intervention and 2 for waitlist control
Allocation concealment (selection bias)	Low risk	While the group allocation could not be concealed from the ECEC teachers, it was concealed from the parents and data collection researchers.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No blinding of teachers, and although allocation was concealed from the parents, it is likely that the blinding could have been broken. The outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake. Although the group allocation was concealed from parents, it is likely that the blinding could have been broken and the outcome measurement is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "Almost three quarters of the parents (n = 187; 72.2 per cent) returned EPAQ surveys at all three timepoints, and 14 per cent did not return any EPAQ surveys." No information is provided as to whether missing data and reasons for missing data were similar across groups. Study authors stated that "Multiple imputation of the EPAQ data was used to address missing values." Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	The protocol states that the Eating and Physical Activity Questionnaire will be used to measure dietary outcomes, however the outcomes of interest are not specifically reported.
Recruitment bias	Low risk	Group allocation was concealed from parents so it is likely that individuals consented to the study without knowing allocation.
Baseline imbalance	Low risk	Study authors state that "No significant differences were seen between age, gender, country of birth or BMI in the intervention group and waitlist control group." ANOVA calculations found only one significant demographic characteristic difference between the means of fathers' height in each group.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	High risk	There was no accounting for clustering of children within kindergartens.
Contamination	Unclear risk	No evidence to make assessment
Other bias	High risk	No funding statement was provided. No conflict of interest statement was reported.

Namenek Brouwer 2013
Study characteristics
Healthy eating interventions delivered in early childhood education and care settings for improving the diet of children aged six months to six years (Review)

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Namenek Brouwer 2013 (Continued)

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 4 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: centre</p>
Participants	<p>Service type: centre-based (licensed)</p> <p>Operation: not reported</p> <p>Country (region): USA (North Carolina)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: not reported</p> <p>Inclusion criteria: to participate in the study, centres had to provide all foods and beverages to children in care (i.e. parents could not send food from home), not have an open case of abuse or neglect with the state licensing agency, and have at least 3 children between the ages of 3 and 5 years in care on a regular basis.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 4 (2 interventions, 2 control)</p> <p>Number of children randomised: not reported (3 children from each classroom randomly selected for dietary outcome assessment)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 3-5 years</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i> not reported</p> <p>ECEC staff</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> 100%</p> <p><i>Ethnicity:</i> African American: 75%</p> <p><i>Service/ECEC staff SES:</i> not reported</p> <p>Method of recruitment: a letter of invitation was mailed to every licensed centre (n = 6) in the city limits of a small community near the researchers' offices. The letter was followed by a telephone call from the study team. The first 4 centres that agreed to participate were enrolled. Centre directors provided written informed consent to participate in the study; parents were provided a fact sheet describing the</p>

Namenek Brouwer 2013 (Continued)

study and were asked to contact the project director if they did not want their children observed during the dietary assessment.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Watch Me Grow

Number of conditions: 1 intervention, 1 control

Intervention duration: 4 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: the programme included a "crop-a-month" structured curriculum highlighting the garden's targeted crop each month (lettuce, strawberries, spinach and broccoli).

Ethos and environment

Children

Menu modification: garden produce was integrated onto service menu and children were provided taste testing activities. Centres were supported to increase the number and nutritional quality of vegetables and fruits provided to children in care, beyond what the garden would produce.

Activities: providers and children grew: lettuce, strawberries, spinach and broccoli. Activities included reading, gardening, taste testing and songs.

ECEC staff

Education: the curriculum included an overview module, followed by monthly modules designed around a specific crop. Each month, the health educator described 4 discrete activities included in each module so that centre staff could deliver the activities to the children approximately weekly. Staff were encouraged to act as positive role models.

Support: monthly technical assistance from a health educator to teachers. Email support for garden maintenance. Monthly visits to the provider at the centre who was directly responsible for food purchasing and menu planning. These visits were to help centres explore low-cost, sustainable ways to increase the number and nutritional quality of vegetables and fruits provided to children in care.

Service

Environment: an 8' x 4' (approximately 2.5 m x 1.2 m) raised bed outdoor garden was installed at all intervention services.

Resources: intervention classrooms received corresponding curriculum materials (including an existing published children's book) highlighting the target fruit or vegetable of the month. The study provided all garden supplies, including plants, watering cans, brackets, and materials for the raised garden bed.

Support: monthly consultation by a gardener

Partnerships

Families

Event: 1-h early spring kick-off event at each intervention service. Parents and other family members, providers, and children were invited to help plant the gardens.

Healthcare

Support: a health educator met monthly with the provider at the centre who was directly responsible for food purchasing and menu planning. The intent was to help centres explore low-cost, sustainable

Namenek Brouwer 2013 (Continued)

ways to increase the number and nutritional quality of vegetables and fruits provided to children in care, beyond what the garden would produce.

Intensity of intervention: 1 x crop/month (with related class materials); 1 x installed garden in an appropriate location (plus gardening supplies, plus gardening expertise); 1-h early spring kick-off event; curriculum included overview modules, monthly module, 4 x activities provided to children weekly

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: wait-list control

Outcomes
Outcomes relating to child dietary intake:

Fruit intake, vegetable intake, dark vegetable intake, white potato intake

Number of participants analysed:

Intervention baseline: 6

Intervention follow-up: 6

Control baseline: 6

Control follow-up: 6

Data collection measure: in-care observation

Data collector: trained registered dietitian

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child cognitive performance: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Following baseline data collection, centres were randomised via a simple randomisation scheme (randomisation without restriction) to either the intervention or control condition in a 1:1 ratio, using the Research Randomizer (http://www.randomizer.org/form.htm).
Allocation concealment (selection bias)	Low risk	Baseline data collected before centres were allocated to groups
Blinding of participants and personnel (performance bias)	High risk	Teachers were aware of allocation and may have encouraged children to eat more fruits and vegetables on the days of diet observation.

Namenek Brouwer 2013 (Continued)

Diet outcomes

Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Children's dietary intake was observed by a trained Registered Dietitian who was blinded to treatment group.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	There is no information regarding the number of participants at baseline or follow-up. It is also unknown if the children observed at baseline were the same as those observed at follow-up. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Low risk	Individual recruitment and child consent (opt-out) to participate occurred before randomisation of clusters.
Baseline imbalance	Unclear risk	No baseline details on children provided; only details on the ECEC included
Loss of clusters	Low risk	Only 3 students were observed pre- and post-interventions. Appears no ECEC was lost to follow-up
Incorrect analysis	High risk	There was no accounting for clustering of children within centres.
Contamination	Unclear risk	All 4 centres were located within the city limits of a small community near the researchers' offices. Only 2 other centres existed in that community that were not chosen to participate. It is possible that ECEC staff from an intervention centre started working at a control centre, or for a child attending an intervention centre to switch to a control centre. However, there is not enough information provided to assess whether contamination exists.
Other bias	High risk	Study authors stated that "we randomly selected a classroom and then three children within that classroom for dietary observation at intervention and control centres before and after the intervention." No further information is provided as to how classrooms and children were chosen. It is possible that choices were made in a biased way. No funding statement was provided.

Natale 2014a
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 3 months Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based Operation: subsidised Country (region): USA (Miami-Dade County, Florida) Country income classification: high Low-SES sample: yes

Natale 2014a (Continued)

Population description: Miami-Dade County, Florida, is one of the only counties in the USA that is 'minority majority': 64% of its residents identify as Hispanic, and 20% as African American. Over 51% of its 2.3 million residents were born outside the USA (138 countries identified). Nearly a quarter of the population is younger than 18 years, > 15% of the school-aged population has limited English proficiency (Spanish and Haitian Creole as their primary languages), the graduation rate is only 45%, and 22% of young adults have limited literacy skills. Rates of obesity are higher among ethnic-minority children in Miami-Dade County, compared with ethnic-minority children nationally (31% vs 26%, respectively). In addition, there are more than 1400 child-care centres in the county serving over 20,000 children; 18% live below the poverty line.

Inclusion criteria: centres' study inclusion criteria consisted of (a) serve > 30 children, (b) serve low-income children, and (c) ethnic make-up had to be reflective of the county as a whole (minority majority). Low income was determined based on whether or not the child received subsidised child care.

Exclusion criteria: not reported

Number of services randomised: 8 (6 intervention, 2 control)

Number of children randomised: 307 (238 intervention, 69 control)

Characteristics

Children

Age:

Intervention: 2 years: 14.3%; 3 years: 35.7%; 4 years: 36.6%; 5 years: 13.5%
 Control: 2 years: 29%; 3 years: 33.3%; 4 years: 31.9%; 5 years: 5.8%

Gender (% female):

Intervention: 49.2%
 Control: 47.8%

Ethnicity:

Intervention: Hispanic/other: 35.7%; Hispanic/Cuban: 24%; African American: 19.3%; Hispanic/Puerto Rican: 3.8%; Haitian: 1.3%; Hispanic/Mexican: 2.1%; other Caribbean black: 2.5%; white: 0.8%; other: 4.2%; unknown: 6.3%
 Control: Hispanic/other: 20.3%; Hispanic/Cuban: 27.5%; African American: 30.4%; Hispanic/Puerto Rican: 1.5%; Haitian: 7.5%; Hispanic/Mexican: 1.4%; other Caribbean black: 0%; white: 4.4%; other: 1.5%; unknown: 5.8%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: all participants were recruited at the child-care centre. Parents were approached during drop-off or pick-up times.

Missing data/dropout: attrition rates were calculated based on available data for child BMI as well as parent measures for each of the time points. At baseline, there were 318 child and parent dyads; at 6 months, there were 239 child and parent dyads; and at 1 year, there were 185 parent and child dyads

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Healthy Inside - Healthy Outside (HI-HO) program

Natale 2014a (Continued)

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: the 6-month intervention presented a developmentally, culturally, and linguistically appropriate curriculum that targets preschoolers.

Ethos and environment

ECEC staff

Training: 2 x training sessions. Teachers and staff were trained on the role and rationale of the Hip Hop to Health Jr. programme, taught implementation strategies, and provided lessons to use with the children.

Support: weekly technical assistance visits with the teachers and a Hip Hop to Health specialist to ensure the implementation of a low-fat, high-fibre diet that included more fruits and vegetables with an emphasis on cultural barriers.

Service

Policy: the development of policies to increase physical activity and healthy eating

Menu modification: a nutritionist worked with each ECEC centre to modify menus to improve the health profile, make them compliant with the policies, and also to ensure that the USDA nutritional requirements were met.

All participants

Cultural: the programme was designed to be culturally sensitive, given the ethnic diversity of the families, teachers, and administrators and staff at participating schools.

Partnerships

Families

Education: the parent curriculum was modelled after a modified version of the Eating Right Is Basic and Hip-Hop to Health Jr. programmes. Monthly educational dinner in which nutrition and physical activity were discussed. Sessions were provided by registered dietitians who were of the same cultural background as the parents.

Resources: monthly newsletters, and at-home activities. For each of the 6 x at-home activities that each family completed, they received a healthy snack bag. At the end of the programme, parents who attended ≥ 3 dinners received a certificate of completion.

Healthcare

Delivery: a nutritionist assisted centres in menu modification.

Intensity of intervention:

Teacher component: 2 x training sessions/centre; monthly educational parent dinner; monthly parent newsletters; monthly at-home activities; each centre agreed on a drink policy; a snack policy and physical activity policy.

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: Socio-Ecological Model Framework

Description of control: alternative intervention control (safety education)

Outcomes

Outcomes relating to child dietary intake: not reported

Natale 2014a (Continued)

Outcomes relating to child anthropometric measures:

Weight z-score, BMI z-score

Number of participants analysed: not reported

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: Miami-Dade County Children's Trust (grant number 764-287)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by the research assistants and are not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	Data were available for 239 (75%) of child-parent dyads at 6-month follow-up and 185 (58%) dyads at 1-year follow-up. Distribution of loss not provided, and reasons for loss not reported. Due to the magnitude of missing data over the short-term and long-term follow-up, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Differences noted, however there is no report on whether these were statistically significant. Models included age in months, race, and gender as potential confounders. Ethnicity was not controlled for in the models yet there appears to be baseline differences between groups.

Natale 2014a (Continued)

Loss of clusters	High risk	Study authors stated that there was an "unexpected closure of a control centre." There were only 2 control centres, so this may be a large proportion of controls.
Incorrect analysis	High risk	There was no accounting for clustering of children within centres.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	No conflict of interest statement was reported.

Natale 2014b
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 1 school year (varies with outcomes)</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: part of the USDA food program and SNAP-eligible</p> <p>Country (region): USA (Miami-Dade County, Florida)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: low income, ethnically diverse</p> <p>Inclusion criteria: to be included in the randomisation process, centres met the following inclusion criteria: (1) have 30 children ages 2-5 years enrolled, (2) serve low-income families, (3) be part of the USDA food program and SNAP (Supplemental Nutrition Assistance Program)-eligible, (4) reflect the ethnic distribution of the Miami-Dade County Public School System (63% Hispanic, 19% African-American, and 18% white), and (5) centre directors agree to participate and sign a letter of commitment as evidence of such.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 28 (12 intervention, 16 control)</p> <p>Number of children randomised: 1224 (767 intervention, 457 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 46.72 months (SD 11.18)</p> <p><i>Gender (% female):</i> 50.12%</p> <p><i>Ethnicity:</i> Hispanic (Cuban): 15.35%; other Hispanic: 40.96%; non-Hispanic black (Haitian): 14.12%; other non-Hispanic Black: 19.02%; non-Hispanic white: 6.69%; other: 3.86%</p> <p>Parents</p> <p><i>Age (years):</i> 18-24: 15.05%; 25-30: 37.19%; 31-40: 37.99%; 41-50: 8.57%; 51+: 1.2%</p>

Natale 2014b (Continued)

Gender (% female): 90%

Ethnicity: Hispanic (Cuban): 15.35%; other Hispanic: 40.96%; non-Hispanic black (Haitian): 14.12%; other non-Hispanic black: 19.02%; non-Hispanic white: 6.69%; other: 3.86%

Parent/family SES:

Level of education: < 12th grade: 35.19%; completed high school or equivalency: 52.02%; completed education beyond high school: 12.79%

Method of recruitment: not reported

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Healthy Caregivers-Healthy Children

Number of conditions: 1 intervention, 1 control

Intervention duration: 6-10 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: weekly lesson plans were designed to incorporate and reinforce the policy standards (drink policy, snack policy, physical activity policy and screen-time policy)

Ethos and environment

Children

Role modelling: by means of role modelling, parents and teachers were encouraged to implement change at the family/home and ECEC centre level.

Cultural: curriculum is available in both English and Spanish, with culturally sensitive language and activities.

ECEC staff

Education: 6 x monthly nutritional gatekeeper training (along with parents) using evidence-based nutrition and physical activity curriculum

Meetings: parent-teacher meetings conducted by research staff that focused on an evidence-based nutrition and physical activity curriculum.

Support: teachers were provided with lesson plans and received weekly technical assistance instruction by curriculum specialists on how to promote wellness within a group's child-care setting.

Role modelling: nutrition professionals served as role models for the teachers and parents.

Service

Policy: development of a centre policy for dietary requirements for meals and snacks, drinks, physical activity and screen time.

Partnerships

Families

Education: 6 x monthly nutritional gatekeeper training (along with teachers) using evidence-based nutrition and physical activity curriculum.

Natale 2014b (Continued)

Healthcare

Support: nutrition professionals served as role models for the teachers and parents.

Intensity of intervention: 29 weeks of teacher curriculum technical sessions; 6 x monthly teacher-parent role-modelling training; parent-teacher meetings (frequency and duration not reported)

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: Reach Effective Adoption Implementation and Maintenance Framework

Description of control: alternative intervention control (safety education)

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, fruit intake, fried intake, fast food intake, snack food intake, soda intake, fruits and vegetables intake, junk food intake

Number of participants analysed:

Intervention baseline: 767

Intervention follow-up: 767

Control baseline: 457

Control follow-up: 767

Data collection measure: Healthy Kids Checklist

Data collector: parent/caregiver

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI percentile, healthy BMI percentile, unhealthy BMI percentile

Number of participants analysed:

Intervention baseline: 767

Intervention follow-up: 767

Control baseline: 457

Control follow-up: 457

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost:

Total costs, resource costs, projected lifetime savings

Number of participants analysed (intervention group only):

Services: 12

Natale 2014b (Continued)

Children: approximately 1200

Data collection measure: detailed staffing and financial records

Data collector: researcher

Validity of measures used: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The USDA (Grant number: AFRI/NRI-2009-0506, RCT, registration number: NCT017220321) and USDA NRI/AFRI Grant # 2009-05065

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	A random number table was used to randomly assign 28 centres to intervention or control. However, an additional 4 centres were added to the control arm due to low enrolment at the centres. These additional centres do not appear to have been randomly chosen or assigned.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Cost	Low risk	No clear blinding of participants and personnel to study allocation, however due to measures used for data collection, the outcome is unlikely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake via questionnaire. Blinding of parents was not possible and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by trained staff and were not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Cost	Low risk	No clear blinding of participants and personnel to study allocation, however due to measures used for data collection, the outcome is unlikely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	The number of children available at follow-up is not reported. Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	The number of children available at follow-up is not reported. Risk of attrition bias is unclear.

Natale 2014b (Continued)

Incomplete outcome data (attrition bias) Cost	Low risk	Data were calculated based on all participating services.
Selective reporting (reporting bias)	Unclear risk	Reporting of dietary components in the protocol is unclear. Protocol also includes waist circumference, which is not reported.
Recruitment bias	High risk	Sample sizes differ between protocol and manuscript, suggesting individual recruitment after randomisation.
Baseline imbalance	Unclear risk	There were significant baseline differences between the treatment and control groups, where the treatment group started at a higher consumption of fruits and vegetables, making interpretation of these changes difficult. Therefore, models with the child Consumption of Fruit/Vegetables used the change of child Consumption of Fruit/Vegetables from Time 1 to Time 2 as the outcome measure, and baseline Consumption of Fruit/Vegetables was included as a covariate. There were several caregiver demographic differences by group that were not accounted for in analysis (e.g. caregiver languages spoken at home, caregiver level of education, birthplace of caregiver, etc.), though there is no statistical analysis to determine if differences are significant.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "A random effect was included to measure the variation of schools nested in treatment groups. In the models including teacher factor scores, another random term was included for the clustering effect of teachers (classrooms) nested within schools."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Natale 2021
Study characteristics

Methods	<p>Study design: cluster-RCT (this study reported on a comparison of 2 RCTs that included different samples. As Phase 1 (RCT 1) is reported in Natale 2014b, only Phase 2 (RCT 2) is reported for Natale 2021 (i.e. treated as a singular RCT)</p> <p>Length of follow-up from baseline: 10 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: centre</p>
Participants	<p>Service type: centre-based</p> <p>Operation: not reported</p> <p>Country (region): USA (Miami-Dade County)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: low resource, predominantly ethnic minority families</p>

Natale 2021 (Continued)

Inclusion criteria: ECEC centres must have met the following criteria to be included in the study: (1) have > 50 children enrolled who are 18-66 months in age, (2) serve low-income families (i.e. the child meets state eligibility as receiving school readiness funds), (3) reflect the ethnic diversity of the MDC Public School System (63% Hispanic, 19% non-Hispanic black, and 18% non-Hispanic white), and (4) obtain agreement from child-care centre directors and teachers to participate.

Exclusion criteria: ECEC centres were excluded if they did not meet the inclusion criteria and if they had a high prevalence of special needs children (i.e. a child with a diagnosed disability with an Individual Education Plan). Special needs did not include children with food allergies and sensitivities; these children were included if their parent consented to study participation. Children who brought their own meals because of diet restrictions and those who were identified by parents on the demographic form as failure to thrive were also excluded.

Number of services randomised: 24 (12 intervention, 12 control)

Number of children randomised: 825 (465 intervention, 360 control)

Characteristics
Children

Age: 43.4 months (SD 13.3)

Gender (% female): 52.5%

Ethnicity: Hispanic Cuban: 20.5%; other Hispanic: 43.5%; non-Hispanic black: 25.2%; non-Hispanic white: 4.9%; other: 5.8%

Parents

Age (years): 18-24: 6.9%; 25-30: 21.1%; 31-40: 30.1%; 41-50: 6.7%; 51+: 1.5%; missing: 33.8%

Gender (% female): unclear

Ethnicity: not reported

Parent/family SES: < 12th grade or GED: 5.3%; completed high school: 7.1%; completed education > high school: 66.6%; missing: 31.4%

Method of recruitment: centre directors and teachers were invited to attend a project orientation describing the activities at their centres. Parents/guardians were recruited for participation in the study via verbal announcements, flyers, and letters sent home. Family members who returned a signed interest form were contacted by telephone.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

 Interventions

Programme name: Healthy Caregivers-Healthy Children Phase 2

Number of conditions: 1 intervention, 1 controls

Intervention duration: 2 school years (approximately 10 months)

Intervention setting: ECEC

Intervention strategies:

Health curriculum
Children

Education: the child curriculum had lesson plans for instructional needs that were consistent with the policies outlined in the toolkit (3 plans focus on beverage/snack policies and 3 plans focus on physical

Natale 2021 (Continued)

activity/screen-time policies). Consisted of physical activities and health-orientated messages incorporated into everyday activities.

Ethos and environment

ECEC staff

Support: monthly technical assistance

Curriculum: role modelling curriculum delivered via train-the trainer model

Service

Materials/Policy: The Health Caregivers Healthy Children toolkit consists of material designed to incorporate all current nutrition and physical activity policy requirements for preschool children in Florida and embrace best-practice guidelines (snack policy, beverage policy, physical activity policy, and screen-time policy).

Partnerships

Parents

Workshops: 6 monthly role modelling workshops the University of Florida Institute of Food and Agricultural Sciences Extension Family Nutrition Program staff

Intensity of intervention: 6 x 3-h monthly workshops for teachers; 6 monthly role-modelling workshops for parents; child lesson plans (frequency and duration not reported)

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: Reach Effective Adoption Implementation and Maintenance Framework, Social Cognitive Theory and Adult Learning Theory

Description of control: alternative intervention control (safety education)

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, fruit intake, fried intake, fast food intake, snack food intake, soda intake

Number of participants analysed:

Intervention baseline: 465

Intervention follow-up: 465

Control baseline: 360

Control follow-up: 360

Data collection measure: Healthy Kids Checklist

Data collector: parent/caregiver

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI percentile, healthy BMI percentile, unhealthy BMI percentile

Number of participants analysed:

Intervention baseline: 465

Intervention follow-up: 465

Control baseline: 360

Natale 2021 (Continued)

Control follow-up: 360

Data collection measure: objectively measured (US Health and Human Services (HHS) guidelines)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The USDA NRI/AFRI (grant numbers #2009-05065 and #2014-08403) and National Institutes of Health (F31DK116533)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A total of 24 ECEC centres were randomly assigned (via a random number table) to 1 of 2 study arms.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, child-care service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake via questionnaire. Blinding of parents was not possible and the outcome measurement is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	The number of children available at follow-up is not reported. Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	The number of children available at follow-up is not reported. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting

Natale 2021 (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	High risk	There was a statistically significant difference between the intervention group and the control group for child race/ethnicity, child age, caregiver age, caregiver relationship to child, caregiver language spoken in home, caregiver level of education, and birthplace of caregiver.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "All models also accounted for clustering of students within centers."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Nekitsing 2019a
Study characteristics

Methods	<p>Study design: cluster-RCT (2 x 2 factorial design)</p> <p>Length of follow-up from baseline: 12 weeks</p> <p>Unit of allocation: preschools</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschools)</p> <p>Operation: not reported</p> <p>Country (region): UK (Leeds, Brighouse, and Halifax)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: not reported</p> <p>Inclusion criteria: preschools were eligible to take part in the case that they were not participating in other nutrition health programmes and were able to commit to the time frame of the study (9 months). All children aged 2-5 years attending their preschool class on the agreed test day were included.</p> <p>Exclusion criteria: children were excluded from the study in the case that they had any relevant food allergies, a medical condition that would prevent them from eating the test vegetable, or if their parents opted out of the study.</p> <p>Number of services randomised: 11 (2 Intervention 1; 3 Intervention 2; 3 Intervention 3; 3 control)</p> <p>Number of children randomised: 219 (62 Intervention 1; 68 Intervention 2; 55 Intervention 3; 34 control)</p> <p>Characteristics</p> <p>Children</p> <p>Age:</p>

Nekitsing 2019a (Continued)

Intervention 1: 38.11 months (SD 0.83)
 Intervention 2: 43.42 months (SD: 0.54)
 Intervention 3: 40.54 months (SD 0.65)
 Control: 41.75 months (SD 0.87)

Gender (% female):

Intervention 1: 51.1%
 Intervention 2: 52.1%
 Intervention 3: 64.1%
 Control: 37.5%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: 55 preschools from Leeds, Brighouse, and Halifax (West Yorkshire, UK) were sent a recruitment e-mail in July 2016, followed by a telephone call.

Missing data/dropout: lost at baseline: intervention 1: 0/62; Intervention 2: 11/68; Intervention 3: 0/55; Control: 2/34

Lost at follow-up: intervention 1: 2/62; Intervention 2: 4/68; Intervention 3: 2/55; Control: 3/34

Reasons for dropout: children missed intake assessment days

Characteristics of dropouts: no differences were found in baseline characteristics or intake of the children who were lost to follow-up compared with those who completed the study.

Interventions

Programme name: not reported

Number of conditions: 3 interventions, 1 control

Intervention duration: 10 weeks

Intervention setting: ECEC

Intervention strategies:

Intervention 1: Taste exposure

Ethos and environment

Children

Exposure: ECEC staff offered children mooli (40-g portions) during usual snack time once/week, for 10 weeks.

Intervention 2: Nutrition education

Health curriculum

Children

Education: staff members were instructed to teach 2 specific components of the PhunkyFood Program as often as possible during the 10-week period.

Ethos and environment

ECEC staff

Training: staff members were trained to deliver the existing PhunkyFoods program.

Resources: ideas and inspiration for classroom carousel play activities (e.g. stories, role-play, and games), practical food handling/preparation activities, educational displays for the classroom and

Nekitsing 2019a (Continued)

parental involvement opportunities. Resources were available in both online and offline formats. Staff members were given materials to support their teaching (e.g. photo cards, posters, a floor mat, game ideas, interactive video stories, music, food preparation, tasting ideas, and drawing and colouring activities).

Partnerships

External provider

Delivery: The PhunkyFoods team trained educators.

Intervention 3: Taste Exposure + Nutrition Education

Health curriculum

Children

Education: staff members were instructed to teach 2 specific components of the PhunkyFood Program as often as possible during the 10-week period.

Ethos and environment

Children

Exposure: ECEC staff offered children mooli (40-g portions) during usual snack time once/week, for 10 weeks.

ECEC staff

Training: staff members were trained by the PhunkyFoods team to deliver the existing PhunkyFoods program.

Resources: ideas and inspiration for classroom carousel play activities (e.g. stories, role-play, and games), practical food handling/preparation activities, educational displays for the classroom and parental involvement opportunities. Resources were available in both online and offline formats. Staff members were given materials to support their teaching (e.g. photo cards, posters, a floor mat, game ideas, interactive video stories, music, food preparation, tasting ideas, and drawing and colouring activities).

Partnerships

External provider

Delivery: The PhunkyFoods team trained educators.

Intensity of intervention:

Intervention 1: children were offered 40-g portions of the vegetable snack once/week for 10 weeks.

Inervention 2: staff trained in PhunkyFoods; 2 specific components of the PhunkyFood Program delivered to children as often as possible during the 10-week period

Intervention 3: children were offered 40-g portions of the vegetable snack once a week for 10 weeks; staff trained in PhunkyFoods; 2 specific components of the PhunkyFood Program delivered to children as often as possible during the 10-week period.

Intervention delivered by:

Intervention 1: research team, ECEC staff

Intervention 2: ECEC staff, healthcare staff

Intervention 3: research team, ECEC staff, healthcare staff

Modality:

Intervention 1: face-to-face

Intervention 2: face-to-face, online, written

Intervention 3: face-to-face, online, written

Nekitsing 2019a (Continued)

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Intake of test vegetable (mooli)

Number of participants analysed:

Intervention 1 baseline: 32-47

Intervention 1 follow-up: 44-47

Intervention 2 baseline: 31-38

Intervention 2 follow-up: 38

Intervention 3 baseline: 25-29

Intervention 3 follow-up: 25-39

Control baseline: 12-16

Control follow-up: 12-16

Data collection measure: each vegetable portion was weighed before and after each snack time using a digital scale

Data collector: researcher

Validity of measures used: not reported

Outcomes relating to child physical measures:

not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: White Rose Doctoral Training Centre (WRDTC) Economic and Social Research Council (ESRC) Collaborative Award. The collaborative partner is Purely Nutrition Ltd. Contribution in kind, which includes storybooks and photo cards, were received from Purely Nutrition Ltd.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Preschools were stratified by size and randomly assigned to one of 4 intervention conditions using an online list generator (https://www.random.org/lists).
Allocation concealment (selection bias)	Low risk	Preschool managers were not informed of their condition allocation until all preschools were recruited (after consent) and randomised. It was possible to conceal condition allocation between clusters but not within a cluster.
Blinding of participants and personnel (performance bias)	High risk	Teachers were aware of allocation and could have encouraged students to eat or try more of the vegetable on testing days.

Nekitsing 2019a (Continued)

Diet outcomes

Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Blinding not reported, however vegetable portions were measured before and after intake to the nearest 0.01 g to determine consumption. The outcome measurement is not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data were available for 140 (64%) children allocated to a treatment group at follow-up, with follow-up rates between 47%-76% across the 4 groups. Study authors stated that "due to the nature of the study design there was a high rate of missing data over time for the complete set of intake data, including follow-ups (36%). As a result of this, there was a substantially smaller sample size in the control condition" Due to the magnitude of missing data and difference in the proportions of participants followed up between groups, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	Trial registered with primary outcome reported as described. Secondary outcome measure of intake of usual vegetables, however this outcome was not reported in the study.
Recruitment bias	Low risk	Individuals and schools were recruited before randomisation of clusters. Study authors state that "Preschool managers were not informed of their condition allocation until all preschools were recruited (after consent) and randomized. It was possible to conceal condition allocation between clusters but not within a cluster."
Baseline imbalance	Low risk	No baseline differences noted between groups with regards to sex distribution or mean BMI z-score, but there were differences in mean age. Age was controlled for in analyses.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Because children were recruited using a cluster design, it was important to account for the influence of cluster assignment. In addition, for repeated measures, each data point was clustered within child. Therefore all the models described below corrected for this using the complex samples procedure within SPSS version 24 to incorporate the contribution of these variance components to the data."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Deviation from methods noted. Study authors stated that "However, given that many children did not eat mooli at baseline, the data were significantly skewed and not suited to simple parametric analysis. Therefore, children were categorized according to their eating pattern at postintervention, Follow-up 1 and Follow-up 2 (noneater, eater) and these are shown in Table 2." There is insufficient information to assess whether an important risk of bias exists. A commercial organisation provided in-kind support.

Nemet 2011a
Study characteristics

Methods	Study design: cluster-RCT
	Length of follow-up from baseline: 12 months
	Unit of allocation: kindergarten class

Nemet 2011a (Continued)

Unit of analysis: child

Participants

Service type: kindergartens (within schools)

Operation: not reported

Country (region): Israel (Sharon)

Country income classification: high

Low-SES sample: yes

Population description: low-SES communities in the Sharon area, Israel. SES was determined with criteria set by the Israeli Central Bureau of Statistics. A scale of 1-10 refers to the SES, whereas low SES was defined by a score of 1-4. The score is comprised of the level of education, employment/unemployment status, income level, number of children per family, number of people per household, and additional standard of living characteristics (e.g. brand and model of cars)

Inclusion criteria: kindergartens from low-SES communities in the Sharon area, Israel. Low-SES classification refers to 1-4 on 10-point scale with criteria set by the Israeli Central Bureau of Statistics.

Exclusion criteria: not reported

Number of services randomised: 30 classes (15 intervention, 15 control)

Number of children randomised: 725 (376 intervention, 349 control)

Characteristics

Children

Age:

Intervention: 5.2 years (SD 0.02)

Control: 5.24 years (SD 0.03)

Gender (% female):

Intervention: 46%

Control: 44%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: 70 children did not complete the study (8.8%) (29/378 control, 41/417 intervention)

Reasons for dropout: children absent on the days of follow-up measurements

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Nemet 2011a (Continued)

Intervention duration: 1 year

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: topics such as food groups, vitamins, healthy food choices, food preparation and cooking methods, and information on fast-food versus home cooking were taught by preschool teachers through short lectures/talks, games, and story reading. Children were encouraged to increase their habitual afterschool physical activity and to reduce sedentary activities.

Ethos and environment

Children

Exposure: children participated in 45-min/d (divided to 3 x 15-min sessions/d) of exercise training (6 d/week). Once a week, the training was directed by a professional youth coach. During the rest of the week similar physical activity sessions were co-ordinated by the preschool teacher or assistant. Training took place indoors or outdoors, varied in intensity and duration, was designed primarily as games, and consisted primarily of endurance type activities (e.g. team sports and running).

ECEC staff

Training: teachers attended an all-day seminar (lectures and hands-on sessions) in which they were acquainted with the programme and were trained by the study team so that preschool staff (i.e. teacher and assistant teacher) could perform all the nutritional aspects of the intervention and most exercise classes. 2 additional training days were offered to collect feedback on the programme and to introduce new materials to the teachers.

Meeting: summary meeting for teachers at the end the year.

Resources: written materials around programme. Preschool teachers were given a CD collection of children's songs related to nutrition and exercise.

Partnerships

Families

Events: parents and children were invited to 2 x "Healthy Day Festivals" that focused on healthy nutrition, prevention of child obesity, and beneficial effects of exercise in children. The festivals included lectures given by the study team and games for both children and parents.

Resources: monthly flyers detailing nutritional information were sent home via children.

Activities: children were asked to present the flyer on nutritional information to their parents, and parents were asked to discuss the information with their children.

Healthcare

Delivery: once a week, the exercise training was directed by a professional youth coach to children.

Intensity of intervention: 2 x staff training days; 2 x healthy day festivals with parents; nutrition activities delivered to children (frequency and duration not reported); monthly nutrition flyers sent home for children and parents to discuss; 3 x 15-min physical activity sessions/week for children; 1 x CD with song on nutrition and physical activity

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Nemet 2011a (Continued)

Outcomes relating to child physical measures:

Weight, BMI, BMI percentile

Number of participants analysed:

Intervention baseline: 376

Intervention follow-up: 376

Control baseline: 349

Control follow-up: 349

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The Rosalinde and Arthur Gilbert Foundation, and the Israel Heart Fund

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Kindergarten classes were randomly assigned by computerised program to intervention or control group
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were measured by an experienced technician who was blinded to group assignment.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Study authors stated that "Seventy children did not complete the study (8.8%), because they were absent on the days of follow-up measurements (29/378 control, 41/417 intervention) and therefore were excluded from the study. Seven hundred twenty-five participants completed the study (349 control subjects, 376 subjects treated with intervention)." Missing data were similar between groups and for similar reasons. Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting

Nemet 2011a (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	Baseline characteristics of age, sex, and weight status were reported, although no statistical test of difference is reported.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "A two-way repeated measures analysis of variance was used to compare effects of the intervention on body weight, height, BMI, BMI percentiles, nutrition and physical activity knowledge and preferences and fitness between the intervention participants and the control participants with time serving as the within group, and intervention as the between group factor. When differences between the 2 groups were identified, a mixed model analysis was performed, to ensure no class effect."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Nemet 2011b
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 1 school year</p> <p>Unit of allocation: kindergarten classes</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (kindergartens)</p> <p>Operation: not reported</p> <p>Country (region): Israel (Central Israel)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: low-SES communities</p> <p>Inclusion criteria: not reported</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 11 (5 intervention, 6 control)</p> <p>Number of children randomised: 342 (154 intervention, 188 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention: 5.36 years (SD 0.03) Control: 5.4 years (SD 0.02)</p>

Nemet 2011b (Continued)

Gender (% female):

Intervention: 45%

Control: 45%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: 45 children did not complete the study (13.0 %)

Reasons for dropout: mainly due to absence in the final data collection day

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 1 school year

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: topics such as food groups, vitamins, healthy food choices, food preparation and cooking methods, and information on fast-food versus home cooking were taught by preschool teachers through short lectures/talks, games, and story reading. Children were encouraged to increase their habitual afterschool physical activity and to reduce sedentary activities.

Ethos and environment

Children

Exposure: children participated in 45-min/d (3 x 15-min/d) sessions of exercise training (6 d/week). Once a week, the training was directed by a professional youth coach. During the rest of the week similar physical activity sessions were co-ordinated by the preschool teacher or assistant. Training took place indoors or outdoors, varied in intensity and duration, was designed primarily as games, and consisted primarily of endurance type activities (e.g. team sports and running).

ECEC staff

Training: teachers attended an all-day seminar (lectures and hands-on sessions) in which they were acquainted with the programme and were trained by the study team so that preschool staff (i.e. teacher and assistant teacher) could perform all the nutritional aspects of the intervention and most exercise classes. 2 additional training days were offered to collect feedback on the programme and to introduce new materials to the teachers.

Meeting: summary meeting for teachers at the end the year.

Resources: written materials around programme. Preschool teachers also were given a CD collection of children's songs related to nutrition and exercise.

Partnerships

Nemet 2011b (Continued)

Families

Events: parents and children were invited to 2 x "Healthy Day Festivals" that focused on healthy nutrition, prevention of child obesity, and beneficial effects of exercise in children. The festivals included lectures given by the study team and games for both children and parents.

Resources: monthly flyers detailing nutritional information were sent home via children. Children were asked to present the nutritional information to their parents, and parents were asked to discuss the information with their children.

Healthcare

Delivery: once a week, the exercise training was directed by a professional youth coach to children.

Intensity of intervention:

Teachers: 1 x all-day staff seminar; 2 additional staff training days; 2 x "Health Festival" days (lectures) with parents

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

Weight, BMI, BMI percentile

Number of participants analysed:

Intervention baseline: 134

Intervention follow-up: 134

Control baseline: 163

Control follow-up: 163

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: a grant from the Rosalinde and Arthur Gilbert Foundation and the Israel Heart Fund

Risk of bias
Bias
Authors' judgement
Support for judgement

Nemet 2011b (Continued)

Random sequence generation (selection bias)	Low risk	Study authors stated that "Kindergarten classes were randomly assigned by computerized program to participate in a year-round, in-school, combined, nutritional and physical activity intervention or to serve as controls (six kindergarten classes in the control group and five the intervention group)."
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Study authors stated that "Measurements were performed by an experienced technician who was blinded to the group assignment."
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Study authors stated that "Forty-five children did not complete the study (13.0%) because they were absent at the days of follow-up measurements (25/188 control and 20/154 intervention) and were therefore excluded from the study." As this is < 20% and numbers are similar across groups and unlikely due to the true outcome, this is unlikely to affect outcomes. Missing data were similar between groups and for similar reasons. Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting
Recruitment bias	Unclear risk	Study authors stated that "Children were included after parental consent" though it is unclear if individual recruitment occurred before or after randomisation of clusters.
Baseline imbalance	Low risk	Study authors stated that "No significant differences in age, gender, body weight, height, BMI, or BMI percentile were found between groups before the intervention."
Loss of clusters	Low risk	No clusters appear to have been lost, based on attrition and reasons.
Incorrect analysis	Low risk	Study authors stated that "When differences between the two groups were identified, a mixed model analysis was performed to ensure no class effect."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	No conflict of interest statement was reported

Pearson 2022
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 4 months Unit of allocation: centre Unit of analysis: child
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Pearson 2022 (Continued)

Participants

Service type: centre-based

Operation: Lunchbox services

Country (region): Australia (Hunter New England)

Country income classification: high

Low-SES sample: no

Population description: the sample area includes major metropolitan centres and inner regional communities, with a small proportion (14%) of people in remote communities.

Inclusion criteria: ECEC services from the region that required parents to provide food for consumption at the service (i.e. lunch box services). Recruitment for the trial occurred in 2 phases. Initially, ECEC services were eligible to participate in the trial if they enrolled children aged 3-6 years and were existing users of the designated parent communication app. As this eligibility criterion did not result in adequate ECEC services being recruited, phase 2 recruitment extended the eligibility criteria to include ECEC services not yet using the app but willing to commence using the app for the trial. Parents or carers of children aged 3-6 years were eligible to participate if their child attended during the designated days of data collection and if they used or indicated a willingness to download the intervention app on the consent form.

Exclusion criteria: services were excluded if they were participating in any other trial related to improving child nutrition, catered exclusively for children with special needs or are a Department of Education community-run service (as they are not covered within the ethics arrangement). Children were excluded if they had special dietary requirements or allergies that would necessitate specialised tailoring of their diet.

Number of services randomised: 18 (9 intervention, 9 control)

Number of children randomised: 400 children (191 intervention, 209 control)

Characteristics

Children

Age:

Intervention: 3.9 years (SD 0.68); control: 3.9 years (SD 0.67)

Gender (% female):

Intervention: 52.1%

Control: 51.6%

Ethnicity: not reported

Parents

Parent/caregiver age (years): not reported

Parents gender (% female): not reported

Parent/Caregiver Ethnicity: not reported

Parent/family SES:

Low SES: intervention: 62.8%

Control: 55.7%;

High SES: intervention: 37.2%

Control: 44.3%

Pearson 2022 (Continued)

Parent education:
 Attended or completed high school:

Intervention: 23.4%

Control: 22.2%;

Technical or further education (TAFE) certificate or diploma: intervention: 31.6%

Control: 32.8%

Completed university or college degree or higher

Intervention: 44.9%

Control: 45%

Method of recruitment: for both phases, recruitment involved research assistants posting and emailing information statements and consent forms to ECEC services outlining the study, data collection procedures, and requesting participation. To obtain parental consent for participation in the study, ECEC service staff distributed hard copies of parent information statements and consent forms. Parents could also consent on the day of the data collection.

Missing data/dropout: a service in the intervention arm ceased using the required app and withdrew from the study (before baseline data but after random allocation). Consumption data were collected for 88% (352/400) of children at baseline and for 84.3% (337/400) after the intervention.

Reasons for dropout: a service in the intervention arm ceased using the required app and withdrew from the study. Child attrition reasons were not reported.

Characteristics of dropouts: not reported

Interventions

Programme name: SWAP IT for Childcare

Number of conditions: 1 intervention, 1 control

Intervention duration: 10 weeks

Intervention setting: ECEC and home

Intervention strategies

Ethos and environment

Service

Endorsement: the service managers were asked to communicate their endorsement of the intervention and guidelines to educators via a staff meeting or individual briefings and provide hard copies of the SWAP IT messages and the SWAP IT Lunchbox guidelines.

Support: a health promotion officer conducted a brief onsite visit with the service manager to familiarise them with the guidelines and provide support to integrate these with existing service lunchbox policies (if required).

Monitoring: a record of implementation was given to service managers to enable them to record their delivery of the agreed tasks during the intervention period.

Parents

Communication: service managers were asked to send 2 communications to parents via the app or other preferred communication methods (e.g. hard copy newsletters).

Partnerships

Parents

Resource: parents were given access to the Skoolbag app which encourages the use of service-endorsed 'SWAP IT Options' lunchbox guidelines recommending which foods and drinks to 'swap from' and which to 'swap to' when packing a healthy lunchbox. The guidelines were developed by dietitians and provide specific guidance in line with the Australian Guide to Healthy Eating, recommendations outlined in the NSW Ministry of Health nutrition sector-specific resource and health and well-being requirements outlined in national accreditation standards. Parents were also able to access messages and images, and through attachments and links to the 'SWAP IT Childcare' webpages, videos, fact sheets and other websites.

Pearson 2022 (Continued)

Communication: push notifications alerted parents to messages sent via the service's app for 10 weeks (1/week).

Intensity of intervention:

Parents: 1 x push notification for 10 weeks, plus an additional notification in the first week. 2 x communication by service (via app, email or preferred communication methods)
Service: 1 on-site visit (if required), implementation record

Intervention delivered by: ECEC staff, healthcare staff

Modality: face-to-face, online, written

Theoretical basis: Behaviour Change Wheel

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, fruit intake, discretionary foods intake, breads and cereals intake, dairy intake, meat and alternatives intake, mean energy from discretionary foods, mean energy, saturated fat, total and added sugars, sodium consumed from all foods and calorific drinks packed in children's lunch boxes

Number of participants analysed

Intervention baseline: 138

Intervention follow-up: 137

Control baseline: 165

Control follow-up: 164

Data collection method: weighed plate waste enhanced with digital photography and written records

Data collector: researchers

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: owing to the null findings, a cost-effectiveness analysis, as specified in the study protocol, was not conducted.

Outcome relating to adverse consequences:

Changes in the frequency of parent complaints or concerns regarding healthy lunch box policy

Number of participants analysed: not reported

Data collection method: service manager pen and paper survey

Data collector: service manager

Validity of measures used: not reported

Notes

Funding source: this research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. Infrastructure funding was provided in kind by Hunter New England Population Health.

Pearson 2022 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors stated that "ECEC services were randomly allocated to the intervention group or no intervention control group in a 1:1 ratio by a statistician independent of the trial using a computerized random number generator."
Allocation concealment (selection bias)	Low risk	Centres were allocated to groups following recruitment.
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	Study authors state "Owing to the nature of the intervention, ECEC services and parents were not blinded to the intervention; however, outcome assessors were blinded to the service allocation." It is unclear whether lack of blinding would affect the outcome. For example, teachers could have encouraged their students to eat more of certain foods from their lunches on the days of observation, though this is unknown.
Blinding of participants and personnel (performance bias) Adverse consequences	Unclear risk	Services were not blind to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Study authors state "outcome assessors were blinded to the service allocation."
Blinding of outcome assessment (detection bias) Adverse consequences	Unclear risk	Services were not blind to study allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Study authors stated that "Consumption data were collected for 88% (352/400) of children at baseline and for 84.3% (337/400) after the intervention."
Incomplete outcome data (attrition bias) Adverse consequences	Unclear risk	The number of services and participants that reported on this outcome at follow-up is unclear.
Selective reporting (reporting bias)	High risk	Study authors stated that "Owing to the null findings, neither a cost-effectiveness analysis, as specified in the study protocol, nor the planned analysis of data collected on the usual daily dietary intake of children (to be able to detect any compensatory dietary behaviors) was conducted."
Recruitment bias	Low risk	Allocation took place after recruitment and before baseline data collection.
Baseline imbalance	Low risk	Study authors stated that "Characteristics were similar across groups; however, the intervention group had a higher proportion of parents located in the outer regional areas than the control group. As the intervention was delivered at the cluster level rather than at the individual level, geographical remoteness was accounted for by stratifying services by this factor during randomisation and not controlled for as part of the analysis."
Loss of clusters	High risk	Study authors stated that "A service in the intervention arm ceased using the required app and withdrew from the study (before baseline data but after random allocation)."

Pearson 2022 (Continued)

Incorrect analysis	Low risk	Study authors stated that "Models were adjusted for potential ECEC service level clustering through a service random effect and controlled for baseline service Environment and Policy Assessment and Observation score and if ECEC services were existing app users before the trial."
Contamination	Low risk	Study authors stated that "No contamination was reported; that is, the app was not used to send any other health or nutrition information. No ECEC services in the intervention or control groups reported exposure to additional nutrition interventions throughout the duration of the trial."
Other bias	Low risk	No other clear source of bias

Peñalvo 2015
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 3 years</p> <p>Unit of allocation: schools</p> <p>Unit of analysis: school and child</p>
Participants	<p>Service type: preschool (within schools)</p> <p>Operation: public schools</p> <p>Country (region): Spain (Madrid)</p> <p>Country income classification: high</p> <p>Low-SES sample: no</p> <p>Population description: not reported</p> <p>Inclusion criteria: participating schools were selected from among all public schools in the city of Madrid, Spain, on the basis of size (> 50 children/class) and availability of cafeteria service. The study focused only on schools located in the city of Madrid, having full canteen services, and with ≥ 2 classrooms per preschool level (needed to attain the 50 students per level used in sample size calculation).</p> <p>Exclusion criteria: schools on the extremes of the distribution for percentage of immigration and percentage scholarships were excluded.</p> <p>Number of services randomised: 24 (12 intervention, 12 control)</p> <p>Number of children randomised: 2062 (groups not reported)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 3-5 years</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p>

Peñalvo 2015 (Continued)

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: 20% of children 3 years of age (3-year intervention), 13% of children 4 years of age (2-year intervention), and 3.2% of children 5 years of age (1-year intervention) were lost to follow-up.

Reasons for dropout: this was due to 1 intervention school discontinuing the study because the school's principal was replaced after the first year.

Characteristics of dropouts: not reported

Interventions

Programme name: The SI! Program for Cardiovascular Health Promotion in Early Childhood

Number of conditions: 1 intervention, 1 control

Intervention duration: 3 years

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: didactic units, including 7 key activities/unit, relating to 4 lifestyle-related components: diet, physical activity, knowledge of the human body and heart, and management of emotions. Teachers delivered the intervention through classroom materials for a minimum of 20 h for the diet, physical activity, and human body components and a minimum of 10 h for the emotion management component. The Program SI! is embedded in the school curriculum and implemented in the classroom on 4 complete weeks during every school year.

Ethos and environment

Children

Resources: Sesame Street audio visuals, books and games, and cooking workshops, and tales of healthy living.

ECEC staff

Resources: all preschool teachers had access to an online repository of the intervention resources. Teachers also interacted via the intervention website on a blog where activities were shared between participating schools and in an open forum where they discussed any aspect of the intervention. Training: in each school, a teacher volunteered as the intervention co-ordinator and received regional, government-certified training in the SI! Program contents and strategies (an expert-led 30-h course).

Support: continuing counselling from programme staff to liaisons.

Service

Event: parents, children and teachers were invited to an annual Health Fair.
 Resources: documentation of healthy recommendations in schools

Support: periodical meetings between principal and programme liaisons

Partnerships

Families

Resources: families were given access to the programme website and given informative letters and leaflets.

Activities: families were provided activities to do over the weekend.

Peñalvo 2015 (Continued)

Event: parents were invited to whole-school events such as the annual health fair.

Intensity of intervention: 70 h x health curriculum for children; 30 h x teacher training each year; 12 h x parent components (health fair; information; activities); 2 h x school component.

Intervention delivered by: ECEC staff, healthcare staff

Modality: face-to-face, online, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI percentile, BMI z-score, waist circumference, skinfold thickness tricep, skinfold thickness sub-scapular, obese, overweight

Number of participants analysed: not reported

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: research grant FIS-PI11/01885 (Fondo de Investigación Sanitaria del Instituto de Salud Carlos III), Fondo Europeo de Desarrollo Regional (FEDER 2007–2013), and the Daniel and Nina Carasso Foundation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The random sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height, weight, waist circumference, and skinfold thickness were measured and not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias)	Low risk	Study authors stated that "During follow-up, 20% of children 3 years of age (3-year intervention), 13% of children 4 years of age (2-year intervention), and

Peñalvo 2015 (Continued)

Physical outcomes

3.2% of children 5 years of age (1-year intervention) were lost to follow-up. This was due to 1 intervention school discontinuing the study because the school's principal was replaced after the first year. No significant differences were found in baseline demographic or outcome-related variables (KAH score and anthropometric measures) for those children lost to follow-up compared to the rest of participants (intervention or control groups)." Therefore, risk of attrition bias was considered to be low.

Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Stratified randomisation was conducted to account for discrepancies in SES, however baseline demographic data are not reported for treatment groups.
Loss of clusters	High risk	One intervention cluster lost because the school's principal was replaced after the first year.
Incorrect analysis	Low risk	Study authors stated that "Mixed-linear models that account for the cluster randomized design were used to test for intervention effect. Fixed effects in each model were the corresponding baseline score, school year, and treatment group. Schools were handled as random effects. No correction for multiple comparisons was used."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Study authors stated that "Despite finding strong statistical associations, the lack of adjustment for multiple comparisons could have affected the results." There is insufficient information to assess whether an important risk of bias exists. No conflict of interest statement was reported.

Pinket 2016
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 12 months Unit of allocation: municipalities Unit of analysis: child
Participants	Service type: centre-based: (Germany: kindergartens; Bulgaria: kindergartens; Spain: kindergartens; Poland: kindergartens; Greece: kindergartens and day-care centres; Belgium: preschool settings) Operation: not reported Country (region): 6 European countries (Belgium, Bulgaria, Germany, Greece, Poland and Spain) Country income classification: Belgium: high; Germany: high; Greece: high; Poland: high; Spain: high; Bulgaria: upper-middle Low-SES sample: unclear Population description: not reported

Pinket 2016 (Continued)

Inclusion criteria: kindergartens were considered eligible for inclusion in the intervention if (i) they were located within a radius of 50 km around the local institutes; (ii) headmasters and teachers provided signed consent form and (iii) families'/children's participation rate was at least 50%. Children with-in recruited kindergartens were eligible if (i) they were aged between 3.5 and 5.5 years at the time of recruitment (i.e. born between January 2007 and December 2008); (ii) their parents/caregivers provided a signed consent form and (iii) were not participating in any other clinical trial or other health-oriented project during the academic years 2012–2013 and 2013–2014.

Exclusion criteria: not reported

Number of services randomised: 309 (groups not reported)

Number of children randomised: 4964 (groups not reported)

Characteristics
Children

Age: 4.7 years (SD 0.4)

Gender (% female): 48.5%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

SES (years of school education mother), % lower SES (= % ≤ 14 years of education): 38.5%

Method of recruitment: not reported

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

 Interventions

Programme name: The ToyBox-intervention

Number of conditions: 1 intervention, 1 control

Intervention duration: 24 weeks in the school year

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum
Children

Education: teachers promoted the 4 targeted energy balance-related behaviours (i.e. water consumption, snacking, physical activity and sedentary behaviour) on a regular basis and predefined time within each day, in the classroom/kindergarten. Teachers implemented interactive classroom activities, aiming at total class participation, minimum for 1 h/week.

Ethos and environment
Children

Pinket 2016 (Continued)

Exposure: teachers remind children to drink water regularly and do short movement breaks twice in the morning and twice in the afternoon, arranging a daily break for the whole class to eat healthy snacks and performing 2 physical education sessions/week with a duration of 45 min each.

Role modelling: teachers were also instructed to use the kangaroo hand puppet and perform these 4 topics, so as to enhance the effects of the intervention via role modelling

ECEC staff

Training: 2 x voluntary teacher training sessions to explain the programme and materials. An additional non-compulsory training session was also offered. Teachers were not tested, but researchers provided certificates of attendance to the teachers as incentives.

Resources: a box including the ToyBox-intervention material (teacher's guide, classroom activity guide, kangaroo hand puppet) was provided to teachers.

Service

Environment: installation of water stations and the 'magic snack plate' to assist water and healthy snack consumption; rearrangements of the classroom/kindergarten to create some free space to assist children's movement.

Partnerships

Families

Resources: 9 x newsletters, 8 x tip cards and 4 x posters, coloured by their child, which aimed to encourage parents/caregivers to apply relevant environmental changes at home, act as role models and implement these lifestyle behaviours together with their children.

Intensity of intervention: 3 x teacher training sessions; permanent environmental changes; teachers promote targeted behaviours every day; 2 x 45 min physical education lessons/week for children; 1 h/week interactive classroom activity; 9 x parent newsletters; 8 x parent tip cards; 4 x parent posters; 1 box of intervention materials provided to teachers.

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, written

Theoretical basis: PRECEDE-PROCEED Model

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Plain yoghurt intake, cheese intake, fresh fruit intake, raw vegetable intake, sugared or aromatised yoghurt intake, chocolate and candy bars intake, milk-based desserts intake, cake intake, biscuit intake, sugar-based dessert intake, salty snack intake, healthy snack intake, unhealthy snack intake, unhealthy snacks intake, plain water intake, tea intake, soft drink intake, light soft drink intake, pure fruit juice intake, pre-packaged fruit juice intake, smoothie intake, plain milk intake, sugared and chocolate milk, total water, fruit juice intake, soft drink intake, water intake

Number of participants analysed:

Intervention baseline: 3255

Intervention follow-up: 3255

Control baseline: 1715

Control follow-up: 1715

Data collection measure: FFQ

Data collector: parent/caregiver

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Pinket 2016 (Continued)

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: Seventh Framework Programme (CORDIS FP7) of the European Commission under grant agreement n° 245200

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation of the recruited municipalities to intervention and control group was conducted centrally using Excel by the co-ordinating centre in a 2:1 ratio within each SES strata.
Allocation concealment (selection bias)	Low risk	Allocation to intervention and control group was conducted centrally by the co-ordinating centre, after the completion of baseline measurements.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake via a FFQ. Blinding of parents not reported, and the outcome measurement is likely to be influenced by a lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "Completer analysis was carried out to handle missing data, which means that only preschoolers with valid data at both baseline and follow-up were included in the analyses." Data were available for 4970 (70%) of children whose parents consented to the study. No information is provided as to reasons for missing data or whether the loss or reasons for loss differed by intervention group. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	Outcomes are not clearly reported in the trial registration or trial protocol, so it was unclear whether there was selective outcome reporting.
Recruitment bias	Low risk	Individuals and centres were recruited before randomisation of municipalities. Randomisation of the municipalities to treatment group was conducted centrally by the co-ordinating centre, after the completion of baseline measurements.
Baseline imbalance	Low risk	Descriptive analyses showed that there was no significant difference between the intervention and control groups regarding sex, age, intake of healthy snacks, and intake of unhealthy snacks at baseline. Clusters were stratified by SES prior to random selection and all analyses were corrected for preschool children's sex and age.
Loss of clusters	Unclear risk	There is a large number of missing data, however it is unclear if there were losses of clusters.

Pinket 2016 (Continued)

Incorrect analysis	Low risk	Study authors stated that "To take clustering of baseline and follow-up measurements of preschool children in kindergarten classes in kindergartens into account, multilevel modeling was used."
Contamination	Low risk	Study authors stated that "After the recruitment of kindergartens and to avoid contamination between kindergartens in the same municipality, kindergartens' municipalities were randomly assigned to the intervention or control group (2:1)." Therefore, contamination is unlikely.
Other bias	Low risk	No clear other source of bias

Puder 2011
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 11 months</p> <p>Unit of allocation: preschool class</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschools)</p> <p>Operation: public</p> <p>Country (region): Switzerland (St Gallen and Lausanne)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: public preschool classes in areas with a high migrant population from 2 different sociocultural and linguistic regions in Switzerland. The study was conducted in the German-speaking (city of St Gallen; 70,000 inhabitants) and the French-speaking (urban surroundings of Lausanne, canton Vaud; 50,000 inhabitants) regions of Switzerland during the school year 2008-9. All children in Switzerland attend preschool. The city of St. Gallen and the Lausanne area were chosen due to a high prevalence (i.e. at least 40%) of children of migrant background. Migrant background was defined as at least one parent born out of Switzerland.</p> <p>Inclusion criteria: inclusion criteria were > 40% prevalence of migrant children and no participation in any other prevention project.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 40 (20 intervention, 20 control)</p> <p>Number of children randomised: 727 (342 intervention, 310 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 5.2 years (SD 0.6)</p> <p><i>Gender (% female):</i> 50%</p> <p><i>Ethnicity:</i></p> <p>Mainly speak a foreign language at home (any language other than German or French): 40%</p>

Puder 2011 (Continued)

Most common migrant regions (according to country of birth of father): Former Yugoslavia: 25% (91); Portugal: 17%; rest of Europe: 31%; Africa: 12%; rest of world: 15%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity:

1 parent migrant: 24%; both parents migrant: 48%

Migrant areas: Yugoslavia: 25%; Portugal: 17%; rest of Europe: 31%; Africa: 12%; rest of world: 15%

Parent/family SES:

Parental low education level (max 9 years education): neither parent: 62%; 1 parent: 21%; both parents 17%

Method of recruitment: not reported

Missing data/dropout: all ECEC classes retained. Of the 655 children with consent, 652 were present at baseline for BMI measures

Reasons for dropout: 26 children dropped out of the intervention due to moving away.

Characteristics of dropouts: not reported

Interventions

Programme name: Ballabeina

Number of conditions: 1 intervention, 1 control

Intervention duration: 1 school year

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: 22 sessions on healthy nutrition, media use, and sleep

Ethos and environment

Children

Exposure: 45-min physical activity sessions prepared by an exercise physiologist with the aim to improve aerobic fitness and co-ordination skills. Taught weekly by a health promoter for the first 4 months and then reduced to twice a month and taught by preschool teachers. Children in preschool classes are exclusively offered water and healthy food.

Resources: every other week children received a new fun physical activity or nutrition activity card to take home and a CD with music.

ECEC staff

Workshops: teachers participated in 2 x workshops before the intervention to learn about the content and the practical aspects of the intervention.

Meeting: 1 formal meeting to exchange their experience and involved in evenings organised for the parents.

Support: teachers were supported to deliver physical activity sessions through hands-on training by health promoters during the initial visits. Health promoters also assisted in the choices regarding how to adapt the built environment in and around the preschool class.

Service

Puder 2011 (Continued)

Environment: healthy snacks during recess and healthy treats for special occasions were promoted and water and healthy food was exclusively offered during class. Fixed and mobile equipment were installed or provided in and around classrooms, including a “movement corner.”

Materials: coloured poster of the "Ballabeina track", was hung in classroom and stickers were pasted on the poster to show progress.

Event: a Ballabeina event was organised with games implementing the main messages of the intervention.

All participants

Cultural: intervention culturally tailored based on evaluation of norms and needs.

Partnerships

Families

Meetings: 3 x interactive information and discussion evenings. Organised by health promoters in collaboration with preschool teachers

Resources: brochures, information leaflets, physical activity or nutrition activity cards and worksheets. The information leaflets for parents were provided in 10 different languages, and native speakers of the main foreign languages were available to answer questions.

Healthcare

Delivery: health promoters assisted in the delivery of the intervention.

Intensity of intervention: 4 x 45-min sessions of physical activity each week (trained staff delivered these once a week, which was reduced to twice a month after 4 months) for children; 22 sessions on healthy nutrition/media use and sleep for children; take home messages once/week for children; 1 x Ballabeina event (organised games, and materials provided); 2 x teacher workshops; 3 x interactive parent information evenings

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: Social Ecological Model

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Proportion healthy eaters

Number of participants analysed:

Intervention baseline: 342

Intervention follow-up: 333

Control baseline: 310

Control follow-up: 292

Data collection measure: semi-qualitative FFQ

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, percentage body fat, sum of 4 skin folds, waist circumference, overweight or obese

Number of participants analysed:

Intervention baseline: 342

Puder 2011 (Continued)

Intervention follow-up: 333

Control baseline: 310

Control follow-up: 292

Data collection measure: objective measure (IOTF)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance:

Attention, spatial working memory

Number of participants analysed:

Intervention baseline: 342

Intervention follow-up: 333

Control baseline: 310

Control follow-up: 292

Data collection measure: Konzentrations-Handlungsverfahren für Vorschulkinder and Intelligence and Development Scales

Data collector: parent

Validity of measures used: validated

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life:

Quality of life

Number of participants analysed:

Intervention baseline: 342

Intervention follow-up: 333

Control baseline: 310

Control follow-up: 292

Data collection measure: general health questionnaire (PedsQL 4.0)

Data collector: parent

Validity of measures used: validated

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Study authors state only, "No injuries or other adverse events occurred during physical activity sessions in the intervention classes"

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Puder 2011 (Continued)

Notes

Funding source: mainly supported by the Swiss National Science Foundation (grant No 3200B0-116837) and Health Promotion Switzerland (project No 2104). Additional funding was obtained from a research award for interdisciplinary research from the University of Lausanne, a Takeda research award, the Wyeth Foundation for the Health of Children and Adolescents, the Freie Akademische Gesellschaft, and an unrestricted educational grant from Nestlé.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Classes were randomised (1:1) with the use of opaque envelopes.
Allocation concealment (selection bias)	Low risk	Allocation took place after all classes were recruited and selected by someone from the school health services who was not involved in the study.
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. Specially trained researchers measured outcomes and were blinded to group allocation. Eating habits were assessed by the parents with a semi-qualitative FFQ.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Language and cognitive performance outcomes	Low risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. Specially trained researchers measured outcomes and were blinded to group allocation. The outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Quality of life outcomes	Unclear risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. Specially trained researchers measured outcomes and were blinded to group allocation. It is unclear whether the outcome could be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Adverse consequences	Unclear risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. It is unclear whether the outcome could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Unclear risk	Eating habits were assessed by the parents with a semi-qualitative FFQ. Parents were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. It is unclear if blinding could have been broken.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Specially trained researchers measured children's height, weight, bioelectrical impedance analysis, skinfold thickness, and waist circumference and were blinded to group allocation.
Blinding of outcome assessment (detection bias) Language and cognitive performance outcomes	Low risk	Attention and spatial working memory were assessed by specially trained researchers who were blinded to group allocation.

Puder 2011 (Continued)

Blinding of outcome assessment (detection bias) Quality of life outcomes	Unclear risk	Parents completed the health-related quality of life questionnaire. Parents were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. It is unclear if blinding could have been broken.
Blinding of outcome assessment (detection bias) Adverse consequences	Unclear risk	Teachers, parents, and children were informed that the intervention aimed to promote children's health but were unaware of the main objectives of the study. It is unclear whether the outcome could be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 333 (97%) children in the intervention group and 292 (94%) children in the control group. Amount of loss and reasons for loss to follow-up similar between groups (i.e. child moved away after baseline testing). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 333 (97%) children in the intervention group and 292 (94%) children in the control group. Amount of loss and reasons for loss to follow-up similar between groups (i.e. child moved away after baseline testing). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Language and cognitive performance outcomes	Low risk	Data were available for 333 (97%) children in the intervention group and 292 (94%) children in the control group. Amount of loss and reasons for loss to follow-up similar between groups (i.e. child moved away after baseline testing). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Quality of life outcomes	Low risk	Data were available for 333 (97%) children in the intervention group and 292 (94%) children in the control group. Amount of loss and reasons for loss to follow-up similar between groups (i.e. child moved away after baseline testing). Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Adverse consequences	Unclear risk	The number of services and participants that reported on this outcome at follow-up is unclear.
Selective reporting (reporting bias)	Low risk	The study protocol and trial registration are available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Recruitment bias	Low risk	Individuals and classes were recruited before randomisation.
Baseline imbalance	Low risk	There were no differences in baseline characteristics and outcome variables between the intervention and control groups (all $P \geq 0.2$).
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Analyses were performed on an intention to treat basis, by using data from individual children but adjusting for clustering of outcomes within preschool classes."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Grant money was received from a commercial organisation.

Ray 2020

Study characteristics

Methods

Study design: cluster-RCT

Length of follow-up from baseline: 5 months

Unit of allocation: preschool centre

Unit of analysis: child

Participants

Service type: centre-based (preschools)

Operation: not reported

Country (region): Finland

Country income classification: high

Low-SES sample: no

Population description: municipalities that had a high number of preschools and had a large variety in educational and income levels among inhabitants were recruited.

Inclusion criteria: municipalities that had a high number of preschools and had a large variety in educational and income levels among inhabitants as well as being located within a convenient distance from the Helsinki region were invited to participate.

Exclusion criteria: municipalities that were already part of the comprehensive DAGIS survey in 2015–2016 were excluded.

Number of services randomised: 32 (13 intervention, 19 control)

Number of children randomised: 802 (361 intervention, 441 control)

Characteristics
Children
Age:

Intervention: 5.14 years (SD 1.04)

Control: 5.24 years (1.06)

Gender (% female):

Intervention: 47.8%

Control: 46%

Ethnicity: not reported

Parents
Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Parental education

Intervention: low: 35.4%; middle: 46.4%; high: 18.2%

Control: low: 29.9%; middle: 43.6%; high: 26.5%

Ray 2020 (Continued)

Method of recruitment: altogether, 7 municipalities were invited to participate in the study, and an oral presentation on the study was offered. 5 municipalities had an oral presentation; 2 of these municipalities chose to participate. Researchers visited each preschool to inform early educator professionals about the project and their role in the project. The recruitment phase lasted 1–2 weeks, and families returned informed consents (or refusals to participate) to preschools in sealed envelopes.

Missing data/dropout: between 10%-18% of children were missing across diet outcomes.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: The Increased Health and Wellbeing in Preschools (DAGIS) intervention

Number of conditions: 1 intervention, 1 control

Intervention duration: 23 weeks (5 months)

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: educators delivered a programme around 5 healthy energy balance-related behaviours (self-regulation skills; physical activity; fruit and vegetables; screen time; and sugary foods and beverages).

Ethos and environment

Children

Exposure: self-regulation skills were promoted by brain breaks, which were a few minutes' calming down and breathing sessions 3 times/d, led by early educators.

ECEC staff

Training: 2 x training (approximately 8 h total)

Support: email support from researchers throughout the intervention.

Service

Environment: materials that were produced during the activity afternoons were expected to be displayed at the preschool, so that families could see each other's work.

Partnerships

Families

Workshops: children and families were invited to 5 activity afternoons delivered by preschools. The focus was set on the children's energy balance-related behaviours, and on how parents, by acting as role models and changing the availability and accessibility of the home environment can influence children's energy balance-related behaviours.

Resources: information letters, emails containing videos or articles, bingos related to energy balance-related behaviour, and 2 fairy tales

Intensity of intervention: 2 x training, totaling 8 h; 20-25 weeks of child program; parent-child workshops (frequency and duration not reported); parents received materials

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, online, written

Theoretical basis: Social Cognitive Theory, Theory of Planned Behaviour, and Self-Determination Theory

Ray 2020 (Continued)

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Sugary everyday food and beverages intake, sugary treats intake, fruit and vegetable intake

Number of participants analysed:

Intervention baseline: 293-299

Intervention follow-up: 192-200

Control baseline: 307-323

Control follow-up: 236-238

Data collection measure: 51-item FFQ (expanded from the original 47-item survey)

Data collector: parent

Validity of measures used: validated

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance:

Cognitive self-regulation skills

Number of participants analysed:

Intervention baseline: 313

Intervention follow-up: 256

Control baseline: 383

Control follow-up: 324

Data collection measure: 5 items derived from the Child Social Behavior Questionnaire

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child social/emotional measures: emotional self-regulation skills

Number of participants analysed:

Intervention baseline: 313

Intervention follow-up: 256

Control baseline: 383

Control follow-up: 324

Data collection measure: 5 items derived from the Child Social Behavior Questionnaire

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: financially supported by the Ministry of Education and Culture in Finland, The Ministry of Social Affairs and Health, The Academy of Finland (Grants: 285439, 287288, 288038, 315816),

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the Päivikki and Sakari Sohlberg Foundation, Signe and Ane Gyllenberg Foundation, and the Medicinska Föreningen Liv och Hälsa. Folkhälsan Research Center and University of Helsinki provided the infrastructure and the funding for PIs (N.S., M.E., E.R.) and key personnel (C.R., R.L.). Open access funding was provided by University of Helsinki. The funding bodies were not involved and did not interfere with the study at any stage.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was made at the preschool manager-level, separately for the 2 municipalities by an online randomisation program (https://www.randomlists.com/team-generator).
Allocation concealment (selection bias)	Low risk	Preschools were divided into small and large preschools before randomisation. After the baseline measurements, preschools were informed whether they had been randomised into the intervention or control group.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	No blinding of participants and personnel to study allocation, and the outcome is likely to be influenced by lack of blinding
Blinding of participants and personnel (performance bias) Language and cognitive performance outcomes	Unclear risk	No blinding of participants and personnel to study allocation, and it is unclear whether lack of blinding would affect the outcome
Blinding of participants and personnel (performance bias) Social/emotional outcomes	Unclear risk	No blinding of participants and personnel to study allocation, and it is unclear whether lack of blinding would affect the outcome
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents completed the FFQ. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Language and cognitive performance outcomes	High risk	Parents completed a questionnaire regarding children's cognitive self-regulation skills. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Social/emotional outcomes	High risk	Parents completed a questionnaire regarding children's emotional self-regulation skills. Blinding of parents not reported, and the outcome measurement is likely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Data were available for between 192-200 (64%-68%) children in the intervention group and between 236-258 (74%-80%) children in the control group. Reasons for loss to follow-up are not provided. Study authors stated that "All analyses were based on the intention-to-treat principle so that all randomized participants were included in the analysis in their randomized intervention group." Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias)	Unclear risk	Data were available for 256 (82%) children in the intervention group and 324 (85%) children in the control group. Reasons for loss to follow-up are not provided. Study authors stated that "All analyses were based on the intention-to-

Ray 2020 (Continued)

Language and cognitive performance outcomes		treat principle so that all randomized participants were included in the analysis in their randomized intervention group." Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Social/emotional outcomes	Unclear risk	Data were available for 256 (82%) children in the intervention group and 324 (85%) children in the control group. Reasons for loss to follow-up are not provided. Study authors stated that "All analyses were based on the intention-to-treat principle so that all randomized participants were included in the analysis in their randomized intervention group." Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	The reported self-regulation outcomes are not specified in either the trial registration or protocol paper.
Recruitment bias	Low risk	Full recruitment occurred before randomisation, according to the manuscript's PRISMA diagram.
Baseline imbalance	Unclear risk	Even though most characteristics were similar among groups, a higher percentage of children with high educational-level parents were found in the control group (26%) compared to the intervention group (18%). Study authors report the comparison between the intervention and control groups at follow-up adjusted for respective baseline outcome values.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "The preschool unit was used as a random effect in order to adjust for variability between the preschools."
Contamination	Unclear risk	No evidence to make assessment.
Other bias	Unclear risk	Study authors stated that "Finally, the sample size might not have been sufficiently large to detect significant results. The power calculations were conducted based on means and standard deviations from the DAGIS cross-sectional survey. Some dissimilarities exist between these 2 studies such as the number of preschools and municipalities and the proportion of low parental education level families participating, which might have led to an underpowered study." There is insufficient information to assess whether an important risk of bias exists. One study author is reported to be a board member of a relevant commercial organisation.

Reyes-Morales 2016

Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: public</p> <p>Country (region): Mexico (Mexico City)</p> <p>Country income classification: upper-middle</p>

Reyes-Morales 2016 (Continued)

Low-SES sample: unclear

Population description: "in the Mexican Social Security Institute (IMSS), which is the largest public health institution in Mexico, the prevalence of overweight has increased dramatically in recent years, even among children; in 2012, 38.1% of overweight in insured school children has been reported. In 2009, approximately 30,000 children were enrolled in 142 child-care centres of direct provision of IMSS (ECEC centres run by the IMSS owned and attended by institutional staff). Children of IMSS cardholder working mothers remain under the care of educators and ECEC officers during the working hours of their mothers, receive their food at the ECEC centre and carry out activities in accordance with institutional programmes."

Inclusion criteria: ECEC centres that were selected had registered at least 40 children between the ages of 2 and 4 years and the respective directors agreed to participate in the study. All children of 2 and 3 years of age, regardless of their nutritional status, and attending the selected ECEC centres were deemed eligible. Children whose participation was accepted by their parents by way of written informed consent were included.

Exclusion criteria: children with chronic conditions that interfere with their growth and which would prevent performing physical activity and consequently limit anthropometric measurements, or children with special food requirements, were excluded.

Number of services randomised: 16 (8 intervention, 8 control)

Number of children randomised: 674 (336 intervention, 338 control)

Characteristics

Children

Age:

Intervention: 32.9 months (SD 6.1)

Control: 33.1 months (SD 6.1)

Gender (% female):

Intervention: 51.2%

Control: 48.8%

Ethnicity: not reported

Parents

Age (years):

Intervention: 32.6 (SD 5.6)

Control: 32.5 (SD 6.1)

Gender (% female): 100%

Ethnicity: not reported

Parent/family SES:

mother employment

Intervention: full-time (≥ 35 h/week): 73.7%; part-time: 8.6%; full-time rotary working day: 8.6%; full-time double working day: 5.4%; non-specified: 4.8%

Control: full-time (≥ 35 h/week): 73.7%; part-time: 10.7%; full-time rotary working day: 7.7%; full-time double working day: 4.7%; non-specified: 3.3%

Home monthly income (MXN)

Intervention: < MXN 5,000: 15.5%; MXN 5,000–MXN 15,000: 43.8%; MXN 15,001–MXN 25,000: 14.3%; > MXN 25,000: 5.4%; non-specified: 21.1%

Control: < MXN 5,000: 18.9%; MXN 5,000–MXN 15,000: 38.2%; MXN 15,001–MXN 25,000: 14.2%; > MXN 25,000: 6.2%; non-specified: 22.5%

Reyes-Morales 2016 (Continued)

Method of recruitment: not reported

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 months

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: ECEC officials, with support from educators, conducted 12 interactive educational sessions (1/week) with game dynamics for key eating behaviours and physical activity.

Ethos and environment

Children

Exposure: children were introduced to a variety of healthy snacks and natural water and offered options of different foods and beverages. Children were also presented with purpose-built games to encourage physical activity.

ECEC staff

Training: a 3-d researcher-led workshop was held (24 h in total) for the benefit of educators and ECEC officers, with the aim of facilitating the knowledge and skills required for the delivery of educational sessions for children and the promotion of their role in daily care.

Service

Resources: the material and equipment for each ECEC centre to perform the activities were provided.

Partnerships

Families

Workshops: educators in ECEC centres, in collaboration with the ECEC officers and the research group, conducted an afternoon workshop every 2 months throughout the implementation period, with dynamics in which they communicated key messages to promote behaviour changes in accordance with whatever was touched on in the sessions with the children.

Resources: during the workshop, parents developed posters with the monthly target of changes, included in meetings with the children as well as card games and short messages that were permanently available to the parents throughout the study.

External provider

Delivery: ECEC officials delivered the educational and training sessions.

Intensity of intervention: 3 d (24 h) x teacher training; 12 x 1 h/week education sessions for children; 1 parent workshop every 2 months

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, written

Reyes-Morales 2016 (Continued)

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Sugary water intake, plain water intake, fruit water intake, yogurt intake, fritters intake, hamburgers intake, hot dogs intake, processed juice intake, savoury milk intake, French fries intake, pizza intake, soft drink intake

Number of participants analysed:

Intervention baseline: 336

Intervention follow-up: 366

Control baseline: 338

Control follow-up: 287

Data collection measure:

Frequency of food consumption (144 items), modified from the individual questionnaire of children aged 0-9 years of the National Health and Nutrition Survey

Data collector: parent

Validity of measures used: not reported

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: Consejo Nacional de Ciencia y Tecnología, No. S0008-114027 (National Council for Science and Technology)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Each pair was randomised using a computerised procedure in order to assign a ECEC centre to intervention and non-intervention groups.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	Child-care staff and parents were not blinded to study allocation, and the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake via questionnaire. Parents were not blinded to study allocation and the outcome measurement is likely to be influenced by lack of blinding.

Reyes-Morales 2016 (Continued)

Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "It can be observed that there are differences in the number of children in each group stage because, throughout the study, there were admissions of children from other rooms that met two years of age and departures of others who completed 4 years old and who changed room or left the childcare center. Despite this replacement, the study sample was similar in number during the three stages." Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	High risk	There are differences in the number of children participating in each of the 3 time points throughout the study, with numbers increasing among the intervention group between baseline and 6 months, and numbers increasing in the control group between 6 months and 12 months. Study authors state that "It can be observed that there are differences in the number of children in each group stage because, throughout the study, there were admissions of children from other rooms that met two years of age and departures of others who completed 4 years old and who changed room or left the childcare center."
Baseline imbalance	Low risk	No clear differences or imbalances between clusters noted
Loss of clusters	Unclear risk	Not sufficiently reported
Incorrect analysis	High risk	There was no accounting for clustering of children within centres.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Roberts-Gray 2018
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 22 weeks (varies with outcomes) Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based Operation: not reported Country (region): USA (Texas) Country income classification: high Low-SES sample: no Population description: metro areas Inclusion criteria: ECEC centres that required parents to supply bag lunches Exclusion criteria: not reported Number of services randomised: 30 (15 intervention, 15 control)

Roberts-Gray 2018 (Continued)

Number of children randomised: 633 (351 intervention, 282 control)

Characteristics

Children

Age: 3.51 years (SD 0.69)

Gender (% female): 48.8%

Ethnicity: white: 65.6%; Hispanic: 19.0%; other: 15.4%

Parents

Age (years): 36.44 (SD 5.48)

Gender (% female): 90.1%

Ethnicity: white: 71.5%; Hispanic: 18.0%; other: 10.5%

Parent/family SES:

Annual family income: < USD 19,999: 3.5%; USD 20,000-USD 39,999: 7.6%; USD 40,000-USD 59,999: 6%; USD 60,000-USD 79,999: 10%; USD 80,000-USD 99,999: 15.7%; > USD 100,000: 57.1%

highest level of education: some high school: 1.6%; high school diploma/GED: 3%; some college: 13%; associate or Bachelors: 49.4%; Masters or Doctorate: 33%

Method of recruitment: ECEC centres that required parents to supply bag lunches were recruited during 2010 and 2011 via telephone survey and snowball referral methods.

Missing data/dropout: all 30 of the ECEC centres were retained in the study through the 28-week follow-up

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Lunch is in the bag (LunchBag)

Number of conditions: 1 intervention, 1 control

Intervention duration: 5-week intervention, + one-week booster (23 weeks later)

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: teachers deliver activities to children during class including a project, a food-related book to read at circle time, favourite food show-and-tell at 1 or 2 snack times, and daily using a "Lunch Colors" placemat to unpack the lunch bag and assess contents based on the My Plate groups.

Ethos and environment

Children

Incentive: children received a 'Gold Medal Lunch' certificate to take home when their lunch bag contained food from all 5 of the My Plate groups.

ECEC staff

Training: the programme developers provided training to the teachers immediately prior to the intervention launch.

Resources: classroom kit, which contains lesson plans and resources for teacher-led activities to encourage and support the child's learning about the 5 MyPlate food groups. Notes provided for the

Roberts-Gray 2018 (Continued)

teacher to send to the parents describing the plan for the week and requesting needed items. Newsletters and other materials provided to support the teachers.

Service

Resources: centre-level kit includes newsletters (for distribution to parents), parent-child activity stations (for centre director to install on-site), calendar with intervention sequence within.

Partnerships

Families

Resources: centres provided parents with newsletters, which present menu ideas, portion size information, goal setting and other home practice assignments, as well as suggestions for home-based parent-child fun-focused nutrition learning activities.

Intensity of intervention: implementation was estimated to demand approximately 3.25 h for the centre director and 3.5 h for the classroom teacher each week of intervention. Estimated engaged time when the intervention is implemented as designed is 16.5 h for the child accumulated at the rate of 2.75 h/week and 9 h for the parent accumulated at 1.5 h/week

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, written

Theoretical basis: Social Cognitive Theory, the Theory of Reasoned Action, and an ecological approach

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, fruit intake, wholegrains intake, refined grains intake, meats/beans/eggs/nuts intake, dairy intake, chips intake, sweets intake

Number of participants analysed:

Intervention baseline: 325

Intervention follow-up: 325

Control baseline: 253

Control follow-up: 253

Data collection measure: observation

Data collector: researcher

Validity of measures used: validated

Outcomes relating to child physical measures:

BMI percentile

Number of participants analysed:

Intervention baseline: 325

Intervention follow-up: 325

Control baseline: 253

Control follow-up: 253

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Roberts-Gray 2018 (Continued)

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: funding for this study was made possible by the National Cancer Institute (National Cancer Institute/NIH Grant R01CA149643, Clinical Trial Number NCT01292434) and the Michael and Susan Dell Foundation through the Michael and Susan Dell Center for Healthy Living.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Centres were randomised to the intervention or to a wait-list control condition. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	No blinding of participants and personnel to study allocation, and it is unclear whether lack of blinding would affect the outcome. For example, teachers could have encouraged their students to eat more of certain foods from their lunches on the days of observation, though this is unknown.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Blinding not reported, however direct observation of the contents of the children's parent-provided bagged lunches was conducted by trained observers using a structured food record. The outcome measurement is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by the trained data collectors using standard protocols and the outcome measurements were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Study authors stated that "Nearly all (91%) [parent-child dyads] were retained in the study through the 28-week follow-up." "Numbers of dyads with data at one or more of the lunch observations were 325 or 93% of those in the intervention condition and 253 or 90% of those in the control condition. Numbers of parents who answered the questionnaires at one or more of the measurement periods were 327 or 93% of those in the intervention and 250 or 89% of those in the control condition." Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Study authors stated that "Nearly all (91%) [parent-child dyads] were retained in the study through the 28-week follow-up." Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Low risk	The reported outcomes aligned with those outlined in the trial registration.

Roberts-Gray 2018 (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	The intervention condition had relatively larger proportion of Hispanic children and parents, fewer parents older than 34, fewer parents with overweight or obesity, more parents with college degree, fewer single parents, and higher annual family income. Statistical analyses of the outcomes data included adjustment for these demographic differences, with education preferred over income as a covariate because it had fewer missing values.
Loss of clusters	Low risk	No loss of clusters
Incorrect analysis	Low risk	Study authors stated that "Three-level regression models were constructed to allow random effects at the centre level, as well as at the family level, within and across time periods."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	No conflict of interest statement was reported

Seward 2018
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: service</p>
Participants	<p>Service type: centre-based (long day care)</p> <p>Operation: not reported</p> <p>Country (region): Australia (New South Wales)</p> <p>Country income classification: high</p> <p>Low-SES sample: no</p> <p>Population description: not reported</p> <p>Inclusion criteria: centres were eligible to participate in the trial if they had an onsite cook who prepared and provided at least 1 main meal and 2 mid-meals to children attending the centre; were open ≥ 8 h each day; and the individual centre played a role in planning their own menu.</p> <p>Exclusion criteria: centres that did not prepare meals onsite or those catering exclusively for children requiring specialist care, mobile preschools, and family day care centres were excluded.</p> <p>Number of services randomised: 54 (26 intervention, 28 control)</p> <p>Number of children randomised: 395 (220 intervention, 175 control)</p> <p>Characteristics</p> <p>Children</p> <p>Age:</p>

Seward 2018 (Continued)

Intervention: 3.5 years (SD 1.0)

Control: 3.6 years (SD: 1.0)

Gender (% female):

Intervention: 47.7%

Control: 47.6%

Ethnicity:

Children of Aboriginal or Torres Strait Islander background enrolled in service

Intervention: 66.7%

Control: 61.5%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

ECEC staff (service cook)

Age (years):

Intervention: 43.0 (SD 10.2)

Control: 45.2 (SD 11.7)

Gender (% female):

Intervention: 100%

Control: 92.3%

Ethnicity: not reported

Service/ECEC staff SES: not reported

Method of recruitment: mailed recruitment with follow-up telephone invitation

Missing data/dropout: of the 54 services in the study, 9 services (intervention, n = 1; control, n = 8) withdrew consent prior to baseline data collection and without knowledge of group allocation. Only 1 service did not complete follow-up data collection.

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

ECEC staff

Seward 2018 (Continued)

Training: 1 d face-to-face menu planning workshop provided to service managers and cooks to improve staff knowledge and skills in the application of nutrition guidelines to child-care food service. The workshop incorporated both didactic and interactive components, including small group discussions, case studies, review of existing menu items, facilitator feedback, and opportunities to practise new skills.

Service

Resources: services received a resource pack to support the implementation of nutrition guidelines, which includes the Caring for Children resource, menu planning checklists, recipe ideas and budgeting fact sheets. 2 x newsletters were also distributed.

Support: services were allocated an implementation support officer to provide expert advice and assistance to facilitate guideline implementation. Each intervention service received 2 face-to-face contacts, following the menu planning workshop. Support contacts were provided to service managers and cooks.

Audit and feedback: service menus were audited by a dietitian and feedback was provided at 2 time points (baseline and mid-intervention). Intervention service cooks and service managers received written (email) and verbal (service visit) feedback following each menu assessment via their implementation support officer.

Policy: the implementation support officer, the service manager and cook signed a memorandum of understanding outlining each party's responsibilities in working to improve food service. Service managers were asked to communicate support and endorsement of adhering to nutrition guidelines to other staff and update the service nutrition policy accordingly.

Partnerships
Healthcare

Delivery: experienced implementation support staff and dietitian facilitated staff training and policy support.

Intensity of intervention: 1 x 6-h training session; 1 x resource pack; 2 x newsletters; 2 x rounds of audit and feedback; 2 x face-to-face visits; 1 x written commitment for supervisors and cooks to implement the intervention.

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: Theoretical Domains Framework

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Vegetable intake, fruit intake, breads and cereals intake, meat, dairy intake, discretionary food intake, diet quality (total, vegetable intake, fruit intake, breads and cereals intake, meat, dairy intake, discretionary food intake, water intake, variety intake, healthy fats intake)

Number of participants analysed:

Intervention baseline: 15-220

Intervention follow-up: 13-259

Control baseline: 13-175

Control follow-up: 12-216

Data collection measure: plate waste and educator-reported short-food survey

Data collector: researchers and educator

Validity of measures used: not reported

Seward 2018 (Continued)

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences:

Negative feedbacks, % of meal waste

Number of participants analysed:

Intervention baseline: 22 services

Intervention follow-up: 22 services

Control baseline: 16 services

Control follow-up: 16 services

Data collection measure: cooks' pen-and-paper questionnaire

Data collector: service cook

Validity of measures used: not reported

Notes

Funding source: priority Research Centre for Health Behaviour and received infrastructure funding from Hunter New England Population Health and the University of Newcastle.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation schedule for the main trial was prepared a priori by an independent statistician. Centres were randomised to the intervention or control group via block randomisation (block size ranged between 2 and 6), using a central concealed random allocation process. Of these, 25 centres were approached in random order using a random number list generated in Microsoft Excel and invited to participate in the nested study.
Allocation concealment (selection bias)	Low risk	Allocation was conducted by an independent statistician after recruitment.
Blinding of participants and personnel (performance bias) Diet outcomes	High risk	The study was conducted as an open trial as it was not possible to blind the ECEC centre staff receiving the intervention. The outcome is likely to be influenced by the lack of blinding.
Blinding of participants and personnel (performance bias) Adverse consequences	Unclear risk	The study was conducted as an open trial as it was not possible to blind the ECEC centre staff receiving the intervention. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Children's dietary intake (outcomes which were included in meta-analysis) was assessed via questionnaire by centre educators who were not blinded to group allocation. Study authors state that, "While educators were not specifically targeted by the intervention, this could have resulted in detection bias

Seward 2018 (Continued)

		where centres were more likely to report favorable outcomes due to receipt of the intervention."
Blinding of outcome assessment (detection bias) Adverse consequences	Unclear risk	The study was conducted as an open trial as it was not possible to blind the ECEC centre staff receiving the intervention. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "there was a significant amount of missing data for the questionnaire with approximately 21% of children at baseline or follow-up, missing at least one item on the record. However, no significant differences in child age or gender were found among children with and without missing data and multiple imputation and intention to treat analysis did not result in any changes to statistical significance of trial outcomes." Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Cost	Low risk	Data were available for 38 of the 45 (84%) participating services.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	Unclear risk	Baseline data collection occurred after randomisation of centres, however it is unclear whether individual recruitment occurred before or after randomisation.
Baseline imbalance	Unclear risk	There were no differences in age or sex between groups, but these are the only 2 individual-level variables measured.
Loss of clusters	High risk	One intervention cluster lost to follow-up, and 2 intervention clusters and 1-2 control clusters did not provide questionnaire data at baseline and/or follow-up
Incorrect analysis	Low risk	Study authors stated that "Group differences for all outcome data were assessed through a group by time interaction using generalized linear mixed models, adjusting for clustering within centres."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Study authors stated that "Additionally, the self-reported dietary measure required childcare educators to recall child diet over the past month and as such is subject to recall bias." There is insufficient information to assess whether an important risk of bias exists.

Stookey 2017
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 1 year Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based

Stookey 2017 (Continued)

Operation: not reported

Country (region): USA (San Francisco)

Country income classification: high

Low-SES sample: yes

Population description: ECEC centres that primarily serve low-income children in San Francisco and do not have federal, state or school district funding.

Inclusion criteria: all ECEC centres that participated in Child Care Health Program (CCHP) nutrition screenings in 2011–2012 were eligible.

Exclusion criteria: ECEC centres that were closed in Autumn 2012 or declined Child Care Health Program (CCHP) services for 2012–2013 before the randomisation were ineligible for the Healthy Apple Program (HAP) pilot. Child-care centres with funding from Head Start, the San Francisco Unified School District, or Community College District were ineligible to receive CCHP screenings, and excluded from the HAP pilot. ECEC centres that declined one or both BMI screenings in any given year were excluded from evaluation analyses for that year, because of missing data regarding the primary outcome of interest, annual change in BMI between the Autumn and Spring screenings. Children who declined 1 or both screenings or were absent on the date(s) of screening in any given year were excluded from evaluation analyses for that year.

Number of services randomised: 43 (19 intervention, 24 control)

Number of children randomised: 902 (522 intervention, 380 control)

Characteristics

Children

Age:

Intervention: 2 years: 5%; 3 years: 40%; 4 years: 54%; 5 years: 1%
 Control: 2 years: 14%; 3 years: 40%; 4 years: 45%; 5 years: 0%

Gender (% female): not reported

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: the programme was offered to those centres that completed the Child Care Health Program. A USD 25 gift card was offered to 1 representative/child-care centre for participation in the Healthy Apple Program pilot.

Missing data/dropout: 6/43 centres had missing data at follow-up (2 intervention, 4 control).

Reasons for dropout: 3 ineligible for CCHP BMI screenings (1 intervention, 2 control) and 3 declined 1 or both CCHP BMI screenings for the year (1 intervention, 2 control)

Characteristics of dropouts: not reported

 Interventions

Programme name: Healthy Apple Program (HAP)

Number of conditions: 1 intervention, 1 control

Stookey 2017 (Continued)

Intervention duration: 6 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: children received nutrition education (circle time for children).

Ethos and environment

ECEC staff

Training: public health nurses or health workers introduced the HAP resources and process, in-person, to child-care centre staff and spent up to 16 h per ECEC centre, providing one-on-one support to each ECEC provider about the programme.

Workshops: 2 x optional, tailored workshops (1 on nutrition, 1 on physical activity) to address participant needs

Service

Resources: Healthy Apple Program (HAP) resources included an invitation packet, which included information about the HAP, a self-assessment for ECEC providers, and information about the gift card incentive for completing the self-assessment. The HAP resources also included a goal-setting worksheet, hard copy Tip Sheets and online technical assistance materials.

Incentive: a USD 25 gift card was offered to 1 representative/ECEC centre for participation in the study.

Partnerships

Healthcare

Health checks: bi-annual BMI screenings offered by public health nurses or health workers at ECEC centres.

Community

Co-ordination: citywide co-ordination of quality improvement processes for ECEC providers.

Intensity of intervention: up to 16 h staff training; 2 x optional workshops

Intervention delivered by: ECEC staff, healthcare staff

Modality: face-to-face, online, written

Theoretical basis: not reported

Description of control: delayed intervention control, plus included bi-annual BMI screening; health education; dental and nutrition screening

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

Annual change in BMI percentile, annual change in BMI z-score

Number of participants analysed: unclear

Data collection measure: objectively measured (CDC)

Data collector: health workers

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Stokey 2017 (Continued)

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost:

Total operation cost, time

Number of participants analysed: not reported

Data collection measure: not reported

Data collector: not reported

Validity of measures used: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: CDC Community Transformation Grant. Funding for the HAP pilot evaluation was provided by the Feeling Good Project, funded by USDA SNAP-Ed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	For each health worker, eligible ECEC centres were listed in alphabetical order. A list of the same length, of random, unique, unsorted numbers was generated using randomizer.org. For each health worker, ECEC centres had an equal chance of being assigned to 1 of 2 intervention groups.
Allocation concealment (selection bias)	Low risk	Baseline data collected before cluster randomisation
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	The programme health workers and ECEC providers were not blinded to treatment allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Cost	Unclear risk	The programme health workers and ECEC providers were not blinded to treatment allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	No blinding of outcome assessors, however children's height and weight were measured using a standardised protocol and calibrated instruments, and are unlikely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Cost	Unclear risk	No blinding of outcome assessors. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	The number of ECEC centres and children included in the HAP evaluation analysis varied each year, depending on the availability of BMI change data (primary outcome). Study authors stated that "Due to lack of unique child identifiers across child care centres, the analysis did not track the BMI changes of the same children across years." As a result, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias)	Low risk	The outcome was collected as an average cost per service.

Stookey 2017 (Continued)

Cost

Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Children's income, race, ethnicity, and social determinants of health were unknown and not controlled for in the research design or analysis.
Loss of clusters	High risk	9 of the 19 centres in the intervention group did not receive the allocated intervention. 7 of the 24 centres in the control group did not receive the allocated intervention. Loss of 6 clusters in Year 1 and 9 clusters in Year 2
Incorrect analysis	Low risk	Study authors stated that "The Child Care Health Program + HAP vs. Child Care Health Program + HAP Delayed groups were compared in intention-to-treat analyses, which accounted for clustered data. Year-specific hierarchical linear models used child-level data to test for a main effect of time between the Autumn to Spring screenings."
Contamination	Unclear risk	No evidence to make assessment
Other bias	High risk	Study authors stated that "Many potentially confounding and/or effect modifying factors, including local, statewide, and National initiatives, were operating in the background during the HAP pilot evaluation period." (Detailed explanation in study.) Authors also stated that "Randomization may not have eliminated bias related to treatment assignment, due to the relatively small number of child care centres and uneven demographic distribution across child care centres. Randomisation would not have controlled for time-varying factors that happened to correlate with HAP exposure, and independently predict changes in child BMI."

Toussaint 2021
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 9 months Unit of allocation: preschool Unit of analysis: child
Participants	Service type: centre-based (preschools) Operation: not reported Country (region): The Netherlands (Amsterdam Nieuw-West) Country income classification: high Low-SES sample: yes Population description: the sample comprised preschools of the largest ECEC organisation in the deprived area Amsterdam Nieuw-West, the Netherlands. Nieuw-West is characterised by inhabitants with a migration background and low SES.

Toussaint 2021 (Continued)

Inclusion criteria: toddlers and their parents were included if the toddler was 2.5-3.5 years old.

Exclusion criteria: ECEC teachers who worked at multiple preschool locations were excluded.

Number of services randomised: 41 (21 intervention, 20 control)

Number of children randomised: 249 (137 intervention, 112 control)

Characteristics
Children

Age: 3.0 years (SD 0.2)

Gender (% female): 49%

Ethnicity: Dutch: 19%; Moroccan: 35%; Turkish: 18%; other Western: 9%; other non-Western: 20%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: lower education: 20%; intermediate education: 43%; higher education: 37%

ECEC staff (teachers)

Age (years): 42 (SD 9.0)

Gender (% female): 100%

Ethnicity: Dutch: 38%; Moroccan: 33%; Turkish: 7%; other Western: 11%; other non-Western: 11%

Service/ECEC staff SES: lower education: 0%; intermediate education: 73%; higher education: 28%

Method of recruitment: all ECEC teachers (n = 162) at the 41 included preschools were approached via information meetings. Parents were individually approached (face-to-face) at preschools by the research staff in close co-operation with the centre.

Missing data/dropout: 7 teachers dropped out of the study: 6 teachers in the control group and 1 teacher in the intervention.

Reasons for dropout: teachers in the control group indicated that the measurements were too time consuming/invasive, 2 teachers in the control group were no longer working at the participating child-care organisation, and 1 teacher in both the intervention and control group withdrew their consent to participate in the study.

Characteristics of dropouts: not reported

 Interventions

Programme name: a Healthy Start and PLAYgrounds for TODdlers (2 separate programmes applied in succession)

Number of conditions: 1 intervention, 1 control

Intervention duration: 9 months

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

ECEC staff

Toussaint 2021 (Continued)

Education: the first programme was A Healthy Start: 3 x 2-h face-to-face meetings organised for 8 groups of ECEC teachers (led by 1 of the coaches and a member of the research staff) including theory and practical assignments from the basic national 'A Healthy Start' module about a healthy ECEC environment and in-depth national A Healthy Start modules about nutrition, physical activity and body weight. First meeting focused on self-reflection; second meeting focused on interaction with children; and the third meeting focused on interaction with parents. The second programme was PLAYgrounds for TODdlers (PLAYTOD): 2 x 2-h face-to-face training sessions organised for 4 groups of ECEC teachers. Each meeting was led by 2 certified PLAYTOD trainers. The first training session included theory about the importance of (outdoor) physical activity and a basic inviting structure of the playground (with the use of different activity zones) for variation in fundamental movement skills was demonstrated and practiced.

Coaching: after 2 weeks of the second program, ECEC teachers received a coaching on-the-job session. In the second training session, the activating role of the teachers (prompts) on the playground was practiced and reviewed in more detail.

Incentive: ECEC teachers who attended at least 2 meetings of A Healthy Start and 1 training session of PLAYTOD received certificates.

Partnerships
External provider

Delivery: coaches and PLAYTOD trainers delivered the meetings.

Intensity of intervention: 3 x 2 A Healthy Start meetings; 2 x 2 h training sessions; 1 x on-the-job session

Intervention delivered by: research team, ECEC staff

Modality: face-to-face

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI z-score, BMI, fat-free index, fat-free mass index

Number of participants analysed:

Intervention baseline: 64-101

Intervention follow-up: 64-101

Control baseline: 62-93

Control follow-up: 62-93

Data collection measure: objectively measured (WHO)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Toussaint 2021 (Continued)

Outcome relating to adverse consequences: not reported

Notes

Funding source: the study was funded by 'Nationaal Regieorgaan Praktijkgericht Onderzoek SIA', grant no. 2015-02-07P (www.regieorgaan-sia.nl) (PJMw).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study authors stated that "The randomisation was performed by an independent researcher with the use of computer-generated lists."
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	We assumed that due to the nature of the intervention, ECEC service staff delivering the intervention were not blind to the study allocation. The study team was co-ordinated by 3 unblinded researchers and 1 blinded researcher. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were measured by trained research staff and students, though blinding was not reported. The study team was co-ordinated by 3 unblinded researchers and 1 blinded researcher, however the outcome is not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	At baseline, 137 students were allocated to intervention and 112 students to control. However, only 101 students (74%) were analysed from the intervention group and 93 students (83%) from the control group. Not all missing data accounted for, and it is unclear if the reasons for missing data are similar between groups.
Selective reporting (reporting bias)	High risk	Study authors states in the protocol that "Parents will be asked to fill in the 3-day food record for their toddler on 2 week days and 1 weekend day... The intake of foods will be converted (by coding and converting household measures into grams) into energy and nutrient intake using the Dutch Food Composition Database 2016 and a database with portion sizes." These findings were not reported because the authors stated that "For children, the recorded intake of foods and physical activities were not included in further analysis, as most of the parents did not fill in the records (or, at least not adequately)."
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Models were adjusted for sex, age, and ethnicity, however, it is unclear whether additional baseline differences between children in the intervention and control exist as statistical comparisons were not reported between groups.
Loss of clusters	Unclear risk	2 clusters were lost from the intervention group due to discontinued intervention. However, this was a small proportion of clusters and ITT analyses were used.
Incorrect analysis	Low risk	Study authors stated that "preschool location was added as random intercept to take into account the clustered data structure."
Contamination	Low risk	Protocol states that "In total, 42 preschools of child care organization Impuls were available for allocation. One location was excluded because of practical reasons and 4 preschools were combined in the allocation as they shared a

Toussaint 2021 (Continued)

building or playground." Additionally, "ECEC teachers who worked at multiple preschool locations were excluded."

Other bias	Unclear risk	No conflict of interest statement was reported.
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Vaughn 2021
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 8-10 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: not reported</p> <p>Country (region): USA (North Carolina)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: Central North Carolina, including a mix of rural and suburban counties</p> <p>Inclusion criteria: centres having a 3–4-year-old classroom, having a 3–5-star quality rating or being exempt from rating, providing lunch, not exclusively serving children with special needs</p> <p>Exclusion criteria: at least 7 parents had to sign consent for the centre to remain eligible.</p> <p>Number of services randomised: 92 (48 intervention, 44 control)</p> <p>Number of children randomised: 853 (446 intervention, 407 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 47.93 months (SD 6.96)</p> <p><i>Gender (% female):</i> 49.20%</p> <p><i>Ethnicity:</i> white: 46.4%; black or African American: 36.3%; other: 17.4%; Latino ethnicity: 8.6%</p> <p>Parents</p> <p><i>Age (years):</i> 33.46 (SD 7.82)</p> <p><i>Gender (% female):</i> 85.30%</p> <p><i>Ethnicity:</i> white: 53.3%; black or African American: 36.9%; other: 9.8% Latino ethnicity: 6.2%</p> <p><i>Parent/family SES:</i> family income: under USD 30,000: 28.1%; USD 30,000-USD 59,999: 18.3%; USD 60,000: 37.9%; Prefer not to answer: 15.7%</p> <p>Method of recruitment: community organisations shared information about the study with local centre directors and endorsed participation. Research staff followed-up by phone to gauge initial interest and eligibility, and then in person to verify interest and obtain a Memorandum of Understanding. In-</p>

Vaughn 2021 (Continued)

formation packets were shared with eligible classroom teachers (i.e. teachers of 3–4 year-olds, able to write/speak English). At least 1 teacher had to sign consent for the centre to remain eligible. Research staff worked with participating teachers to distribute similar packets to eligible parents (i.e. parent of a 3–4 year old, able to write/speak English) and conduct in-person visits to answer questions and collect written consent. At least 7 parents had to sign consent for the centre to remain eligible.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Healthy Me, Healthy We

Number of conditions: 1 intervention, 1 control

Intervention duration: 8 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: as part of the kick-off event, the classroom activity involved the Healthy Me, Healthy We theme song and dance. Plus, 4 x 6-week units where teachers used activity cue cards to lead 8 classroom activities to build children's knowledge and skills.

Ethos and environment

Children

Resources: a welcome letter from Dr. Fitbodi (Healthy Me, Healthy We mascot) was added in wave 2 to help teachers introduce the campaign.

ECEC staff

Training: directors and teachers received 2 x training sessions (5 h total) to support centres' ability to deliver the campaign.

Support: 3 x informal check-ins (< 1 h) by the study interventionist to deliver programme materials, offer technical assistance and inquire about event planning

Resources: in wave 2, teachers received an outreach toolkit with resources to boost parent engagement (e.g. social media posts about classroom activities).

Service

Environment: hanging the Healthy Me, Healthy We centre banner and classroom posters (1 per classroom).

Event: the campaign initiated with a kick-off event and concluded with a celebration event (promoting the event to parents, displaying a certificate of completion, having teachers wear Healthy Me, Healthy We buttons, posting pictures of activities, having children perform the Healthy Me, Healthy We song, and awarding children Healthy Me, Healthy We ribbons).

Partnerships

Families

Invitation: sending invitations to parents, signing the Fit Family Promise (at school and at home)

Resources: teachers distributed Our Turn cards to prompt parents to do at-home activities. Parents received a Family Guide magazine at the start of each unit that introduced unit goals, presented benefits of healthier behaviours, encouraged practices to support healthier behaviours, and offered at-home activities. Parents received an activity tracker to log at-home activities.

Vaughn 2021 (Continued)

Intensity of intervention: 4 x 6-week units for children; 2 x teacher training sessions (3 h and 2 h); 3 x check-ins (< 60 min); 1 conclusion event

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, online, written

Theoretical basis: development was guided by Social Marketing Approach and informed by the Social Ecological Framework, Exchange Theory, and Social Cognitive Theory

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake:

Diet quality (total)

Number of participants analysed:

Intervention baseline: 446

Intervention follow-up: 446

Control baseline: 407

Control follow-up: 407

Data collection measure: combination of observation (using the Diet Observation in Child Care protocol) and parent-completed food diary

Data collector: researchers and parent

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, BMI z-score

Number of participants analysed:

Intervention baseline: 446

Intervention follow-up: 446

Control baseline: 407

Control follow-up: 407

Data collection measure: objectively measured (CDC)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: funded by the National Heart, Lung and Blood Institute [R01HL120969]. Support was also received from the Center for Disease Control and Prevention [U48DP005017] and National Institute of Diabetes and Digestive and Kidney Diseases [P30DK056350].

Vaughn 2021 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centres were stratified by county, and the study statistician created randomisation tables using a permuted block approach (with blocks of 2 and 4). The project manager used these tables to assign centres to the intervention or control arm.
Allocation concealment (selection bias)	Low risk	Randomisation occurred on a rolling basis after baseline measures were collected and sufficient data had been confirmed (i.e. at least 7 children per centre with usable diet and physical activity data).
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	Only the study statistician, project manager, and those delivering the intervention knew allocation assignments. Investigators and data collectors remained blind to study allocation. Teachers were not blind to the treatment, and it is unclear whether the outcome could be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	Only the study statistician, project manager, and those delivering the intervention knew allocation assignments. Investigators and data collectors remained blind to study allocation. The outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Unclear risk	Parents recorded children's dietary intake in food diaries, and intake at child care was assessed by research staff using the Diet Observation in Child Care protocol. Parent-reported outcome may be influenced by lack of blinding. Even though research staff were blinded to assignment, intervention posters were hung in the intervention classrooms and could have led to broken blinding for observers.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height, weight, and waist circumference were measured by research staff who were blinded to group assignment.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "Hypotheses were tested under the intent-to-treat (ITT) principle using Generalized Linear Mixed Models (GLMM)." However, information on missing data is not reported. Risk of attrition bias is unclear.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	Study authors stated that "Hypotheses were tested under the intent-to-treat (ITT) principle using Generalized Linear Mixed Models (GLMM)." However, information on missing data is not reported. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	Waist circumference mentioned in protocol and methods of study, but findings not reported
Recruitment bias	Low risk	Randomisation occurred on a rolling basis once baseline measures were collected and sufficient data had been confirmed (i.e. at least 7 children/centre with usable diet and physical activity data).
Baseline imbalance	Low risk	There were slight differences between arms in terms of children's Latino ethnicity ($P = 0.02$), family income ($P = 0.03$), and parents' marital status ($P = 0.04$). These variables were incorporated as covariates in fully adjusted models.
Loss of clusters	Unclear risk	Not sufficiently reported
Incorrect analysis	Low risk	Study authors stated that "Hypotheses were tested under the intent-to-treat (ITT) principle using Generalized Linear Mixed Models (GLMM) that accounted for the correlation induced by the clustering of children within the childcare

Vaughn 2021 (Continued)

centres. Models did not account for clustering of children within classrooms as it is common for children to move between classrooms; hence, this level of clustering was not tracked."

Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Vereecken 2009
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 6 months</p> <p>Unit of allocation: preschools</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (preschools)</p> <p>Operation: not reported</p> <p>Country (region): Belgium (Flanders)</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: not reported</p> <p>Inclusion criteria: not reported</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 16 (8 intervention, 8 control)</p> <p>Number of children randomised: 1432 (867 intervention, 565 control) at baseline</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i></p> <p>Intervention year of birth: < 2002: 41%; 2002: 28%; ≥ 2003: 31% Control year of birth: < 2002: 51%; 2002: 24%; ≥ 2003: 26%.</p> <p><i>Gender (% female):</i></p> <p>Intervention: 53% Control girls: 44%</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i></p> <p>Intervention: 94%</p>

Vereecken 2009 (Continued)

Control: 95%

Ethnicity: not reported

Parent/family SES:

Mothers' education

Intervention: low (secondary school or less): 49%; medium (Bachelor): 34%; high (Bachelor with supplementary education or Masters): 16%

Control: low (secondary school or less): 49%; medium (Bachelor): 35%; high: (Bachelor with supplementary education or Masters): 16%

Fathers' education

Intervention: low (secondary school or less): 60%; medium (Bachelor): 22%; high (Bachelor with supplementary education or Masters): 18%

Control: low (secondary school or less): 57%; medium (Bachelor): 26%; high (Bachelor with supplementary education or Masters): 17%

Method of recruitment: schools were asked by mail if they would be willing to participate in an intervention study to promote healthy eating.

Missing data/dropout: 46% returned a completed questionnaire at follow-up

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Beastly Healthy at School

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 months

Intervention setting: ECEC and home

Intervention strategies:

Health curriculum

Children

Education: developmental education (e.g. explanation of concepts of food triangle)

Ethos and environment

Children

Exposure: guided and self-guided activities based on experiential education (e.g. tasting). Healthy foods made available to children

Support: role model, feedback and reinforcement by teachers

Resources: cooking equipment made available to children (for use under supervision)

ECEC staff

Training: 2 x full-day training sessions for principals and cafeteria staff

Resources: an educational package, including an educational map for the teachers, an educative story and educational material (e.g. life-size food education model based on the Flemish "Active Food Triangle") was developed. Food messages and newsletters directed at the school staff were provided. A digital learning environment was provided.

Support: group discussions with teachers; help on demand via email; examples of good practices.

Audit and feedback: feedback provided to schools.

Partnerships

Families

Vereecken 2009 (Continued)

Resources: parents were provided with food messages and newsletters, and work sheets and creations by children.

Activities/meetings: parent evenings and other school activities with parents

Intensity of intervention: 2 d staff training; support on demand was offered via email; child curriculum (frequency and duration not reported)

Intervention delivered by: research team, ECEC staff

Modality: face-to-face, online, written

Theoretical basis: The Intervention Mapping Protocol

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Water intake, fruit juice intake, sugared soft drinks intake, sugared milks intake, milk intake, fresh fruit intake, snacks intake, vegetable intake

Number of participants analysed:

Intervention baseline: 308-618

Intervention follow-up: 308-618

Control baseline: 168-445

Control follow-up: 168-445

Data collection measure: FFQ and teachers' audit

Data collector: parent and teacher

Validity of measures used: validated (FFQ) and not reported (teachers audit)

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: the development of the intervention was funded by the PWO (Project-related Scientific Research)-funding of University College Arteveldehogeschool. Funds for the evaluation were provided by the Provincial Government East-Flanders. Carine Vereecken is a postdoctoral researcher funded by the Research Foundation-Flanders (FWO-Flanders).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	8 control and 8 intervention schools were randomly selected and stratified on school authority, location, and size of the school. For 1 school in the intervention group, 3 departments at different locations participated. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Low risk	Recruitment materials indicated there was a 50% chance that schools be randomised to the control group.

Vereecken 2009 (Continued)

Blinding of participants and personnel (performance bias) Diet outcomes	High risk	We assumed that due to the nature of the intervention, ECEC service staff and study personnel delivering the intervention were not blind to the study allocation. The outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	High risk	Parents reported children's dietary intake, and data on available snacks and drinks were recorded by the teachers on a pre-defined list. Parents and teachers were not blinded to treatment allocation and the outcome measurement is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Study authors stated that "Of all children approached at baseline (n = 1432) and follow-up (1637), respectively 884 (62%) and 761 (46%) returned a completed questionnaire; of whom 570 could be matched. Only those completed by the same respondent at both measurement occasions were kept for analyses: 308 intervention children and 168 control children." Due to the magnitude of missing data, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Study authors state that "The control group contained considerably (borderline significantly) more boys and children from the youngest age group." Analyses of the FFQs were controlled for gender of the child and year of birth, however no other baseline data were reported (only gender, year of birth, education of mother and father, and who completed the FFQ were reported). There may be unmeasured differences between groups.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Unclear risk	Study authors stated that "Linear mixed models (SPSS 15.0) were used to investigate the effect of the condition on changes in consumption and food policy aspects." No further information is provided. There is not enough information to assess whether an important risk of bias exists.
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	No conflict of interest statement was reported.

Ward 2020a
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 9 months Unit of allocation: family child-care homes (i.e. family day care) Unit of analysis: child
Participants	Service type: family child-care homes Operation: not reported

Ward 2020a (Continued)

Country (region): USA (North Carolina)

Country income classification: high

Low-SES sample: yes

Population description: counties across central North Carolina; to help target family child-care homes in high-need areas, recruitment efforts focus primarily on counties with a higher-than-average prevalence of childhood overweight and obesity among children aged 2-4 years and below average median household income.

Inclusion criteria: eligible family child-care homes must have had at least 2 children currently enrolled who are between the ages of 18 months and 4 years (but not entering kindergarten before follow-up measures), serve at least 1 meal and 1 snack to children, and have been in business for 2 years (as a demonstration of business stability) with no plans to close in the coming year.

Exclusion criteria: not reported

Number of services randomised: 166 (83 intervention, 83 control)

Number of children randomised: 496 (242 intervention, 254 control)

Characteristics

Children

Age: 35.7 months (SD 11.4)

Gender (% female): 50.4%

Ethnicity: black or African American: 63.3%; white: 27.2%; other: 9.5%; Hispanic or Latino: 4.1%

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

ECEC staff (family child-care home provider)

Age (years): 49.3 (SD 9.1)

Gender (% female):

Ethnicity: black or African American: 74.1%; white: 18.1%; other: 7.8%; Hispanic or Latino: 4.8%

Service/ECEC staff SES: education

high school diploma or GED: 24.7%; Associate's degree or 60 h college credit: 49.4%; Bachelor's degree or greater: 25.3%

Method of recruitment: community partners shared information about the project with local family child-care homes. Then, study staff followed up with family child-care home providers via mail, email, and telephone to invite study participation. During telephone follow-ups, family child-care homes were screened for eligibility (i.e. enrolling at least 2 children aged 1.5–4 years, providing at least 1 meal and snack/day, being open year-round, and having been in business for 2 years with no plans to close in the coming year). Study staff then visited eligible family child-care home providers to explain study details and obtain written informed consent. Study staff worked through the family child-care home provider to share study information with parents (including project contact information for questions) and collect informed consent.

Ward 2020a (Continued)

Missing data/dropout: at postintervention 38% were lost to follow-up.

Reasons for dropout: children no longer being enrolled in the family child-care home, or family child-care home providers refusing to participate in measures.

Characteristics of dropouts: not reported

Interventions

Programme name: Keys to Healthy Family Child Care Homes

Number of conditions: 1 intervention, 1 control

Intervention duration: 9 months

Intervention setting: family child-care home

Intervention strategies:

Ethos and environment

ECEC staff

Education: module 1 focuses on the provider's own health behaviours and encourages comparison against current recommendations; module 2 focuses on comparing current practices of family child-care homes against recommendations and identifying areas of improvement; module 3 targets financial, record keeping for tax purposes, creating and enforcing policies and contracts, communicating with parents, professionalism, and marketing.

Workshops: 3 x 3-h face-to-face group workshops (1 on each module: Healthy You, Healthy Home, Healthy Business) delivered by health coaches.

Resources: 3 x set of educational materials and toolkit resources (per module). Resources include pedometers, re-useable water cups, child-sized divided plates, poly spots, diet and physical activity-related book.

Support: 12 x one-on-one coaching contacts (lasting approximately 30-45 min) via face-to-face and phone/email (4/module) employing motivational interviewing techniques. During each contact, the health behaviour coach works with the provider to review current goals, assess progress toward goals, problem-solve around any barriers that might be encountered, and revise action plans as needed. Participants are provided with tracking sheets and encouraged to self-monitor on a daily or weekly basis to help them stay on track.

Partnerships

Healthcare

Delivery: health coaches delivered staff workshops and provided support.

Intensity of intervention: 3 x workshops; 3 x home visits; 9 x phone calls

Intervention delivered by: research team, ECEC staff, healthcare staff

Modality: face-to-face, telephone, online, written

Theoretical basis: the Socio-ecologic Framework, Social Cognitive Theory and Self Determination Theory

Description of control: alternative intervention control (a business-focused intervention)

Outcomes

Outcomes relating to child dietary intake:

Diet quality (total, total fruit intake, whole fruit intake, total vegetables intake, greens and beans intake, whole grains intake, dairy intake, total protein intake, seafood and plant protein intake, fatty acids intake, sodium intake, empty calories intake)

Number of participants analysed:

Intervention baseline: 242

Ward 2020a (Continued)

Intervention follow-up: 149

Control baseline: 253

Control follow-up: 142

Data collection measure: diet observation in child-care protocol

Data collector: data collectors

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI, BMI percentile

Number of participants analysed:

Intervention baseline: 242

Intervention follow-up: 149

Control baseline: 253

Control follow-up: 142

Data collection measure: objectively measured (CDC)

Data collector: data collectors

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: National Heart, Lung, and Blood Institute (HL108390), the Centers for Disease Control and Prevention (U48-DP005017), and the National Institute of Diabetes and Digestive and Kidney Diseases (DK056350)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The study statistician used computerised block randomisation to assign family child-care homes into either the intervention or control arm (1:1) (SAS 9.3, Cary, NC).
Allocation concealment (selection bias)	Low risk	Baseline data collected before cluster randomisation
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	We assumed that due to the nature of the intervention, teachers were not blind to the study allocation. It is unclear whether the outcome could be influenced by lack of blinding.
Blinding of participants and personnel (performance bias)	Low risk	We assumed that due to the nature of the intervention, teachers were not blind to the study allocation. However, the outcome is not likely to be influenced by lack of blinding.

Ward 2020a (Continued)

Physical outcomes

Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Children's diet quality was estimated from observed intakes of food and beverages collected via the Diet Observation in Child Care protocol by data collectors who were blinded to arm assignment.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height, weight, and waist circumference were measured by data collectors who were blinded to arm assignment.
Incomplete outcome data (attrition bias) Diet outcomes	Low risk	Data were available for 149 (62%) children in the intervention group and 142 (56%) children in the control group. Most (84%) of the missing data are due to children no longer being enrolled in the service. Study authors stated that "To address missing child-level data, multiple imputation was used, models were re-run, and results were compared against the original. One hundred samples were imputed and analyzed in SAS (Proc MI) using available physical activity, HEI [healthy eating index], and covariate data. Comparison of baseline data from completers and non-completers suggests that data are missing at random." Therefore, risk of attrition bias was considered to be low.
Incomplete outcome data (attrition bias) Physical outcomes	Low risk	Data were available for 149 (62%) children in the intervention group and 142 (56%) children in the control group. Most (84%) of the missing data are due to children no longer being enrolled in the service. Study authors stated that "To address missing child-level data, multiple imputation was used, models were re-run, and results were compared against the original. One hundred samples were imputed and analyzed in SAS (Proc MI) using available physical activity, HEI [healthy eating index], and covariate data. Comparison of baseline data from completers and non-completers suggests that data are missing at random." Therefore, risk of attrition bias was considered to be low.
Selective reporting (reporting bias)	Unclear risk	Waist circumference mentioned in protocol and methods of study, but findings not reported
Recruitment bias	Unclear risk	Study authors stated that "Participants included a convenience sample of family child care home providers in central North Carolina and children aged 1.5-4 years enrolled in these family child care homes, recruited in five cohorts over 2 years." Although randomisation occurred after baseline data collection, it is unclear if additional children were recruited from the same cluster.
Baseline imbalance	Unclear risk	Baseline differences between groups were not reported. Models of child-level outcomes included child age, sex, and BMI as covariates.
Loss of clusters	Unclear risk	Loss of 3 intervention clusters (8 children) and 4 control clusters (11 children). Loss was a small percentage (< 5%) of the overall sample
Incorrect analysis	Low risk	Study authors stated that "Models of child-level outcomes accounted for clustering; included child age, sex, and BMI as covariates; and for primary outcomes (HEI [healthy eating index score], MVPA [moderate-to-vigorous physical activity/hour]) used p values < 0.025."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Witt 2012

Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 3 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: all classrooms offered half-day or full-day care. All classrooms participated in the child and adult care food program and provided meals and snacks to children.</p> <p>Country (region): USA (not reported)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: 15/17 of the classrooms were from the Boise School District's ECEC programme.</p> <p>Inclusion criteria: not reported</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 17 (10 intervention, 7 control)</p> <p>Number of children randomised: 263 (165 intervention, 98 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> the majority of children were 4 or 5 years old.</p> <p><i>Gender (% female):</i> 47%</p> <p><i>Ethnicity:</i> not reported</p> <p>Parents</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> not reported</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Parent/family SES:</i> not reported</p> <p>ECEC staff (lead teachers)</p> <p><i>Age (years):</i> not reported</p> <p><i>Gender (% female):</i> 94%</p> <p><i>Ethnicity:</i> not reported</p> <p><i>Service/ECEC staff SES:</i> not reported</p> <p>Method of recruitment: not reported</p> <p>Missing data/dropout: unclear</p>

Witt 2012 (Continued)

Reasons for dropout: either absent or unenrolled from the centre at follow-up assessments

Characteristics of dropouts: not reported

Interventions

Programme name: Color Me Healthy

Number of conditions: 1 intervention, 1 control

Intervention duration: 6 weeks

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: 12 circle-time lessons and 6 imaginary trips, using colour, music and exploration of the senses to teach children about healthy eating and physical activity. The majority of the Color Me Healthy circle-time lessons focus on fruits and vegetables of different colours.

Ethos and environment

Children

Exposure: several of the lessons provide opportunities for children to try (taste) fruits and vegetables. The imaginary trips allowed children to be physically active and role-play eating nutritious food.

ECEC staff

Training: lead teachers attended a training session that was held prior to programme implementation. The teachers learned about the curriculum and were instructed on how to teach each lesson and imaginary trip.

Materials: a “toolkit” that includes a teacher’s guide, 4 sets of picture cards, classroom posters, a music CD that contains 7 original songs, a hand stamp, and reproducible parent newsletters. Most of the kit materials emphasise fruits and vegetables of different colours.

Partnerships

Families

Resources: 6 interactive take-home activities for parents and children to complete. Parent newsletters.

Intensity of intervention: 2 circle-time lessons and 1 imaginary trip were taught to the children each week for 15-30 min; staff training (frequency and duration not reported)

Intervention delivered by: ECEC staff

Modality: face-to-face, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Fruit snack intake, pineapple intake, cantaloupe intake, strawberry intake, purple grapes intake, vegetable snack intake, carrot intake, cherry tomato intake, celery intake, broccoli intake, Ritz cracker intake, graham cracker intake

Number of participants analysed:

Intervention baseline: 70-83

Intervention follow-up: 70-83

Control baseline: 52-70

Control follow-up: 52-70

Witt 2012 (Continued)

Data collection measure: plate weight before and after

Data collector: not reported

Validity of measures used: not reported

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes **Funding source:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	17 preschool classrooms were randomly assigned to 1 of 2 groups. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	No clear blinding of participants and personnel to study allocation, however teachers were instructed to avoid commenting on the snack and avoid encouraging children to eat the snack during outcome assessment.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Blinding not reported, however children's consumption was measured by weighing the fruit and vegetable snacks before and after intake. The outcome measurement is not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Data for fruit snacks were available for 83 (50%) children in the intervention group and 70 (71%) children in the control group, while data for vegetable snacks were available for 70 (42%) children in the intervention group and 52 (53%) children in the control group. Although some reasons for loss provided, it is not known whether those reasons are exhaustive or equally distributed between treatment groups. Due to the magnitude of missing data and difference in the proportions of participants followed up between groups, the risk of bias was assessed as high.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.
Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Baseline differences between groups were not reported.
Loss of clusters	Unclear risk	Not reported

Witt 2012 (Continued)

Incorrect analysis	Low risk	Study authors stated that "The study design was a 3-level design: the first level was the repeated measures; the second level included child variables; and the third level included classroom and teacher variables."
Contamination	Unclear risk	No evidence to make assessment
Other bias	High risk	There is insufficient information to draw conclusions. Study authors stated that "Two hundred sixty-three parents were invited to participate in the evaluation, and 38% (n=100) completed the initial surveys, which assessed changes in children's fruit and vegetable consumption in the home environment and included a 3-day food diary, food frequency questionnaire, and a general health survey. At follow-up, 14% (n=38) of the parents had completed the surveys. Thus, there were not enough data to make substantive conclusions about changes in fruit and vegetable consumption in the home environment." No funding statement was provided. No conflict of interest statement was reported.

Yeh 2018
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 7 months</p> <p>Unit of allocation: preschool (Head Start programmes)</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based (Head Start)</p> <p>Operation: half day program</p> <p>Country (region): USA (Midwestern metropolitan area)</p> <p>Country income classification: high</p> <p>Low-SES sample: yes</p> <p>Population description: this study took place at the United Children and Family Head Start programmes in a major Midwestern metropolitan area. African American preschool children comprised 95% of the population in the half-day programme. 6 Head Start programmes, each with a morning and an afternoon session, participated in the study.</p> <p>Inclusion criteria: the participants were preschoolers with ages ranging between 3 and 5 years old.</p> <p>Exclusion criteria: not reported</p> <p>Number of services randomised: 6 (2 intervention 1, 2 intervention 2, 2 control)</p> <p>Number of children randomised: 160 (47 intervention 1, 54 intervention 2, 59 control)</p> <p>Characteristics</p> <p>Children</p> <p><i>Age:</i> 3-5 years</p> <p><i>Gender (% female):</i></p> <p>Intervention 1: 49%</p>

Yeh 2018 (Continued)

Intervention 2: 41%
Control: 44%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: not reported

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: Healthy Kids Healthy Lives

Number of conditions: 2 interventions, 1 control

Intervention duration: 7 months

Intervention setting: ECEC

Intervention strategies:

Intervention 1: Group A
Health curriculum

Children

Education: children received 30-min nutrition education sessions 2 x/week, for 7 months, provided by dietetic interns under the supervision of a registered dietitian. The content included the introduction of healthy "body building" foods and discussion of food groups. Hand puppets in the form of vegetables or fruits were used to introduce the content.

Ethos and environment

Children

Exposure: fresh fruit and vegetable tastings included in the nutrition education session

Service

Menu modification: wholegrain products were substituted for products usually made with white flour. Support: researchers worked with the food provider from each centre and purchased the required amount of wholegrain products based on the service menu from local grocery stores.

Meetings: before commencement of this study, the researchers met once with the food service provider centres and went over the food substitution plan and encouraged them to use all the wholegrain products provided and follow the recommended menu and recipes/cooking method.

Monitoring: researchers emphasised the food substitutions and monitored use of the foods during weekly high-fibre food delivery.

Partnerships

Healthcare

Delivery: dietetic interns delivered nutrition education.

Intervention 2: Group B
Health curriculum

Yeh 2018 (Continued)

Children

Education: children received 30-min nutrition education sessions 2 x/week, for 7 months, provided by dietetic interns under the supervision of a registered dietitian. The content included the introduction of healthy "body building" foods and discussion of food groups. Hand puppets in the form of vegetables or fruits were used to introduce the content.

Ethos and environment

Children

Exposure: fresh fruit and vegetable tastings included in the nutrition education session.

Service

Menu modification: wholegrain products were substituted for products usually made with white flour.

Support: researchers worked with the food provider from each centre and purchased the required amount of wholegrain products based on the service menu from local grocery stores.

Meetings: before commencement of this study, the researchers met once with the food service provider centres and went over the food substitution plan and encouraged them to use all the wholegrain products provided and follow the recommended menu and recipes/cooking method.

Monitoring: researchers emphasised the food substitutions and monitored use of the foods during weekly high-fibre food delivery.

All participants

Cultural: the nutrition education was culturally-appropriate (tailored to the African-American, Midwest, Head Start-eligible study population).

Partnerships

Families

Lecture: caregivers received a 1-h nutrition lecture every month. Classes were taught by dietetic interns and held in the 2 centres. The classes included 20-min presentation followed by group discussion and interactive activities related to the topic.

Healthcare

Delivery: dietetic interns delivered family lectures and nutrition education.

Intensity of intervention:

Intervention 1: 2 x 30-min child nutrition education/week, over the course of 2 semesters (7 months)

Intervention 2: 2 x 30-min child nutrition education/week, over the course of 2 semesters (7 months); 1-h caregiver group nutrition classes every month.

Intervention delivered by:

Intervention 1: research team, ECEC staff, healthcare staff

Intervention 2: research team, ECEC staff, healthcare staff

Modality:

Intervention 1: face-to-face, written

Intervention 2: face-to-face, written

Theoretical basis: not reported

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

Yeh 2018 (Continued)

BMI percentile

Number of participants analysed:

Intervention 1 baseline: 47

Intervention 1 follow-up: 47

Intervention 2 baseline: 54

Intervention 2 follow-up: 54

Control baseline: 59

Control follow-up: 59

Data collection measure: objectively measured (CDC)

Data collector: not reported

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: a grant from the Office of the Vice President for Research, Wayne State University.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The 6 participating schools were randomly assigned to one of 3 groups with 2 schools per group. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height and weight were measured by train graduate students and were not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	Study authors stated that "A convenience sample of 203 preschoolers was recruited at baseline. Post-intervention data collection occurred 7 months later and included 164 preschoolers who completed the Head Start program during the academic year (80% retention)." Reasons for missing data and differences between treatment groups are not reported. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting.

Yeh 2018 (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Only BMI was considered so there is insufficient information to assess whether bias exists. At baseline, there was no difference in BMI among the 3 groups. The control group had a higher mean BMI percentile than the intervention groups but the difference was nonsignificant ($P = 0.067$). No significant differences were found when comparing mean BMI and BMI percentiles from baseline to postintervention among the 3 groups.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	High risk	There was no accounting for clustering of children within Head Start centres.
Contamination	Unclear risk	No evidence to make assessment.
Other bias	Unclear risk	The study may have been underpowered. Study authors stated that "It is speculated that if the sample size is increased, the significant reduction in BMI percentile in group A may become apparent." There is insufficient information to assess whether an important risk of bias exists.

Yoong 2020a
Study characteristics

Methods	<p>Study design: cluster-RCT</p> <p>Length of follow-up from baseline: 12 months</p> <p>Unit of allocation: centre</p> <p>Unit of analysis: child</p>
Participants	<p>Service type: centre-based</p> <p>Operation: not reported</p> <p>Country (region): Australia (New South Wales (NSW))</p> <p>Country income classification: high</p> <p>Low-SES sample: unclear</p> <p>Population description: NSW is a demographically and socioeconomically diverse state and contains approximately 387,245 children aged 3–6 years.</p> <p>Inclusion criteria: eligible centres were required to 1) be users of the partner provider's ECEC online reporting software (HubWorks; HubCare ANZ) (~15% of all ECEC services in NSW); 2) prepare and provide ≥ 1 main and ≥ 2 mid-meals to children onsite; 3) make menu-planning decisions onsite; and 4) have a menu planner (typically a cook) with sufficient English to engage with the intervention. Eligible children were required to 1) be aged 2–6 years; 2) be present at the centre on days of data collection; 3) have no dietary requirements preventing consumption of foods while in care; and 4) have parental consent.</p> <p>Exclusion criteria: centres were excluded if they outsourced menu-planning decisions, catered exclusively for special needs children, or were run by the NSW Department of Education because such services had different operational and catering arrangements.</p> <p>Number of services randomised: 35 (groups not reported)</p>

Yoong 2020a (Continued)

Number of children randomised: 522 (288 intervention, 234 control)

Characteristics

Children

Age: 4.6 years (SD 8.2 months)

Gender (% female): 49.6%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: all ECEC centres were posted an invitation letter and information statement about the study 2 weeks before receiving a call from a research assistant to assess eligibility and obtain consent. These centres were asked to distribute information and consent forms to parents of children in the room with the highest number of children aged 2–6 years before the scheduled site visit. Consistent with previous approaches by the research team and to maximise consent, research assistants also approached parents at drop off on the day of the visit.

Missing data/dropout: 14% (n = 31) of children at baseline were retained at follow-up.

Reasons for dropout: changeover of rooms and transition to school

Characteristics of dropouts: not reported

Interventions

Programme name not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 12 months

Intervention setting: ECEC

Intervention strategies:

Ethos and environment

ECEC staff

Training: a health promotion officer with experience using the program conducted a 3-h training session with the supervisor and menu planner within each service. Training consisted of updating centres with sector-specific nutrition guidelines, the main features of the online menu-planning program and how to use them, and supporting the service to make changes to their menu.

Action plan: to generate service-level support for use of the program, the health promotion officer also undertook action planning to ensure that allocated time and resources were provided to the menu planner(s) to access the program.

Support: ongoing support was provided via 2–4 phone calls to ECEC service cooks. The purpose of these calls was to provide technical support with using the program and overcome any reported barriers to using the program. The number of phone calls provided to each service was tailored depending on engagement with the program and menu compliance as assessed via analytics data collected via the program. Centres could also seek technical support via an online “help desk” feature available within the web-based program.

Service

Yoong 2020a (Continued)

Audit and feedback: services were given access to a web-based menu-planning program, which undertook automated assessments on meals and snacks entered by menu planners and provided real-time feedback on the number of servings of each of the core food groups and discretionary foods. The feedback also outlined whether the menu was compliant with that recommended by sector-specific nutrition guidelines

Resources: where menus were not compliant, the online program automatically provided ECEC centres with suggestions and recipes on how to modify the menus to meet guidelines. The online menu-planning tool (“feedAustralia”) also included > 200 healthy recipes that met the guidelines for inclusion in ECEC menus as well as complete 1-week sample menus that were compliant with guidelines. Centres were also provided with a portable tablet to facilitate access to the online program and recipes during food preparation processes.

Reminders: ECEC centres were prompted fortnightly in the main software program to make changes to their menu to increase compliance if noncompliant, or if they had an incomplete menu entered in the online program.

Partnerships

Healthcare

Delivery: health promotion officers conducted training and provided support.

Intensity of intervention: 1 x 3-h training; 2-4 telephone calls

Intervention delivered by: research team, healthcare staff

Modality: face-to-face, telephone, online

Theoretical basis: Technology Acceptance Model and Theoretical Domains Framework

Description of control: usual care

Outcomes

Outcomes relating to child dietary intake:

Vegetables intake, fruit intake, cereals and breads intake, meat and alternatives intake, dairy and alternatives intake, discretionary foods intake, diet quality (total)

Number of participants analysed:

Intervention baseline: 105-112

Intervention follow-up: 150-183

Control baseline: 101-108

Control follow-up: 147-151

Data collection measure: direct observation and short food survey

Data collector: researcher and educator

Validity of measures used: not reported

Outcomes relating to child physical measures:

BMI z-score

Number of participants analysed:

Intervention baseline: 288

Intervention follow-up: 268

Control baseline: 234

Control follow-up: 215

Data collection measure: objectively measured (WHO)

Yoong 2020a (Continued)

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life:

Health rated quality of life

Number of participants analysed:

Intervention baseline: 94

Intervention follow-up: 68

Control baseline: 69

Control follow-up: 27

Data collection measure: parent proxy version of KIDSCREEN-10

Data collector: parent

Validity of measures used: validated

Outcome relating to cost:

Intervention delivery costs, cost per service, average cost-effectiveness ratio, relative value index

Number of participants analysed: not reported

Data collection measure: micro-costing and service questionnaire

Data collector: researcher and nominated supervisors and menu planners

Validity of measures used: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: supported by National Health and Medical Research Council (NHMRC) project grant APP1102943 and Cancer Council NSW (CCNSW) program grant PG16-05. Pilot funding was also provided from the Hunter Cancer Research Alliance and the Priority Research Centre for Health Behaviour, University of Newcastle. Hunter New England Population Health, Hunter Medical Research Institute, and the University of Newcastle provided infrastructure funding. Healthy Australia Ltd provided in-kind support for programming of the web program ("feedAustralia"). Healthy Australia Ltd co-developed the web program and were members of the advisory group which supported decisions related to the design and delivery of the web-based program.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Centres were stratified by SES and randomly assigned after baseline data collection to the intervention or control group in a 1:1 ratio by an independent statistician using a random number function in Microsoft Excel 2010. However, for diet and quality-of-life outcomes, authors stated that "To minimize selection bias, research assistants blinded to center allocation sought consent for dietary observations from all parents. After obtaining consent, research assistants randomly selected 6–9 children per center for dietary observations because 1 individual could only observe ≤ 3 children each." However the random sequence generation is not detailed with regard to the 6-9 children selected

Yoong 2020a (Continued)

		for dietary observation. As the random sequence generation for the primary outcome is not specified, the assessment is rated as unclear.
Allocation concealment (selection bias)	Low risk	Allocation was conducted by an independent statistician after baseline data collection.
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	ECEC staff and those delivering the intervention were aware of group allocation; however, parents were not explicitly informed of centre allocation. The outcome may have been influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	ECEC staff and those delivering the intervention were aware of group allocation, though parents were not explicitly informed of centre allocation. However, the outcome is not likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Quality of life outcomes	High risk	Parents were not explicitly informed of treatment allocation, but they were not blind to it, either. The outcome is likely to be influenced by lack of blinding.
Blinding of participants and personnel (performance bias) Cost	Unclear risk	ECEC staff and those delivering the intervention were aware of group allocation; however, parents were not explicitly informed of centre allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	2 methods were used to obtain child diet outcomes: (1) children's dietary intake was observed by trained research assistants who were blinded to group allocation and (2) children's dietary intake was reported via survey by parents who were not explicitly informed of centre allocation, but they were not blind to it either. The outcomes included in the meta-analyses were by blinded research assistants, therefore, we have assessed as low risk of bias
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Children's height and weight were objectively measured by trained research assistants who were blinded to group allocation.
Blinding of outcome assessment (detection bias) Quality of life outcomes	High risk	Parents reported children's health-related quality of life via interview using the KIDSCREEN-10. Parents were not explicitly informed of centre allocation, but they were not blind to it either. The outcome measurement is likely to be influenced by lack of blinding. Study authors state that "First, the use of questionnaires completed by educators and parents to assess child diet quality and HRQoL [health-related quality of life] is likely subject to recall and social desirability bias."
Blinding of outcome assessment (detection bias) Cost	Unclear risk	ECEC staff and those delivering the intervention were aware of group allocation. It is unclear whether the outcome is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	High risk	Study authors stated that "We attempted to undertake a cohort analysis; however, as expected there was high attrition of children, with only 14% (n=31) of children at baseline retained at follow-up owing to changeover of rooms and transition to school." Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Physical outcomes	High risk	Study authors stated that "We attempted to undertake a cohort analysis; however, as expected there was high attrition of children, with only 14% (n=31) of children at baseline retained at follow-up owing to changeover of rooms and

Yoong 2020a (Continued)

		transition to school." Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Quality of life outcomes	High risk	Study authors stated that "We attempted to undertake a cohort analysis; however, as expected there was high attrition of children, with only 14% (n=31) of children at baseline retained at follow-up owing to changeover of rooms and transition to school." Due to the magnitude of missing data, the risk of bias was assessed as high.
Incomplete outcome data (attrition bias) Cost	Unclear risk	The number of services and participants that reported on this outcome is unclear.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.
Recruitment bias	High risk	Children were recruited over time. Study authors state that "We attempted to undertake a cohort analysis; however, as expected there was high attrition of children, with = only 14% (n 31) of children at baseline retained at follow-up owing to changeover of rooms and transition to school."
Baseline imbalance	Unclear risk	Baseline differences between groups were not reported.
Loss of clusters	High risk	One cluster lost
Incorrect analysis	Low risk	Study authors stated that "For continuous outcomes, group differences were assessed through a group-by-time interaction in mixed-effects linear regression models, which included a random effect to account for potential clustering. For dichotomous outcomes, a logistic regression adjusting for baseline scores and clustering was undertaken."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Low risk	No clear other source of bias

Zask 2012
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 10 months Unit of allocation: preschool Unit of analysis: child
Participants	Service type: centre-based (preschools) Operation: not reported Country (region): Australia (North Coast of New South Wales (NSW)) Country income classification: high Low-SES sample: unclear Population description: not reported

Zask 2012 (Continued)

Inclusion criteria: preschools that submitted an expression of interest to participate

Exclusion criteria: not reported

Number of services randomised: 31 (18 intervention, 13 control)

Number of children randomised: unclear (560 children participated)

Characteristics

Children

Age:

Girls: 50.5 months (SD 6.7)

Boys: 58.8 months (SD 6.8)

Gender (% female): 48.30%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES: not reported

Method of recruitment: preschools that submitted an expression of interest to participate

Missing data/dropout: records from 560 children (yielding a total of 1005 records with 537 and 468 records at pre- and postintervention) in 18 intervention and 13 control preschools were used in the study. Data were collected from 80.7% and 67.2% of all children enrolled pre- and postintervention respectively. Only 6.9% and 5.7% of enrolled children's parents did not consent to participate at pre- and postintervention.

Reasons for dropout: most of the missing data were due to children being absent on the day of testing or having left the preschool between consent and testing.

Characteristics of dropouts: not reported

Interventions

Programme name: Tooty Fruity Veggie

Number of conditions 1 intervention, 1 control

Intervention duration: 10 months

Intervention setting: ECEC

Intervention strategies:

Health curriculum

Children

Education: children received simple consistent messages about 'sometimes' and 'everyday' foods - puppets, staff in fruit and vegetable costumes, stories, and role-play, were used to reinforce this message. Structured 2 x/week fundamental movement skill development through prescribed games suitable for a wide age range.

Ethos and environment

Children

Zask 2012 (Continued)

Exposure: taste testing fruit and vegetables, growing and cooking used to reinforce nutrition messages.

Role-modelling: staff acting as role models and giving positive reinforcement to children about eating healthy food and drinking water.

Service

Audit and feedback: Project Management Committees reviewed playground environment and alterations to encourage more active movement and better access to sports equipment and water during free play times.

Resources: small grants for sports equipment

ECEC staff

Training: preschool staff received a 1-d training in running the 'FunMoves' programme.

Resources: staff were given a kit comprising program notes and 30 laminated cards for each of the games. The cards were designed so that untrained parents or casual staff could quickly read the card and run the activity for 'FunMoves'.

Environment: colourful posters on "better foods" and "foods better left out" on display all year. Drinking water made more accessible to children (so children could drink water without having to ask an adult for assistance).

Policy: Project Management Committees worked with the team to review and adjust food and nutrition policies to explicitly identify appropriate and inappropriate foods in lunch boxes.

Partnerships

Families

Workshop: health professional (dietitians, health promotion officer or child and family health nurse) delivered interactive workshops for parents on limiting sedentary time, promoting physical activity, fundamental movement skills and positive parenting in relation to healthy eating and feeding 'fussy' eaters, delivered by healthcare professionals. Parents were given support and practical, achievable advice to modify risk behaviours.

Resources: a monthly 4-page newsletter containing tips of healthy eating and active playing ideas was provided to each parent. Family Feud/ Food DVD was provided to parents, which models practical ways to improve children's eating habits

Communication: communication of new policy to parents along with lunchbox displays

Healthcare

Engagement: health professionals (dietitians, health promotion officers and child and family health nurses) included in Project Management Committee and delivered the parent workshops.

Intensity of intervention: twice-weekly fundamental movement skills education for children; monthly 4-page newsletter for parents; 1-d staff training; parent workshops

Intervention delivered by: ECEC staff, healthcare staff

Modality: face-to-face, written

Theoretical basis: The Health Belief Model and the Competence Motivational Theory. Capacity building and community participation theories were applied to build community action and ensure sustainability of the project

Description of control: wait-list control

Outcomes

Outcomes relating to child dietary intake: not reported

Outcomes relating to child physical measures:

BMI z-score, waist circumference

Number of participants analysed:

Intervention baseline: 149-335

Zask 2012 (Continued)

Intervention follow-up: 114-286

Control baseline: 108-163

Control follow-up: 99-152

Data collection measure: objectively measured

Data collector: researcher

Validity of measures used: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes

Funding source: The Australian Better Health Initiative, a joint Australian, State and Territory government initiative, and supported by NSW Health and the North Coast Area Health Service

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Preschools were randomly allocated to intervention or control groups in a ratio of approximately 1.4:1. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	Study authors stated that "Preschools that acted as control schools in one year, were on a waiting list for an intervention and were offered the full program in subsequent years (the program continued beyond 2007). After random allocation to either intervention or control arms of the study, we compared preschool localities' SES to ensure the groups were matched. No change in allocation was required. Six intervention and one control preschool participated in the pilot stage in 2006 to test the intervention's feasibility. The 2006 control preschool became an intervention preschool in 2007 with additional 11 intervention and 12 control preschools."
Blinding of participants and personnel (performance bias) Physical outcomes	Low risk	No clear blinding of participants and personnel to study allocation, however the outcome is not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) Physical outcomes	Low risk	Blinding not reported, however children's height, weight, and waist circumference were measured and were not likely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) Physical outcomes	Unclear risk	Study authors stated that "Data were collected from 80.7% and 67.2% of all children enrolled pre- and postintervention respectively. Most of the missing data were due to children being absent on the day of testing or having left the preschool between consent and testing." Missing data is not reported by treatment group. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Low risk	The outcomes reported in the paper were prespecified in the protocol paper.

Zask 2012 (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Unclear risk	Baseline data were reported, however not compared statistically. Study authors state that "The student and preschool variances have been accounted for in all models."
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Low risk	Study authors stated that "Data were further analysed by fitting multi-level regression models in MLwiN to account for the clustered nature of the data (pre/post within students within preschools)."
Contamination	Unclear risk	No evidence to make assessment
Other bias	Unclear risk	Study authors stated that "There were reliability issues with waist circumference measurement so only data in which the same tester measured waist circumference pre and post intervention were included." There is insufficient information to assess whether an important risk of bias exists. No conflict of interest statement was reported.

Zeinstra 2018
Study characteristics

Methods	Study design: cluster-RCT Length of follow-up from baseline: 5 months Unit of allocation: centre Unit of analysis: child
Participants	Service type: centre-based Operation: not reported Country (region): The Netherlands (Utrecht) Country income classification: high Low-SES sample: unclear Population description: not reported Inclusion criteria: all 4 centres belonged to the same organisation. Healthy children without any allergies to the study products could participate. Exclusion criteria: not reported Number of services randomised: 4 (2 interventions, 2 control) Number of children randomised: 250 (125 intervention, 125 control) Characteristics Children Age:

Zeinstra 2018 (Continued)

Intervention: 25.6 months (SD 9.6)
 Control: 25.0 (SD 10.2)

Gender (% female):

Intervention: 44%
 Control: 42%

Ethnicity: not reported

Parents

Age (years): not reported

Gender (% female): not reported

Ethnicity: not reported

Parent/family SES:

Parent education level:
 Intervention: low: 0%; middle: 5%; high: 95%
 Control: low: 0%; middle: 10%; high: 90%

Method of recruitment: information packs were distributed to 526 parents to inform them about the study aims and procedures.

Missing data/dropout: not reported

Reasons for dropout: not reported

Characteristics of dropouts: not reported

Interventions

Programme name: not reported

Number of conditions: 1 intervention, 1 control

Intervention duration: 5 months (21 weeks)

Intervention setting: ECEC

Intervention strategies:

Ethos and environment
Children

Exposure: each vegetable was served in 2 different preparations. Children were offered 1 vegetable product each day, in accordance with a predefined schedule. A vegetable song was played to make the vegetable eating occasion recognisable and fun for the children. The blanched and raw vegetables were offered on a group plate (portion available ~50 g/child). The spreads (~30 g) were offered on 1 or 2 crackers, and the soup was offered in an individual cup (~80 g). The children could eat as much or as little as they wanted from the vegetable products; child-care employees invited the children to taste but never forced them to eat.

ECEC staff

Workshop: all ECEC employees were involved in a 1-h workshop to explain the study procedures and to discuss and resolve any perceived barriers.

Intensity of intervention: 1-h ECEC staff workshop; children were offered 1 vegetable product each day.

Intervention delivered by: research team, ECEC staff

Modality: face-to-face

Theoretical basis: not reported

Zeinstra 2018 (Continued)

Description of control: usual care

Outcomes
Outcomes relating to child dietary intake:

Pumpkin intake, white radish intake, courgette intake

Number of participants analysed: not reported

Data collection measure: research team weighed the vegetable cups before and after consumption; vegetable intake was calculated by subtracting the leftovers from the pre-weight

Data collector: researcher

Validity of measures used: not reported

Outcomes relating to child physical measures: not reported

Outcome relating to child language and cognitive performance: not reported

Outcome relating to child social/emotional measures: not reported

Outcome relating to child quality of life: not reported

Outcome relating to cost: not reported

Outcome relating to adverse consequences: not reported

Notes
Funding source: The Fresh Produce Centre and the Ministry of Economic Affairs (grant number TU 1310-086). Neither organization had any role in the design, analyses, or writing of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	2 ECEC centres were randomly assigned to the intervention condition. The sequence generation procedure was not described.
Allocation concealment (selection bias)	Unclear risk	No information on the method of allocation concealment reported
Blinding of participants and personnel (performance bias) Diet outcomes	Unclear risk	All 4 ECEC centres were part of the same organisation, though the parents and day care employees were not informed about the exact study design and conditions until after the study ended. Study authors stated that "Employees were asked to refrain from making negative faces or negative comments regarding the food's smell, taste, texture, or appearance." However, they were not asked to refrain from encouragement, which could have increased children's intake. Further, "the childcare employees were instructed to maintain a neutral attitude, which may have been somewhat artificial."
Blinding of outcome assessment (detection bias) Diet outcomes	Low risk	Blinding of outcome assessors not reported, however children's consumption was measured by weighing the vegetable cups before and after intake out of the children's view. The outcome measurement is not likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Diet outcomes	Unclear risk	Study authors stated that "The final dataset contained 250 children." However, the number of children at baseline and follow-up is not reported. Risk of attrition bias is unclear.
Selective reporting (reporting bias)	Unclear risk	No prospective trial protocol or trial registration so it was unclear whether there was selective outcome reporting

Zeinstra 2018 (Continued)

Recruitment bias	Unclear risk	It is unclear whether individuals were recruited to the study before or after randomisation of clusters.
Baseline imbalance	Low risk	There were no significant differences between the intervention and the control groups.
Loss of clusters	Unclear risk	Not reported
Incorrect analysis	Unclear risk	There was no accounting for clustering of children within centres, however all 4 centres were part of the same organisation. There is not enough information to assess whether an important risk of bias exists.
Contamination	Unclear risk	All 4 centres were from the same community and belonged to the same organisation. However, this is unlikely to have affected the intervention given the nature of the intervention (repeated exposure to unfamiliar vegetables in the child-care centre).
Other bias	Unclear risk	Discrepancies are noted in the manuscript regarding what teachers were instructed to do (or not do) during pretest and post-test. There is insufficient information to assess whether an important risk of bias exists. The intervention received financial support from a commercial organisation. Study authors state that this company had no operational role.

CDC: Centres for Disease Control; **ECEC:** early childhood education and care; **FFQ:** Food Frequency Questionnaire; **GED:** General Educational Development (tests); **IOTF:** International Obesity Task Force; **ITT:** intention-to-treat; **PedsQL:** Pediatric Quality of Life Inventory; **RCT:** randomised controlled trial; **SD:** standard deviation; **SE:** standard error; **SES:** socioeconomic status; **USDA:** United States Department of Agriculture; **WHO:** World Health Organization

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Aherna 2019	Study design: not a RCT
Ariati 2019	Intervention: targets malnutrition
Batra 2014	Intervention: targets malnutrition
Bayer 2009	Participants: aged > 6 years at baseline
Benjamin 2007	Outcome: no child dietary or anthropometric outcomes
Benjamin 2008	Outcome: no child dietary or anthropometric outcomes
Benjamin 2014	Outcome: no child dietary or anthropometric outcomes
Braga-Pontes 2021	Study design: does not have a minimum of 2 intervention sites and 2 control sites
Brophy-Herb 2017	Intervention: not primarily conducted in ECEC setting
Bryant 2021	Intervention: not primarily conducted in ECEC setting
Buscemi 2019	Study design: not a RCT
Byrne 2002	Outcome: no child dietary or anthropometric outcomes

Study	Reason for exclusion
Carstairs 2020	Outcome: assessed prior to 3 months
Caton 2013	Study design: not a RCT
Chuang 2020	Outcome: no child dietary or anthropometric outcomes
Correia 2014	Study design: does not have a minimum of 2 intervention sites and 2 control sites
Coulthard 2017	Study design: not a RCT
Coulthard 2018	Outcome: assessed prior to 3 months
Dazeley 2015	Outcome: assessed prior to 3 months
De Droog 2014	Outcome: assessed prior to 3 months
De Droog 2017	Outcome: assessed prior to 3 months
De Wild 2013	Study design: not a RCT
De Wild 2015	Study design: not a RCT
De Wild 2017	Study design: not a RCT
De Zwarte 2019	Outcome: no child dietary or anthropometric outcomes
Diktas 2021	Outcome: assessed prior to 3 months
Earnesty 2019	Outcome: no child dietary or anthropometric outcomes
Eichholzer-Helbling 1986	Study design: not a RCT
Esquivel 2016	Study design: not a RCT
Ferris 2012	Study design: not a RCT
Finch 2019a	Outcome: no child dietary or anthropometric outcomes
Finch 2019b	Outcome: no child dietary or anthropometric outcomes
Grady 2020	Outcome: no child dietary or anthropometric outcomes
Hardy 2010	Outcome: no child dietary or anthropometric outcomes
Harnack 2012	Outcome: assessed prior to 3 months
Hausner 2012	Outcome: assessed prior to 3 months
Hughes 2020b	Intervention: not primarily conducted in ECEC setting
Jouret 2009	Study design: not a RCT
Kashef 2021	Study design: not a RCT
Kim 2019	Outcome: assessed prior to 3 months

Study	Reason for exclusion
Kling 2016	Outcome: assessed prior to 3 months
Kostecka 2022	Study design: not a RCT
Lanigan 2019	Outcome: assessed prior to 3 months
Lawatsch 1990	Outcome: no child dietary or anthropometric outcomes
Leahy 2008a	Outcome: assessed prior to 3 months
Leahy 2008b	Outcome: assessed prior to 3 months
Leahy 2008c	Outcome: assessed prior to 3 months
Leung 2019	Intervention: not primarily conducted in ECEC setting
Lin 2016	Intervention: not primarily conducted in ECEC setting
Malden 2019	Outcome: no child dietary or anthropometric outcomes
Mannino 2019	Outcome: no child dietary or anthropometric outcomes
McSweeney 2017	Intervention: not primarily conducted in ECEC setting
NCT03672227	Outcome: assessed prior to 3 months
NCT03957148	Study design: not a RCT
NCT04552678	Study design: not a RCT
NCT05050539	Study design: not a RCT
Neelon 2016	Outcome: no child dietary or anthropometric outcomes
Nekitsing 2019b	Outcome: assessed prior to 3 months
Norman 2019	Participants: aged > 6 years at baseline
O'Connell 2012	Study design: does not have a minimum of 2 intervention sites and 2 control sites
Rhee 2019	Outcome: assessed prior to 3 months
Ritchie 2019	Outcome: no child dietary or anthropometric outcomes
Rollins 2021	Outcome: assessed prior to 3 months
Schuler 2019	Outcome: no child dietary or anthropometric outcomes
Sirasa 2021	Outcome: assessed prior to 3 months
Slining 2021	Study design: not a RCT
Smith 2019	Outcome: assessed prior to 3 months
Sojkowski 2012	Outcome: assessed prior to 3 months

Study	Reason for exclusion
Sweitzer 2010	Study design: not a RCT
Swindle 2021	Study design: not a RCT
Vaughn 2019b	Study design: not a RCT
Vepsäläinen 2022	Outcome: no child dietary or anthropometric outcomes
Verbestel 2014	Intervention: not primarily conducted in ECEC setting
Vitale 2020	Outcome: assessed prior to 3 months
Ward 2008	Outcome: no child dietary or anthropometric outcomes
Ward 2017	Outcome: no child dietary or anthropometric outcomes
Ward 2020b	Outcome: no child dietary or anthropometric outcomes
Williams 1998	Study design: not a RCT
Williams 2002	Study design: not a RCT
Yeom 2019	Study design: not a RCT
Yoong 2016	Outcome: no child dietary or anthropometric outcomes

ECEC: early childhood education and care; **RCT:** randomised controlled trial

Characteristics of studies awaiting classification *[ordered by study ID]*

[ChiCTR2200060958](#)

Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): China (Shenzhen City) Number of services participating: unclear (1400 children)
Interventions	Insufficient information available in trial registry to determine eligibility
Outcomes	Insufficient information available in trial registry to determine eligibility
Notes	ChiCTR1800017292

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

[Armstrong 2019](#)

Study name	CHAMP: a cluster randomized-control trial to prevent obesity in child care centers
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Armstrong 2019 (Continued)

Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (Maryland) Number of services participating: 54
Interventions	Number of conditions: 2 interventions, 1 control Intervention strategies: Intervention 1: CHAMP Health curriculum <i>Children</i> Curriculum: physical activity programme (Get Movin' with Mighty Moves®) to increase gross motor skills and healthful eating programme (Fun with New Foods®), including nutrition activities and opportunities to try new foods Ethos and environment <i>ECEC staff</i> Workshops: ECEC staff will receive 2 training sessions during the year which last approximately 1–2 h each. During the training sessions, staff are provided with general psychoeducation regarding childhood obesity, food neophobia and gross motor development. Materials: detailed implementation manuals on lesson plans and classroom activities will be provided to ECEC staff. ECEC staff and directors will receive a printed manual and have access to a staff website where they can access weekly lesson plans, handouts, additional resources and programme content including music to accompany lessons. Each week, lesson plans are emailed or texted to ECEC staff. Intervention 2: CHAMP + Health curriculum <i>Children</i> Curriculum: physical activity programme (Get Movin' with Mighty Moves®) to increase gross motor skills and healthful eating programme (Fun with New Foods®), including nutrition activities and opportunities to try new foods. Ethos and environment <i>ECEC staff</i> Workshops: ECEC staff will receive 2 training sessions during the year which last approximately 1–2 h each. During the training sessions, ECEC staff are provided with general psychoeducation regarding childhood obesity, food neophobia and gross motor development. Materials: detailed implementation manuals on lesson plans and classroom activities will be provided to ECEC staff. ECEC staff and directors will receive a printed manual and have access to a staff website where they can access weekly lesson plans, handouts, additional resources and programme content including music to accompany lessons. Each week, lesson plans are emailed or texted to ECEC staff. ECEC staff will also receive additional information about the caregiver website. Partnerships <i>Families</i> Education: caregivers were given access to a caregiver education website, hosted by the university. Each week, caregivers will be provided content on physical activity, nutrition, and wellness topics relevant to caregivers of preschoolers and co-ordinated with the activities conducted in the classrooms. Quizzes and monthly challenges will be available to increase caregiver interaction with the online content. Caregivers will be notified weekly (by email or text message) when new content is available on the website.
Outcomes	Outcomes relating to child dietary intake: Fruit intake, vegetable intake, beverage consumption, red meats intake, processed meats intake, take-out food intake, snack food intake, dessert intake Outcomes relating to child anthropometric measures: Height, weight, waist circumference, BMI

Armstrong 2019 (Continued)

Starting date	June 2016
Contact information	Dr Maureen M Black, mblack@som.umaryland.edu
Notes	ClinicalTrials.gov: NCT03111264

Barnes 2020

Study name	A pilot randomised controlled trial of a web-based implementation intervention to increase child intake of fruit and vegetables within childcare centres
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): Australia (Hunter New England) Number of services participating: 22
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Materials: services will have access to a web-based program (Childcare Electronic Assessment Tool and Support (EATS)), which aims to promote: supporting families to provide healthier foods consistent with dietary guidelines, provision of intentional learning experiences about healthy eating to children, use of feeding practices that support children's healthy eating, staff participation in professional development in healthy eating and having a comprehensive written nutrition policy that outlines key healthy eating practices. Feedback: Childcare EATS includes a self-assessment of the implementation of targeted healthy eating practices. Following the completion of the self-assessment, the web-based program will immediately provide centres with feedback on practice performance. ECEC centres will be encouraged to complete the self-assessment at least twice during the intervention period to self-monitor improvements in practice. ECEC centres will be encouraged to use Childcare EATS to set goals and create an action plan to facilitate improvements in practice. Support: ECEC centres allocated to the intervention will receive support from health promotion officers within the local health district with experience working with ECEC centres.
Outcomes	Outcomes relating to child dietary intake: Fruit intake, vegetable intake, sodium intake, saturated fat intake, added sugar intake Outcomes relating to child anthropometric measures: not reported
Starting date	September 2019
Contact information	Dr Courtney Barnes, courtney.barnes@health.nsw.gov.au
Notes	Australian New Zealand Clinical Trial Registry: ACTRN12619001158156

Beckerman 2019

Study name	Communities for healthy living (CHL) - A family-centered childhood obesity prevention program integrated into Head Start services: study protocol for a pragmatic cluster randomized trial
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (Massachusetts) Number of services participating: 16
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Training: staff training Resources: nutrition support resources Partnerships <i>Parents</i> Education: parenting programme Resources: written and media nutrition resources and child health screening reports
Outcomes	Outcomes relating to child dietary intake: Fruit, vegetables, 100% juice, sugary beverages, water, snacks, fast food Outcomes relating to child anthropometric measures: BMI
Starting date	Fall 2017
Contact information	Professor Kirsten K. Davison, kdavison@hsph.harvard.edu; chlheadstart@gmail.com
Notes	ClinicalTrials.gov: NCT03334669

Cosco 2021

Study name	Research design, protocol, and participant characteristics of COLEAFS: a cluster randomized controlled trial of a childcare garden intervention
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (North Carolina) Number of services participating: 15
Interventions	Number of conditions: 1 intervention, 2 controls Intervention strategies: Ethos and environment <i>Staff</i>

Cosco 2021 (Continued)

Workshop: teachers received a one-on-one orientation to the activity guide to ensure that they were prepared to lead 12 activities.

Support: each week, a research assistant will visit the classroom to interview teachers, discuss challenges and successes of the prior week and provide technical assistance

Service

Resources: garden installations, resources, and gardening activities. A coffer storage unit and a garden kit (hand tools, hose, gardening gloves, watering wand, and child-sized cans) will be provided.

Outcomes	<p>Outcomes relating to child dietary intake:</p> <p>Fruit and vegetable consumption</p> <p>Outcomes relating to child anthropometric measures: not reported</p>
Starting date	June 2017
Contact information	Nilda Graciela Cosco, nilda_cosco@ncsu.edu and Nancy M. Wells, nmw2@cornell.edu
Notes	ClinicalTrials.gov: NCT04864574

Helland 2016

Study name	Study protocol for a multi-component kindergarten-based intervention to promote healthy diets in toddlers: a cluster randomized trial
Methods	Study design: cluster-RCT
Participants	<p>Service type: centre-based</p> <p>Country (region): Norway (Vest-Agder and Aust-Agder)</p> <p>Number of services participating: 18 (including 2 dropouts)</p>
Interventions	<p>Number of conditions: 1 intervention, 1 control</p> <p>Intervention strategies:</p> <p>Health curriculum <i>Children</i> Curriculum: children will be delivered Sapere-sensory education in the kindergartens' pedagogical group sessions.</p> <p>Ethos and environment <i>Children</i> Menu modification: children will be offered a cooked, healthy lunch prepared at the kindergarten on the intervention days over the 9-week period.</p> <p><i>ECEC staff</i> Workshop: kindergarten staff will attend a class at the university to learn about the Sapere method and intervention elements. The pedagogical leaders will also attend a class to learn about food neophobia, development of healthy eating habits early in life, and how kindergartens can play a role in healthy eating in children.</p> <p>Materials: all staff will be given a handbook entitled "Overall plan for the intervention" to guide them in implementing the programme. Kindergartens will also be assigned equipment to make cooking easy and feasible. They will also receive 3 different handbooks developed for the project "Home cooked food guide," and 3 food kit boxes (including spices, herbs, vinegar, mustard, and so forth); 1 for each time period. Financial compensation for food costs will be provided after the intervention period. The kindergartens will receive pre-printed postcards and posters.</p> <p>Environment: kindergarten staff will integrate 10 meal principles about feeding practices.</p> <p><i>Families</i></p>

Helland 2016 (Continued)

Materials: parents will be given short postcard messages corresponding to the 10 meal principles.

Outcomes	<p>Outcomes relating to child dietary intake:</p> <p>Fruits intake, berries intake, vegetable intake, potato intake, rice intake, pasta intake, bread intake, cereals intake, porridge intake, unprocessed meat and fish intake, processed foods intake, snacks intake, beverage intake</p> <p>Outcomes relating to child anthropometric measures:</p> <p>Height, weight, BMI</p>
Starting date	2014
Contact information	Associate Professor Sissel Helland, sissel.h.hellandg@gmail.com
Notes	ISRCTN registry: ISRCTN74823448

ISRCTN33134697

Study name	NAP SACC (UK): nutrition and physical activity self-assessment for childcare
Methods	Study design: cluster-RCT
Participants	<p>Service type: centre-based</p> <p>Country (region): UK (Somerset, Swindon, Sandwell and Ayrshire and Arran)</p> <p>Number of services participating: 56</p>
Interventions	<p>Number of conditions: 1 intervention, 1 control</p> <p>Intervention strategies:</p> <p>Ethos and environment</p> <p><i>Staff</i></p> <p>Workshop: specialised staff will deliver workshops to all nursery staff on nutrition and physical activity.</p> <p><i>Service</i></p> <p>Self-assessment: nursery managers will complete a self-assessment.</p> <p>Goal setting and action planning: the NAP SACC UK Partner will work with the nursery manager to develop an action plan, listing 8 goals for improvement.</p> <p>Support: NAP SACC UK Partner will continue regular contact with nurseries to provide support and advice toward them meeting their goals</p> <p>Evaluation: the Review & Reflect self-assessment is repeated by the nursery manager after 6 months and reviewed with the NAP SACC UK Partner to see where improvements have been made or not, and to explore ways to overcome barriers. Action plans will revised to set 8 new goals for the next 6 months.</p> <p>Partnerships</p> <p><i>Partners</i></p> <p>Delivery: specialised staff will deliver workshops to all nursery staff and partners will provide support.</p>
Outcomes	Outcomes relating to child dietary intake:

ISRCTN33134697 (Continued)

Total energy per snack and lunch eating occasion, average size of lunch (per occasion) consumed by children, average size of snacks (per occasion) consumed by children, average percentage of total energy in lunch from non-core food served consumed by children, average percentage of total energy in snacks from non-core food served consumed by children

Outcomes relating to child anthropometric measures:

BMI z-score, overweight and obesity

Starting date	March 2022
Contact information	Dr Ruth Kipping, ruth.kipping@bristol.ac.uk
Notes	ISRCTN registry: ISRCTN33134697

Lee 2019

Study name	Design and methodology of a cluster-randomized trial in early care and education centers to meet physical activity guidelines: Sustainability via Active Garden Education (SAGE)
Methods	Study design: cluster-RCT (2 x 2 factorial design)
Participants	Service type: centre-based Country (region): USA (Phoenix) Number of services participating: 28
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: a garden-based physical activity and nutrition educational programme will be delivered to children. Children learn actively how to plant, water, weed, harvest and do simple food preparation involving washing, cleaning, and sampling fruit and vegetables. SAGE demonstrates how engaging in daily physical activity by tending the garden can contribute to meeting physical activity guidelines. Additional activities in the curriculum include 3 science experiments, a mindful eating exercise in every session and 22 interactive discussions. Ethos and environment <i>Service</i> Materials: gardens (4' X 6' (approx 1.2 m x 1.8 m)) will be installed in centres. Climate appropriate fruits, vegetables, and herbs will be planted in advance of the curriculum with the aid of teachers and ECEC staff so that plants will be available throughout the SAGE curriculum. ECEC personnel will take primary responsibility for watering the garden with additional help from the SAGE team.
Outcomes	Outcomes relating to child dietary intake: Fruit intake, vegetable intake Outcomes relating to child anthropometric measures: not reported
Starting date	January 2017
Contact information	Dr Rebecca Lee, releephd@yahoo.com
Notes	ClinicalTrials.gov: NCT03261492

Malden 2018

Study name	Adapting the ToyBox obesity prevention intervention for use in Scottish preschools: protocol for a feasibility cluster randomised controlled trial
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): Scotland (Glasgow) Number of services participating: 6
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: teacher-led interactive activities Ethos and environment <i>Children</i> Exposure: teacher-led physical activity sessions and movement breaks, as well as interactive stories <i>ECEC staff</i> Training: early years practitioners will receive a 2.5 h training session prior to intervention commencement. The session will cover guidelines for designing a movement-friendly classroom environment, delivery of the physical activity and sedentary behaviour components, use of the practitioner logbook and a briefing on the content and timing of the parental component of the intervention. Support: the lead researcher and coproducing early years practitioner will visit the preschools to assist with any issues, and observe delivery of the programme to ensure it is being delivered as intended. <i>Service</i> Materials: preschools will be provided with a "ToyBox" containing equipment, puppets and classroom activity guides. Partnerships <i>Families</i> Materials: parents will be provided with an introductory pack at the start of the intervention detailing what ToyBox-Scotland is and how it relates to them. They will be given instructions on how to use the wallchart and stickers to incentivise their child's behaviour, and short instructions for each homework game will be provided to parents via the early years practitioners.
Outcomes	Outcomes relating to child dietary intake: Home eating/snacking intake, water consumption Outcomes relating to child anthropometric measures: BMI
Starting date	December 2017
Contact information	Dr Stephen Malden, stephen.malden@strath.ac.uk
Notes	ISRCTN registry: ISRCTN12831555

Mehdizadeh 2018

Study name	Customized intervention program aiming to improve healthy eating and physical activity among preschool children: protocol for a randomized controlled trial (Iran Healthy Start Study)
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): Iran (Mashhad) Number of services participating: 6
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: children are delivered physical activity and nutrition units Ethos and environment <i>ECEC staff</i> Workshop: a workshop at baseline and a booster session at the middle of the intervention period will be conducted. Details of "Literacy, Education, Activity, Play" activities, activity demonstrations, role of educators, collaboration with parents, and other related implementation hints are presented and discussed. <i>Service</i> Materials: comprises 2 illustrated handbooks. The physical activity book containing 20 activity units along with a complementary chapter containing information for educators. The nutrition book contains 20 activity units along with a complementary chapter containing information for educators. This handbook is accompanied with "Healthy-kid Toolkit," which contains utilities and materials for "Literacy, Education, Activity, Play" activity units. A handbook for managers and educators containing modified self-assessment tool, as well as principles of the programme, action planning, policies and practices, details of implementation, log pages, and report pages for both educators and managers. It also contains a suggested healthy weekly menu for serving a snack or a hot meal for children at preschool. Access to a comprehensive website containing details of the programme. Support: an on-site training workshop will be followed by a supplementary booster session during the implementation (3-4 h), as well as ongoing support through mobile and internet-based contacts (Telegram) and weekly visits. Educators and managers of are invited to become a member of the Telegram channel. Partnerships <i>Families</i> Materials: a scientific, user-friendly, and simple book entitled, "Knowledgeable Parents, Healthier Children," will be provided to parents, aiming at improving their knowledge and practice regarding healthy eating for the whole family, especially their preschool child. Access to a comprehensive website containing details of the programme. Support: routine monthly meetings between parents and team nutritionists. <i>Community</i> Broadcasting: a television show and radio talks related to childhood obesity, physical activity in children, healthy nutrition, parenting, and many other related topics were recorded to introduce the programme and report the future outcomes.
Outcomes	Outcomes relating to child dietary intake: diet quality Outcomes relating to child anthropometric measures: Weight, height, mid-arm circumference, waist circumference, BMI, BMI percentile, BMI z-score
Starting date	Dr Hassan Vatanparast, vatan.h@usask.ca
Contact information	International Clinical Trials Registry Platform: IRCT2016041927475N1

Mehdizadeh 2018 (Continued)

Notes

NCT01890681

Study name	Baby nutrition and physical activity self-assessment for child care (NAP SACC) intervention study
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA Number of services participating: unclear (960 children)
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Workshop: training workshops ECEC providers. <i>Service</i> Support: centre self-assessment and targeted technical assistance by Baby NAP SACC consultant for providers Partnerships <i>Families</i> Support: family self-assessment and targeted technical assistance by Baby NAP SACC consultant parents. Parent outreach and support
Outcomes	Outcomes relating to child dietary intake: Dietary intake Outcomes relating to child anthropometric measures: Weight-for-length z-score, skinfold thickness
Starting date	August 2013
Contact information	Professor Sara Benjamin Neelon, sara.neelon@jhu.edu
Notes	ClinicalTrials.gov: NCT01890681

NCT02580123

Study name	Smile-Kids: study on complementary feeding transition
Methods	Study design: RCT
Participants	Service type: centre-based

Healthy eating interventions delivered in early childhood education and care settings for improving the diet of children aged six months to six years (Review)

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NCT02580123 (Continued)

	Country (region): Portugal
	Number of services participating: 25 (children aged 4-12 months)
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Training: educators' training with the researchers Partnerships <i>Families</i> Training: training with parents and infants developed by trained educators
Outcomes	Outcomes relating to child dietary intake: Dietary intake Outcomes relating to child anthropometric measures: Weight, length, BMI
Starting date	May 2012
Contact information	Dr Helena Rafaela Vieira do Rosario, rrosario@ese.uminho.pt
Notes	ClinicalTrials.gov: NCT02580123

NCT03575884

Study name	Fit 5 kids screen time reduction curriculum for Latino preschoolers (Fit5Kids)
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (Seattle, Houston, and the Central Valley of Washington State) Number of services participating: unclear (280 children)
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: Fit5Kids classroom curriculum Partnerships <i>Families</i> Resources: weekly parent newsletters Goal setting: in-person (or by telephone) goal setting on child's screen time, a lending library of resources (e.g. books, games, arts/crafts), and text messages on screen time parenting practices offered over 7-8 weeks in the Fall (Autumn) semester

NCT03575884 (Continued)

Outcomes	Outcomes relating to child dietary intake: Dietary intake Outcomes relating to child anthropometric measures: BMI z-score
Starting date	September 2018
Contact information	Dr Jason Mendoza, jason.mendoza@seattlechildrens.org
Notes	ClinicalTrials.gov: NCT03575884

NCT03601299

Study name	Back to basics: addressing childhood obesity through traditional foods in Alaska
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA Number of services participating: unclear (804 children)
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: a physical activity curriculum in Head Start programmes in all communities Menu: a traditional food in Head Start menu programme in intervention communities Partnerships <i>Families</i> Programme: a home-based nutrition programme in intervention communities Community Resources: a mechanism to document traditional foods important to each community
Outcomes	Outcomes relating to child dietary intake: Traditional food intake Outcomes relating to child anthropometric measures: BMI
Starting date	2018
Contact information	Dr Timothy K Thomas, tkthomas@anthc.org

NCT03601299 (Continued)

Notes ClinicalTrials.gov: NCT03601299

NCT03668678

Study name	iGrow Readers nutrition and physical activity curriculum efficacy
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA Number of services participating: unclear (568 children)
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: as part of the iGrow Readers curriculum, the primary teacher first reads a book as a group with a specific health behaviour theme. Then, children participate in nutrition and physical activities that relate and reinforce the lessons learned in the book. Ethos and environment <i>Families</i> Resources: informational newsletters highlighting healthy behaviours from the stories' themes are provided to parents.
Outcomes	Outcomes relating to child dietary intake: Diet Outcomes relating to child anthropometric measures: Height, weight, body composition, BMI
Starting date	14 August 2014
Contact information	Associate Professor Jessica R Meendering, jessica.meendering@sdstate.edu
Notes	ClinicalTrials.gov: NCT03668678

NCT04082247

Study name	Healthy children 2021 study in childcare centers (HC2021)
Methods	Study design: cluster-RCT
Participants	Service type: centre-based

NCT04082247 (Continued)

	Country (region): Portugal
	Number of services participating: 16
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Training: educators will receive training around healthy eating, physical activity and sleep for children
Outcomes	Outcomes relating to child dietary intake: Dietary intake Outcomes relating to child anthropometric measures: Length and waist, weight
Starting date	September 2019
Contact information	Dr Rafaela Vieira do Rosario, rrosario@ese.uminho.pt
Notes	ClinicalTrials.gov: NCT04082247

NCT04140032

Study name	Addressing obesity in early care and education settings
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (Los Angeles) Number of services participating: 60
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: integration of nutrition and physical activity content into curricula Ethos and environment <i>Service</i> Policy: establishment of organisational policies to support healthy nutrition and physical activity <i>ECEC staff</i> Support: supports for teachers and staff to model healthy behaviour Partnerships <i>Families</i> Materials: engagement of parents as partners in implementing healthy policies in preschool and at home
Outcomes	Outcomes relating to child dietary intake: Dietary intake

NCT04140032 (Continued)

Outcomes relating to child anthropometric measures:

BMI z-score

Starting date	October 2019
Contact information	Dr Burton Cowgill, bcowgill@ucla.edu
Notes	ClinicalTrials.gov: NCT04140032

NCT04164277

Study name	FirstStep2Health intervention
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA Number of services participating: 6
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: preschoolers will receive weekly, age-appropriate, participatory learning co-delivered by teachers and university student educators Partnerships <i>Families</i> Meetings: 3 face-to-face or virtual caregiver meetings where research staff will lead the meetings at Head Start centres (weeks 1, 8, and 16) to connect caregivers to each other, offer health information, and discuss behavioural change strategies Resources: Facebook-based programme including 4 new habit-formation tasks/week. Preschoolers, using stickers, will create 2 letters each week regarding a food or activity presented in the centre-based programme that they liked or want to try at home. Letters will be sent privately to each caregiver, and caregivers will be asked to respond to the letters.
Outcomes	Outcomes relating to child dietary intake: Diet quality Outcomes relating to child anthropometric measures: Overweight, obesity, BMI z-score
Starting date	September 2021
Contact information	Associate Professor Jiyong Ling, lingjiyi@msu.edu
Notes	ClinicalTrials.gov: NCT04164277

NCT04711525

Study name	i-MaChEL Study is a two-group, cluster-RCT, involves 460 preschool's child-parent dyads, to prevent childhood obesity (i-MaChEL)
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): Malaysia Number of services participating: 12
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: children will be exposed to the interactive activities and quizzes using Web 2.0 tools, educational videos of a healthy lifestyle, sensory-based food education activities, cooking demonstrations, fun, and active games, and exercises delivered through interactive classroom instruction Partnerships <i>Families</i> Web-based program: parents will have access to the i-MaChEL Web-based program
Outcomes	Outcomes relating to child dietary intake: Dietary intake Outcomes relating to child anthropometric measures: BMI
Starting date	March 2022
Contact information	Ahmad Faezi Ab.Rashid, faezi.ar@umk.edu.my
Notes	ClinicalTrials.gov: NCT04711525

NCT05112185

Study name	Childcare healthy beverage access, food and beverage intake, and obesity
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA Number of services participating: 14
Interventions	Number of conditions: 1 intervention, 1 control

NCT05112185 (Continued)

Intervention strategies:
Health curriculum
Children

Curriculum: education directed to children to increase the intake of healthy beverages, including lessons for children in ECEC centres

Ethos and environment
Service

Environment: the Healthy Drinks, Healthy Futures intervention consists of increased access to healthy beverages in ECEC centres

Partnerships
Families

Education: education directed to families to increase the intake of healthy beverages, including motivational beverage counselling for families

Outcomes	Outcomes relating to child dietary intake: Caloric intake from beverages, beverage intake frequency Outcomes relating to child anthropometric measures: BMI z-score
Starting date	August 2022
Contact information	Associate Professor Anisha Pate, anipatel@stanford.edu
Notes	ClinicalTrials.gov: NCT05112185

Reeves 2018

Study name	ToyBox study Malaysia: improving healthy energy balance and obesity-related behaviours among pre-schoolers in Malaysia
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): Malaysia Number of services participating: not reported
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: teachers will be encouraged to teach and promote the 4 key energy balance-related behaviours drinking water; eating healthy snacks and meals; reducing sedentary behaviour; and increasing physical activity. Ethos and environment <i>ECEC staff</i>

Reeves 2018 (Continued)

Training: teachers and their assistants will be trained to conduct the ToyBox Study programme, with a 2 d Training of teachers session prior to the start of the programme, and 2 half-day sessions at regular intervals to obtain feedback on the programme up to that point and to provide a refresh-er on the upcoming components.

Service

Environment: the intervention may require making changes to the classroom environment; for ex-ample establishing a drinking water station or clearing an area to make space for physical activi-ties.

Partnerships

Families

Resources: parents and caregivers will be encouraged to get involved and advised via newsletters and tip cards to apply relevant environmental changes at home, act as role models and implement the healthy lifestyle behaviours together with their children.

Outcomes	<p>Outcomes relating to child dietary intake:</p> <p>Dietary intake</p> <p>Outcomes relating to child anthropometric measures:</p> <p>Anthropometric data</p>
Starting date	Not reported
Contact information	Dr Sue Reeves, s.reeves@roehampton.ac.uk
Notes	Not reported

Sisson 2019

Study name	Interventions to promote healthy environments in family child care homes in Oklahoma - Happy Healthy Homes: study protocol for a randomized controlled trial
Methods	Study design: cluster-RCT
Participants	<p>Service type: family child-care homes</p> <p>Country (region): USA (Oklahoma City)</p> <p>Number of services participating: 52</p>
Interventions	<p>Number of conditions: 1 intervention, 1 control</p> <p>Intervention strategies:</p> <p>Ethos and environment <i>ECEC staff</i> Training: the 2 individual educational training sessions, approximately 90 min in length, will be de-livered to educators by trained interventionists. At the end of each module, participants discuss and set specific, measurable, attainable, realistic, and time-sensitive (SMART) goals. A 3-h group nutrition class will be conducted on campus after baseline visits. The class will be a cooking class that repeats key project goals and material in addition to hands-on experience with best practices, food preparation tips, sensory experience, and tasting. Recipe preparation and tasting specific to feeding young children will be provided. Support: check-in telephone calls will be completed between the first and second training sessions to discuss progress on SMART goals set during the first session and to troubleshoot any challenges.</p>
Outcomes	Outcomes relating to child dietary intake:

Sisson 2019 (Continued)

Diet intake

Outcomes relating to child anthropometric measures: not reported

Starting date	October 2017
Contact information	Associate Professor Susan Sisson, susan-sisson@ouhsc.edu
Notes	Clinicaltrials.gov: NCT03560050

Watt 2014

Study name	Methodological development of an exploratory randomised controlled trial of an early years' nutrition intervention: the CHERRY programme (Choosing Healthy Eating when Really Young)
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): England (Cornwall and Islington) Number of services participating: 16
Interventions	Number of conditions: 1 intervention, 1 control Intervention strategies: Ethos and environment <i>ECEC staff</i> Training: a staff training session will be offered to all staff working in the centres. The training session covered various aspects of healthy eating and nutrition for early years and included an introduction and overview of the CHERRY programme. Each training session will be tailored to the needs of the staff, as identified by heads of each intervention centre. Support: intervention centres will be given support and advice to revise and develop their centre's food policies in order to support healthy eating practices and procedures. Partnerships <i>Families</i> Education: 4 x 2-h sessions (1 each week) will be delivered over 4 weeks. The first hour of each session will involve parents discussing and learning about a variety of aspects of healthy eating. The second hour will involve parents and children together for a more practical, 'hands on' cook and eat session involving basic food preparation and tasting. Each session will begin with a recap from the previous week and finish with parents being given a 'CHERRY at home' activity to complete before the following week's session. The intervention group will receive SMS reminders via mobile phones between sessions.
Outcomes	Outcomes relating to child dietary intake: Fruit intake, vegetable intake, soft drink intake, sugary foods intake Outcomes relating to child anthropometric measures: not reported
Starting date	October 2010
Contact information	Professor Richard Geddie Watt, r.watt@ucl.ac.uk
Notes	Trial registration not reported.

Yin 2019

Study name	Study protocol for a cluster randomized controlled trial to test "¡Míranos! Look at Us, We Are Healthy!" - an early childhood obesity prevention program
Methods	Study design: cluster-RCT
Participants	Service type: centre-based Country (region): USA (San Antonio) Number of services participating: 12
Interventions	Number of conditions: 1 relevant intervention, 1 non-ECEC intervention 1 control Intervention strategies: Health curriculum <i>Children</i> Curriculum: 9 modules with short, age-appropriate learning activities, hands-on games, and interactive DVD activities (The Get Healthy Now Show) will be integrated into daily centre routines. Ethos and environment <i>Children</i> Exposure: children will participate in daily physical activity (30-min structured and 60-min non-structured play) during outdoor/indoor play, learning centre time, and transitions. Teachers will use ¡Míranos! Activity Cards (at least one card/d) and equipment supplied by the study to meet the physical activity goals. <i>ECEC staff</i> Wellness program: a staff wellness programme, which consists of a staff wellness manual and challenges, to improve staff's own health and become healthy role models for the children at the centre Materials: teachers will have access to a wellness manual and the ¡Míranos! eBook that will provide weekly intervention schedules, electronic copies of intervention activities, access to online movement music and videos, and online audio/video versions of the children's storybooks. Posters to track staff progress will be posted in a staff-only area and centre directors will report the number of staff who participated in the challenge and who achieved their goal to receive cash incentives for their centre. <i>Service</i> Policy: nutrition policies will be modified to include best practices. Meal modifications: menus will be modified to meet best practices and will be covered by supplemental funding from the study. Materials: a training DVD will be provided to detail lesson implementation and demonstrate gross motor activities to help teachers develop confidence and overcome challenges in leading the activities and to reinforce key concepts from the staff training.
Outcomes	Outcomes relating to child dietary intake: Fruit intake, vegetable intake, beverage consumption Outcomes relating to child anthropometric measures: Height, weight, BMI, BMI z-score
Starting date	May 2018
Contact information	Professor Zenong Yin, zenong.yin@utsa.edu
Notes	ClinicalTrials.Gov: NCT03590834

Zarnowiecki 2021

Study name	Application of the multiphase optimisation strategy to develop, optimise and evaluate the effectiveness of a multicomponent initiative package to increase 2-to-5-year-old children's vegetable intake in long day care centres: a study protocol
Methods	Study design: Phase 1: full factorial design Phase 2: cluster-RCT
Participants	Service type: centre-based Country (region): Australia (Adelaide) Number of services participating: Phase 1: 32 Phase 2: 20
Interventions	Number of conditions: Phase 1: 7 interventions, 1 control Phase 2: 1 intervention, 1 control Intervention strategies: Phase 1 Intervention 1 Health curriculum <i>Children</i> Curriculum: a series of 16 short (~10–20-min) lessons and hands-on activities delivered during intentional teaching time. <i>Children</i> Exposure: a series of 16 snack time occasions where vegetables will be tasted and critical strategies to reinforce children's enjoyment of vegetables can be consolidated. Materials: supporting resources and activities to further familiarise children with vegetables and their senses and a group reward chart to track progress of vegetables tasted. Ethos and environment <i>ECEC staff</i> Education: a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables. Educators will complete an interactive online training module (~45–55 min) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and planning and implementing a strategy within their centre. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the 8 weeks of the implementation period. Training: cooks will complete an online training module, use an online menu planning tool to review their menu and implement the revised menu. Feedback: cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines and will revise their menu based on this feedback. Intervention 2 Ethos and environment <i>ECEC staff</i> Education: a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables. Educators will complete an interactive online training module (~45–55 min) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and

Zarnowiecki 2021 (Continued)

planning and implementing a strategy within their centre. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the 8 weeks of the implementation period.

Training: cooks will complete an online training module, use an online menu planning tool to review their menu and implement the revised menu.

Feedback: cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines and will revise their menu based on this feedback.

Intervention 3
Ethos and environment

ECEC staff

Training: cooks will complete an online training module, use an online menu planning tool to review their menu and implement the revised menu.

Feedback: cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines and will revise their menu based on this feedback.

Intervention 4
Health curriculum

Children

Curriculum: a series of 16 short (~10–20 min) lessons and hands-on activities delivered during intentional teaching time.

Materials: supporting resources and activities to further familiarise children with vegetables and their senses and a group reward chart to track progress of vegetables tasted.

Ethos and environment

Children

Exposure: a series of 16 snack time occasions where vegetables will be tasted and critical strategies to reinforce children's enjoyment of vegetables can be consolidated.

ECEC staff

Education: a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables.

Training: cooks will complete an online training module, use an online menu planning tool to review their menu and implement the revised menu.

Feedback: cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines and will revise their menu based on this feedback.

Intervention 5
Health curriculum

Children

Curriculum: a series of 16 short (~10–20 min) lessons and hands-on activities delivered during intentional teaching time.

Materials: supporting resources and activities to further familiarise children with vegetables and their senses and a group reward chart to track progress of vegetables tasted.

Ethos and environment

Children

Exposure: a series of 16 snack time occasions where vegetables will be tasted and critical strategies to reinforce children's enjoyment of vegetables can be consolidated.

ECEC staff

Education: a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables. Educators will complete an interactive online training module (~45–55 min) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and planning and implementing a strategy within their centre. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the 8 weeks of the implementation period.

Intervention 6
Health curriculum

Children

Curriculum: a series of 16 short (~10–20 min) lessons and hands-on activities delivered during intentional teaching time.

Zarnowiecki 2021 (Continued)

Materials: supporting resources and activities to further familiarise children with vegetables and their senses and a group reward chart to track progress of vegetables tasted.

Ethos and environment

Children

Exposure: a series of 16 snack time occasions where vegetables will be tasted and critical strategies to reinforce children's enjoyment of vegetables can be consolidated.

ECEC staff

Education: a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables.

Intervention 7
Ethos and environment

ECEC staff

Training: educators will complete an interactive online training module (~45–55 min) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and planning and implementing a strategy within their centre. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the 8 weeks of the implementation period.

Phase 2

Authors hypothesise that the optimised initiative package will include all 3 initiatives.

Outcomes	Outcomes relating to child dietary intake: Phase 1: vegetable intake Phase 2: vegetable intake Outcomes relating to child anthropometric measures: not reported
Starting date	Phase 1: January 2021 Phase 2: January 2022
Contact information	Professor Rebecca K Golley, rebecca.golley@flinders.edu.au
Notes	Phase 1: ACTRN12620001301954 Phase 2: ACTRN12620001323910p

ECEC: early childhood education and care; **RCT:** randomised controlled trial

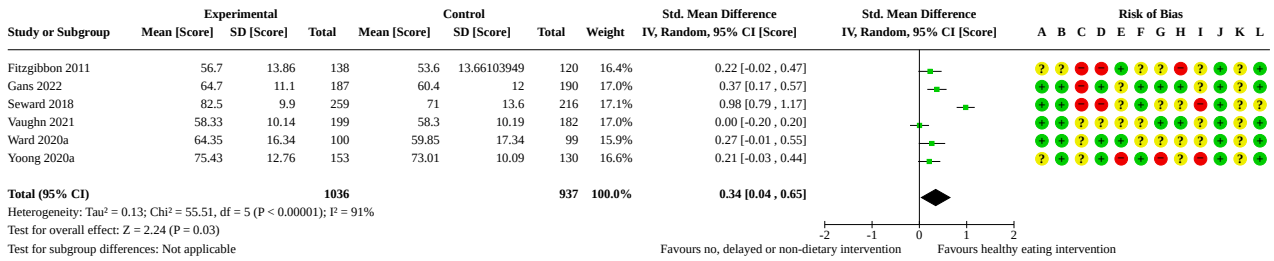
DATA AND ANALYSES

Comparison 1. Diet quality

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Diet quality	6	1973	Std. Mean Difference (IV, Random, 95% CI)	0.34 [0.04, 0.65]
1.2 Diet quality (sensitivity: studies at low overall risk of bias)	3	957	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.03, 0.45]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.3 Diet quality (Health Promoting Schools: curriculum versus no curriculum)	6	1973	Std. Mean Difference (IV, Random, 95% CI)	0.34 [0.04, 0.65]
1.3.1 Curriculum	2	639	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.11, 0.32]
1.3.2 No curriculum	4	1334	Std. Mean Difference (IV, Random, 95% CI)	0.46 [0.08, 0.84]
1.4 Diet quality (SES: low versus high/unclear)	6	1973	Std. Mean Difference (IV, Random, 95% CI)	0.34 [0.04, 0.65]
1.4.1 Low	3	834	Std. Mean Difference (IV, Random, 95% CI)	0.30 [0.16, 0.44]
1.4.2 High/unclear	3	1139	Std. Mean Difference (IV, Random, 95% CI)	0.40 [-0.22, 1.01]
1.5 Diet quality (intervention modality: included face-to-face, telephone and online delivery versus did not include face-to-face, telephone and online delivery)	6	1973	Std. Mean Difference (IV, Random, 95% CI)	0.34 [0.04, 0.65]
1.5.1 Included face-to-face, telephone and online delivery	4	1334	Std. Mean Difference (IV, Random, 95% CI)	0.46 [0.08, 0.84]
1.5.2 Did not include face-to-face, telephone and online delivery	2	639	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.11, 0.32]
1.6 Diet quality (intervention delivery personnel: included healthcare professionals versus did not include healthcare professionals)	6	1973	Std. Mean Difference (IV, Random, 95% CI)	0.34 [0.04, 0.65]
1.6.1 Included healthcare professionals	4	1334	Std. Mean Difference (IV, Random, 95% CI)	0.46 [0.08, 0.84]
1.6.2 Did not include healthcare professionals	2	639	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.11, 0.32]

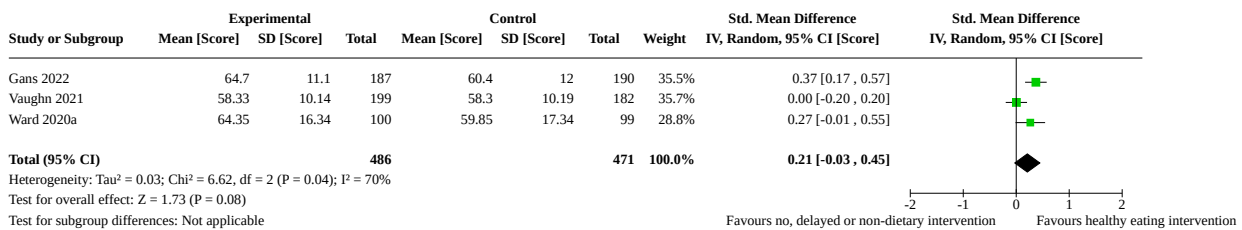
Analysis 1.1. Comparison 1: Diet quality, Outcome 1: Diet quality



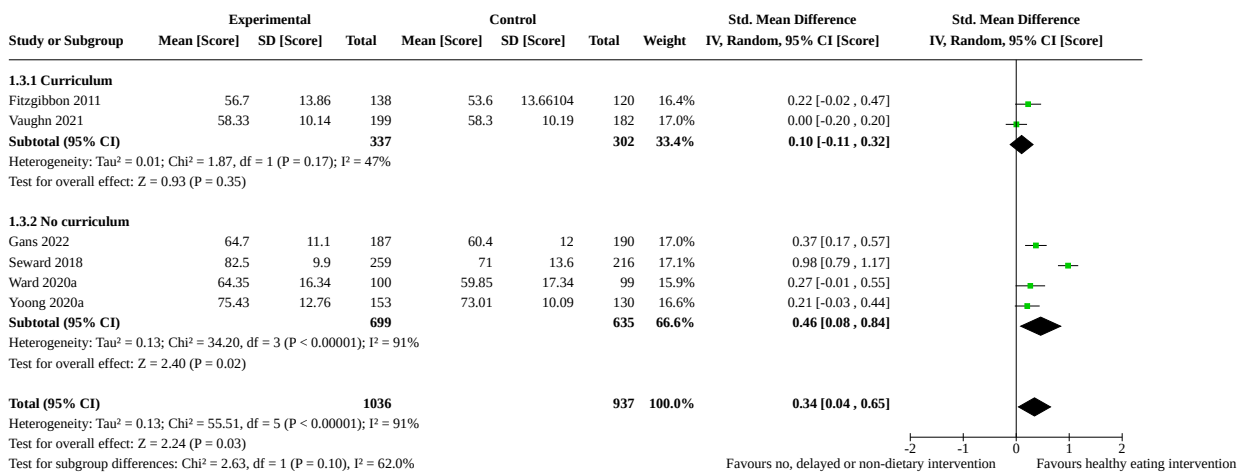
Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Diet outcomes
- (D) Blinding of outcome assessment (detection bias): Diet outcomes
- (E) Incomplete outcome data (attrition bias): Diet outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

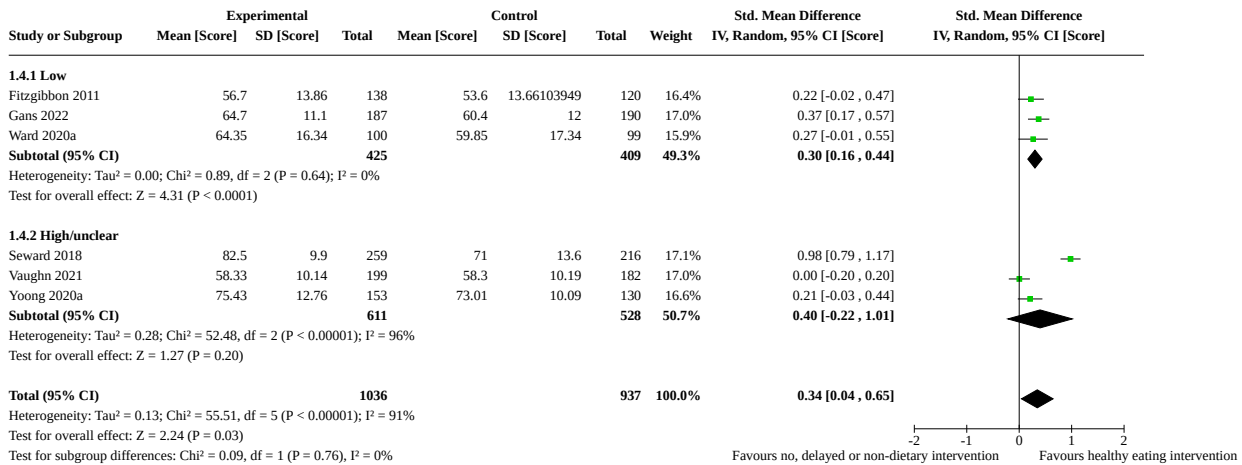
Analysis 1.2. Comparison 1: Diet quality, Outcome 2: Diet quality (sensitivity: studies at low overall risk of bias)



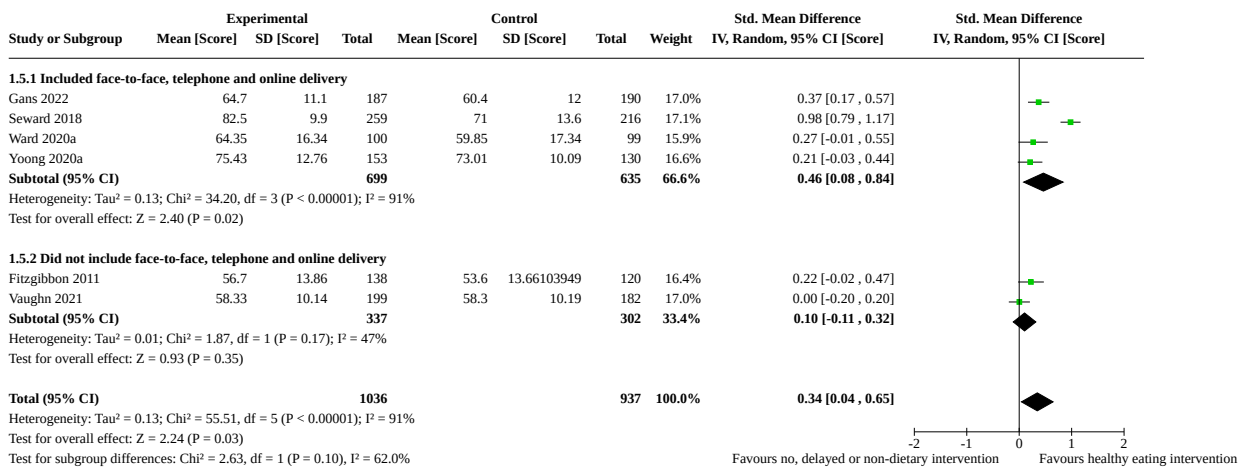
Analysis 1.3. Comparison 1: Diet quality, Outcome 3: Diet quality (Health Promoting Schools: curriculum versus no curriculum)



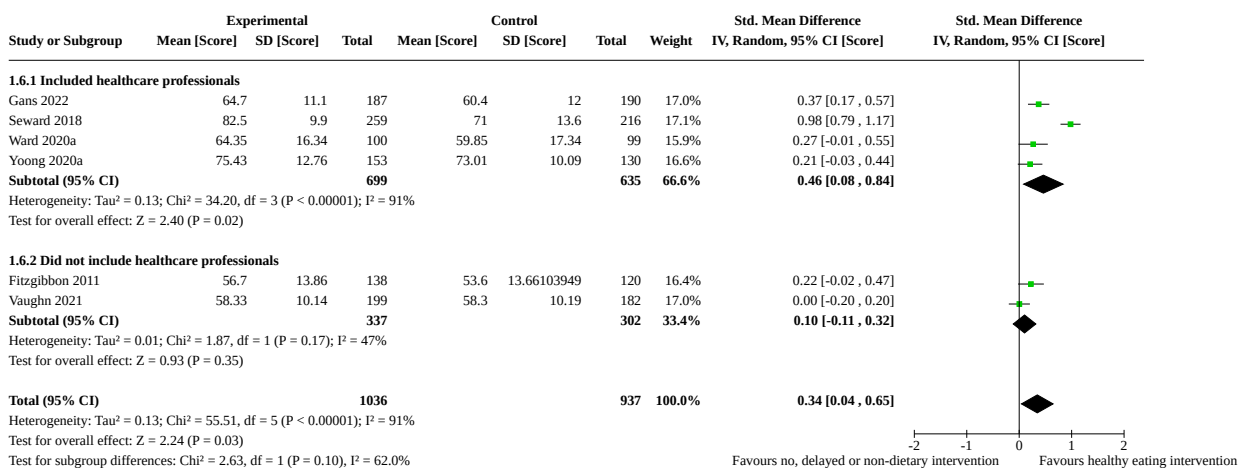
Analysis 1.4. Comparison 1: Diet quality, Outcome 4: Diet quality (SES: low versus high/unclear)



Analysis 1.5. Comparison 1: Diet quality, Outcome 5: Diet quality (intervention modality: included face-to-face, telephone and online delivery versus did not include face-to-face, telephone and online delivery)



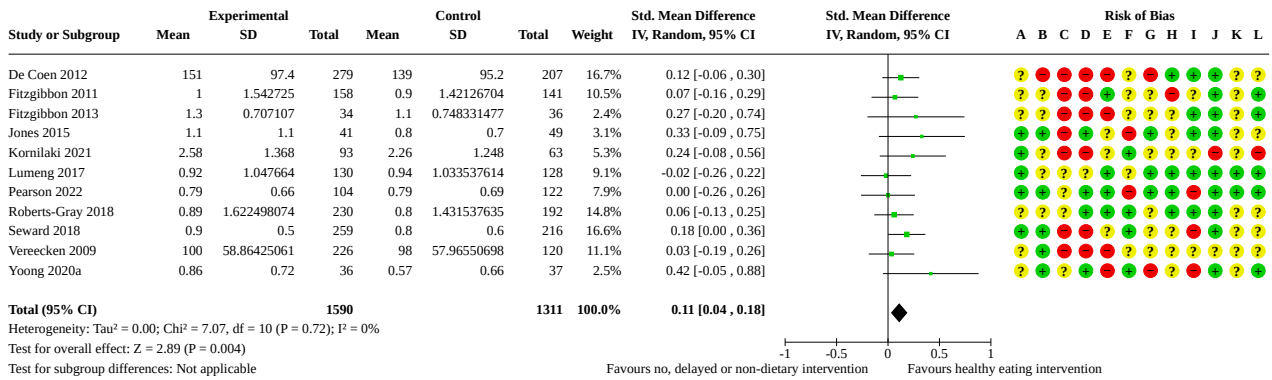
Analysis 1.6. Comparison 1: Diet quality, Outcome 6: Diet quality (intervention delivery personnel: included healthcare professionals versus did not include healthcare professionals)



Comparison 2. Fruit consumption

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Fruit consumption	11	2901	Std. Mean Difference (IV, Random, 95% CI)	0.11 [0.04, 0.18]
2.2 Fruit consumption (sensitivity: studies at low overall risk of bias)	4	996	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.08, 0.17]
2.3 Fruit consumption (Health Promoting Schools: curriculum versus no curriculum)	11	2901	Std. Mean Difference (IV, Random, 95% CI)	0.11 [0.04, 0.18]
2.3.1 Curriculum	7	2037	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.01, 0.17]
2.3.2 No curriculum	4	864	Std. Mean Difference (IV, Random, 95% CI)	0.17 [0.03, 0.32]
2.4 Fruit consumption (SES: low versus high/unclear)	11	2901	Std. Mean Difference (IV, Random, 95% CI)	0.11 [0.04, 0.18]
2.4.1 Low	4	717	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.06, 0.23]
2.4.2 High/unclear	7	2184	Std. Mean Difference (IV, Random, 95% CI)	0.12 [0.03, 0.20]
2.5 Fruit consumption (study size: small (< 400 participants) versus large (≥ 400 participants))	11	2901	Std. Mean Difference (IV, Random, 95% CI)	0.11 [0.04, 0.18]
2.5.1 Small (< 400 participants)	8	1518	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.01, 0.20]
2.5.2 Large (≥ 400 participants)	3	1383	Std. Mean Difference (IV, Random, 95% CI)	0.12 [0.02, 0.23]

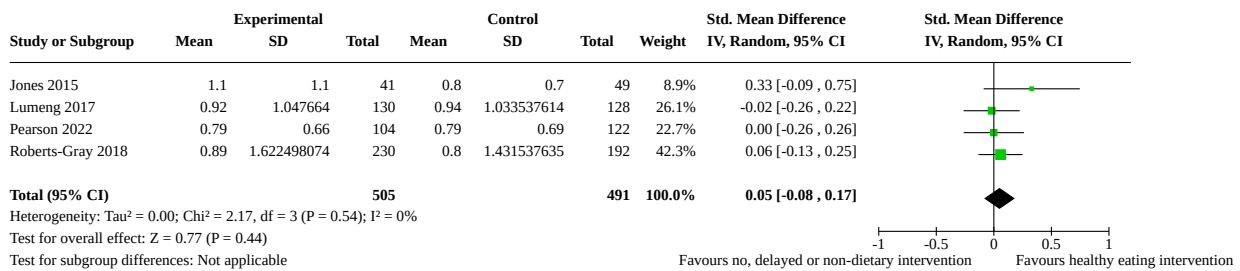
Analysis 2.1. Comparison 2: Fruit consumption, Outcome 1: Fruit consumption



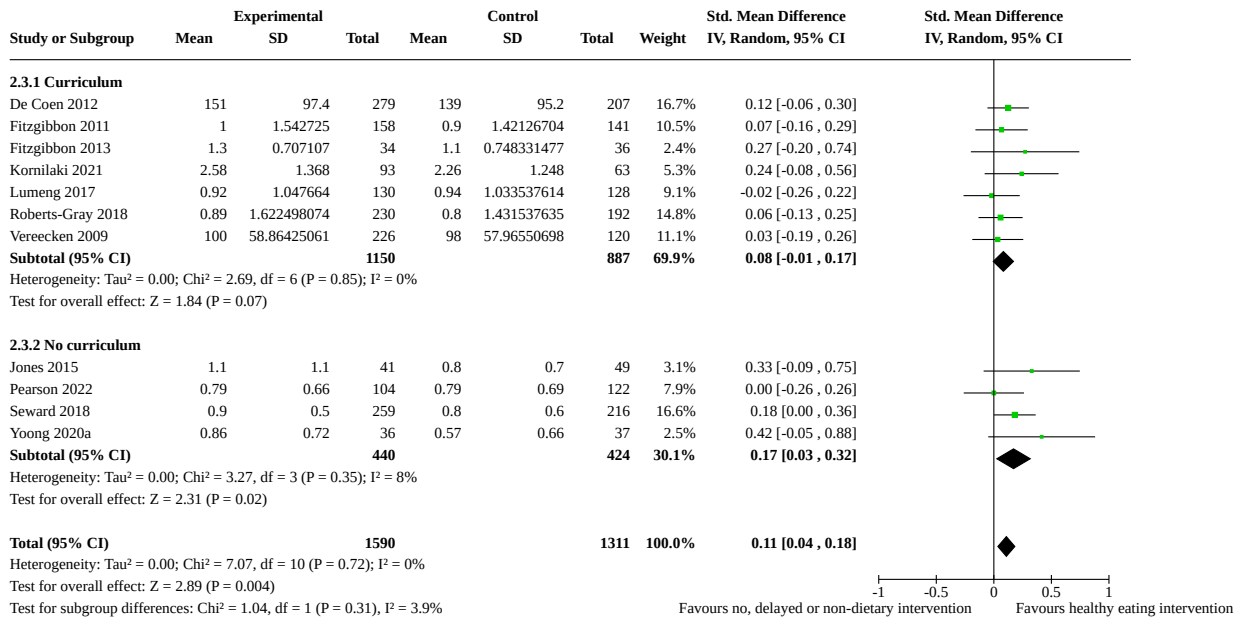
Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Diet outcomes
- (D) Blinding of outcome assessment (detection bias): Diet outcomes
- (E) Incomplete outcome data (attrition bias): Diet outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

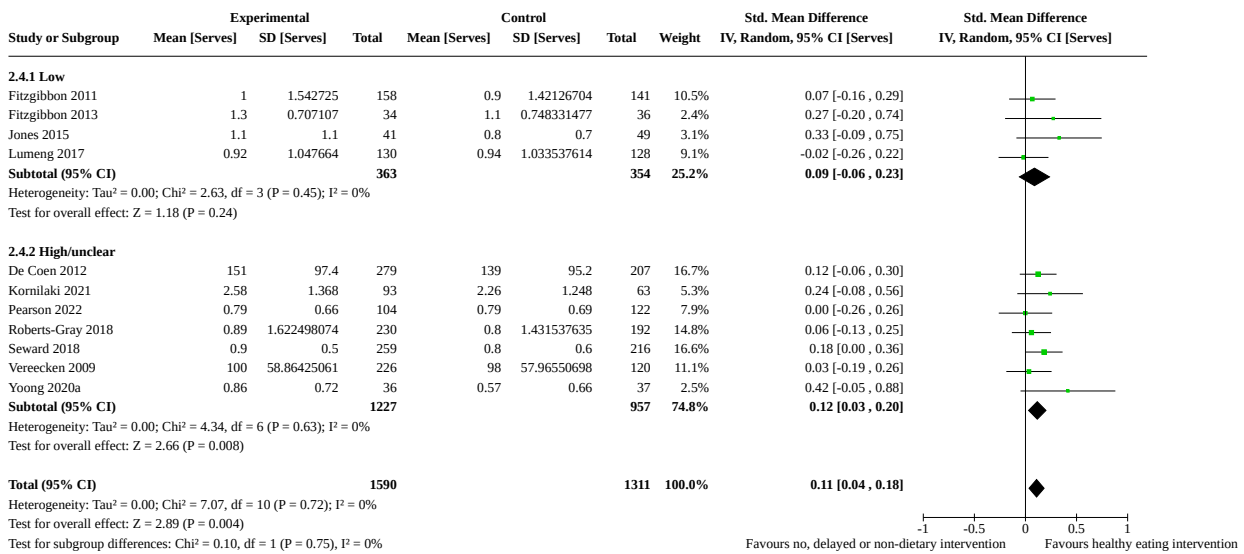
Analysis 2.2. Comparison 2: Fruit consumption, Outcome 2: Fruit consumption (sensitivity: studies at low overall risk of bias)



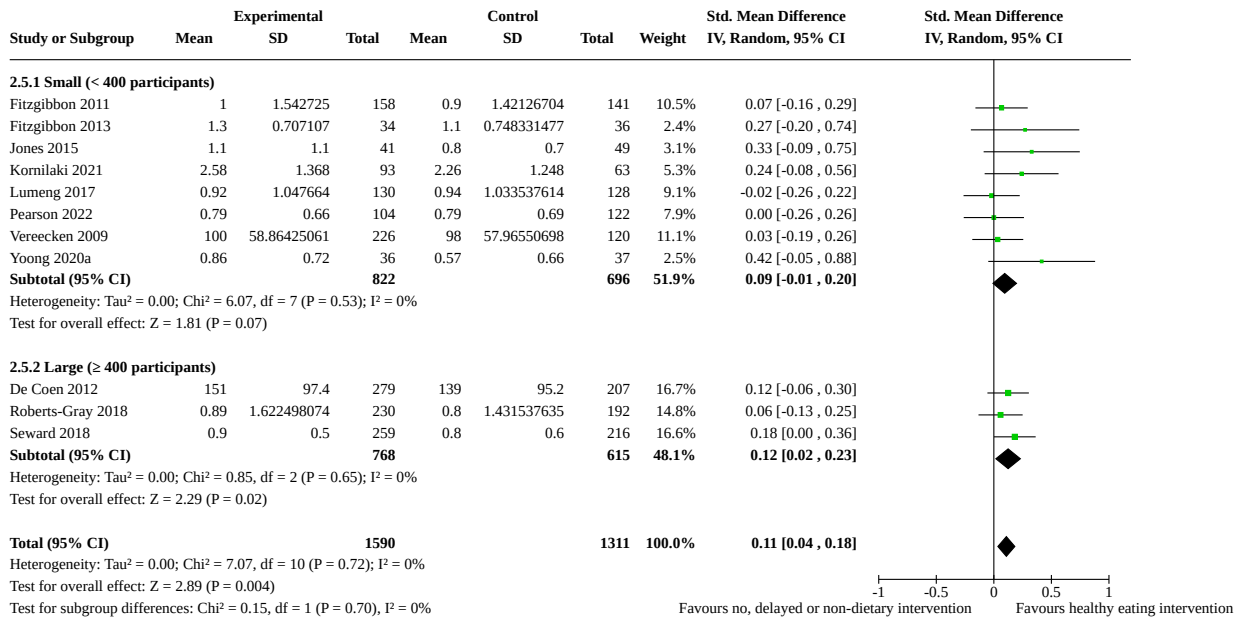
Analysis 2.3. Comparison 2: Fruit consumption, Outcome 3: Fruit consumption (Health Promoting Schools: curriculum versus no curriculum)



Analysis 2.4. Comparison 2: Fruit consumption, Outcome 4: Fruit consumption (SES: low versus high/unclear)



Analysis 2.5. Comparison 2: Fruit consumption, Outcome 5: Fruit consumption (study size: small (< 400 participants) versus large (≥ 400 participants))

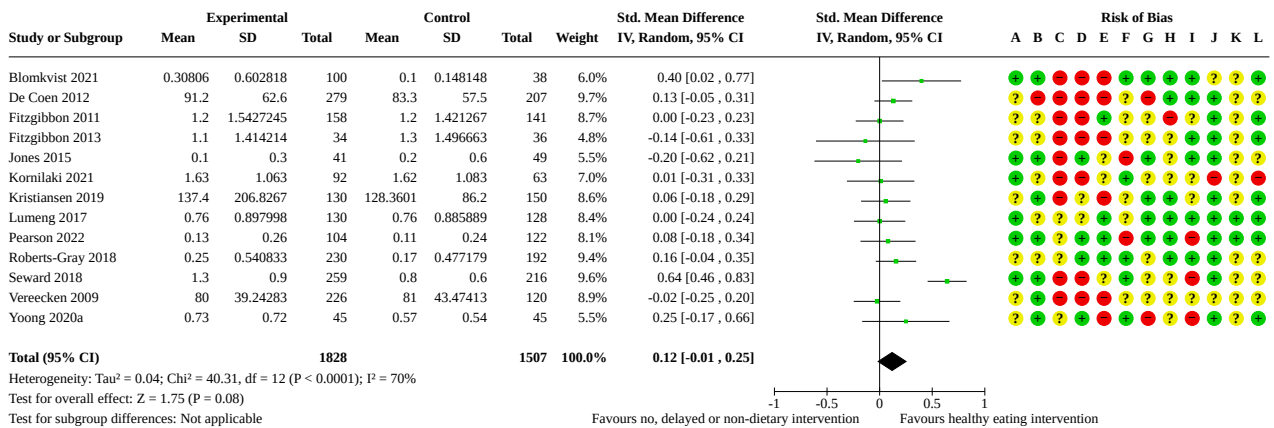


Comparison 3. Vegetable consumption

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Vegetable consumption	13	3335	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.01, 0.25]
3.2 Vegetable consumption (sensitivity: studies at low overall risk of bias)	5	1276	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.05, 0.17]
3.3 Vegetable consumption (Health Promoting Schools: curriculum versus no curriculum)	13	3335	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.01, 0.25]
3.3.1 Curriculum	9	2400	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.01, 0.16]
3.3.2 No curriculum	4	935	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.19, 0.60]
3.4 Vegetable consumption (Health Promoting Schools: partnerships versus no partnerships)	13	3335	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.01, 0.25]
3.4.1 Partnerships	11	3042	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.04, 0.25]
3.4.2 No partnerships	2	293	Std. Mean Difference (IV, Random, 95% CI)	0.19 [-0.19, 0.57]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.5 Vegetable consumption (SES: low versus high/unclear)	13	3335	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.01, 0.25]
3.5.1 Low	4	717	Std. Mean Difference (IV, Random, 95% CI)	-0.04 [-0.19, 0.11]
3.5.2 High/unclear	9	2618	Std. Mean Difference (IV, Random, 95% CI)	0.19 [0.03, 0.35]
3.6 Vegetable consumption (study size: small (< 400 participants) versus large (≥ 400 participants))	13	3335	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.01, 0.25]
3.6.1 Small (< 400 participants)	10	1952	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.06, 0.13]
3.6.2 Large (≥ 400 participants)	3	1383	Std. Mean Difference (IV, Random, 95% CI)	0.31 [-0.02, 0.64]

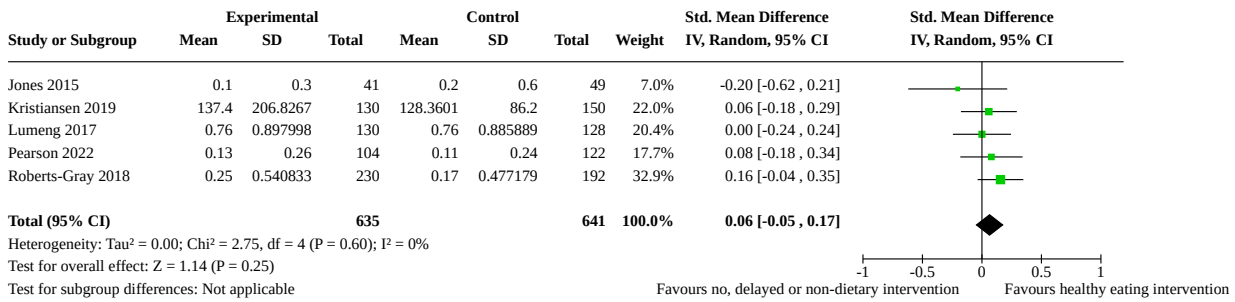
Analysis 3.1. Comparison 3: Vegetable consumption, Outcome 1: Vegetable consumption



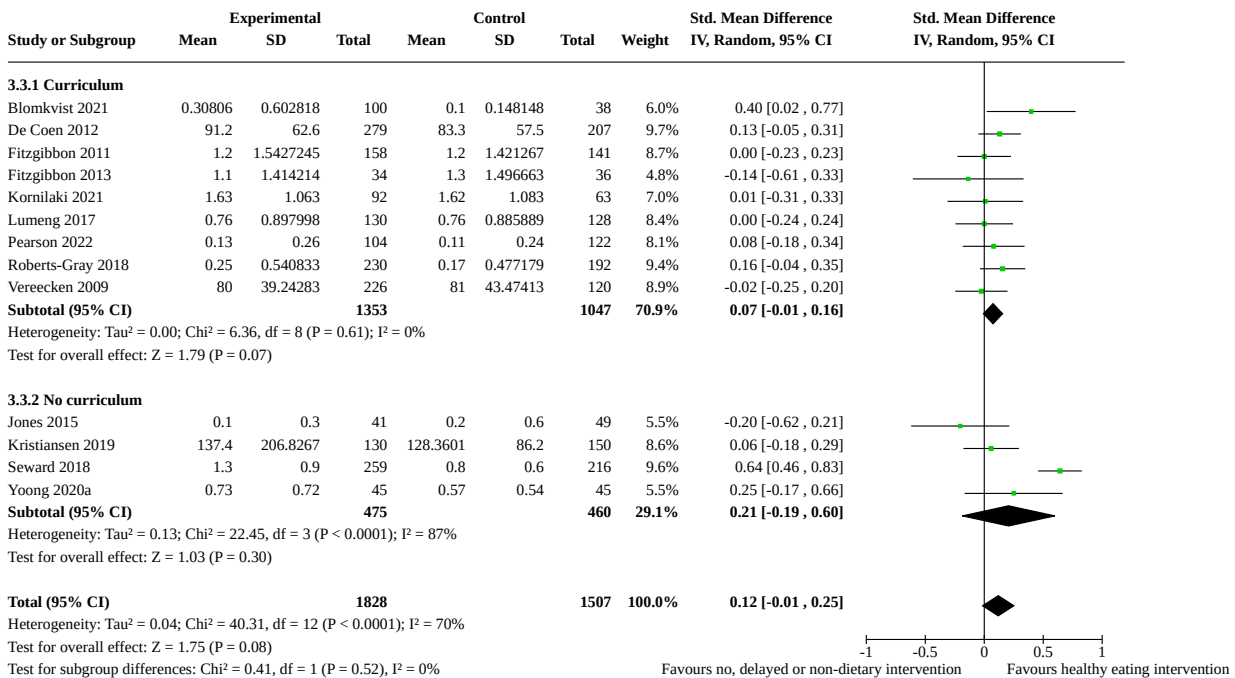
Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Diet outcomes
- (D) Blinding of outcome assessment (detection bias): Diet outcomes
- (E) Incomplete outcome data (attrition bias): Diet outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

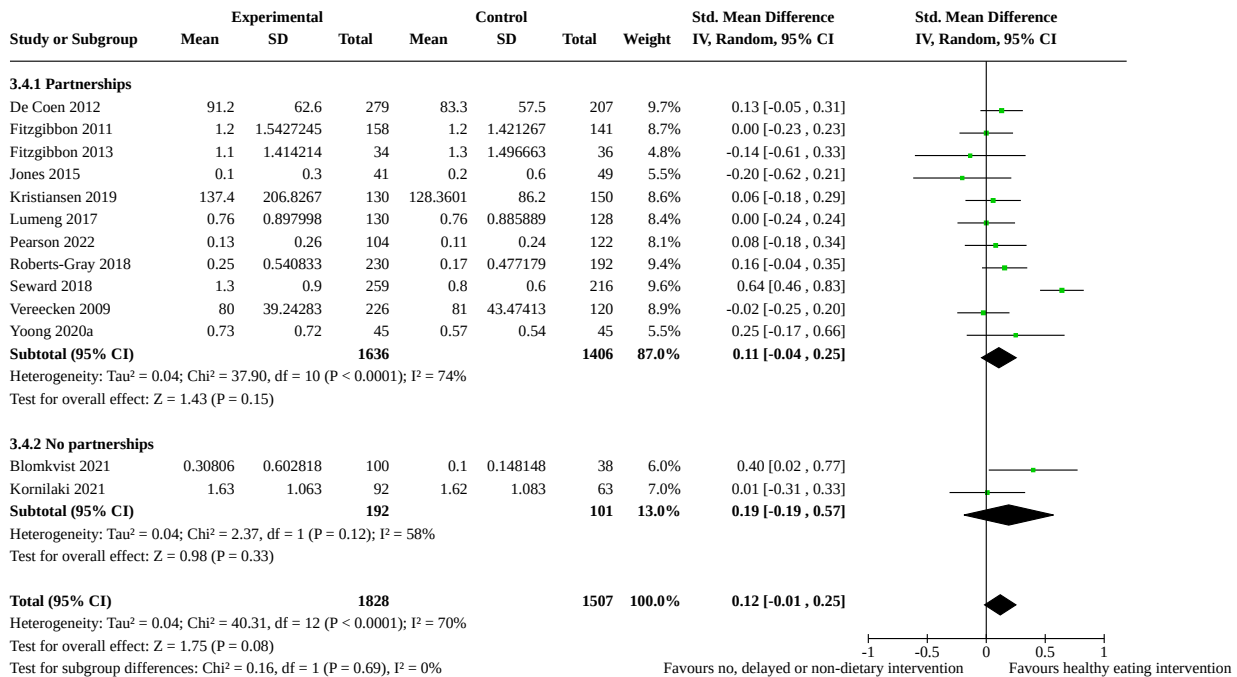
Analysis 3.2. Comparison 3: Vegetable consumption, Outcome 2: Vegetable consumption (sensitivity: studies at low overall risk of bias)



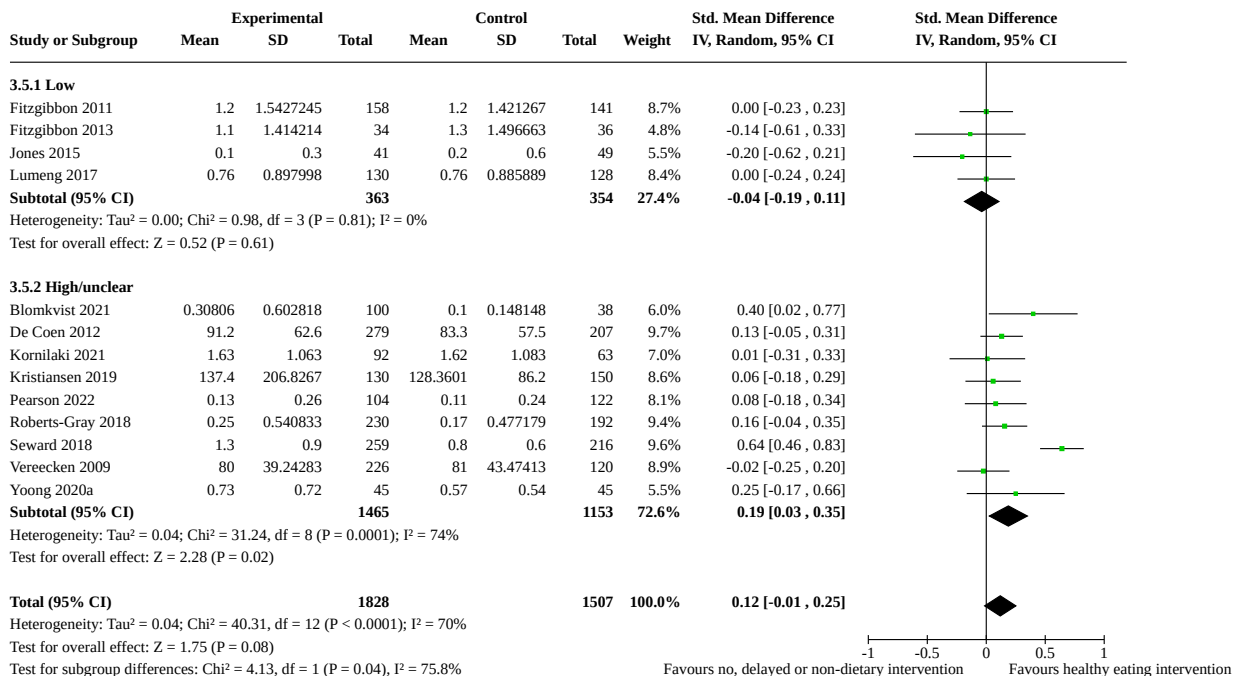
Analysis 3.3. Comparison 3: Vegetable consumption, Outcome 3: Vegetable consumption (Health Promoting Schools: curriculum versus no curriculum)



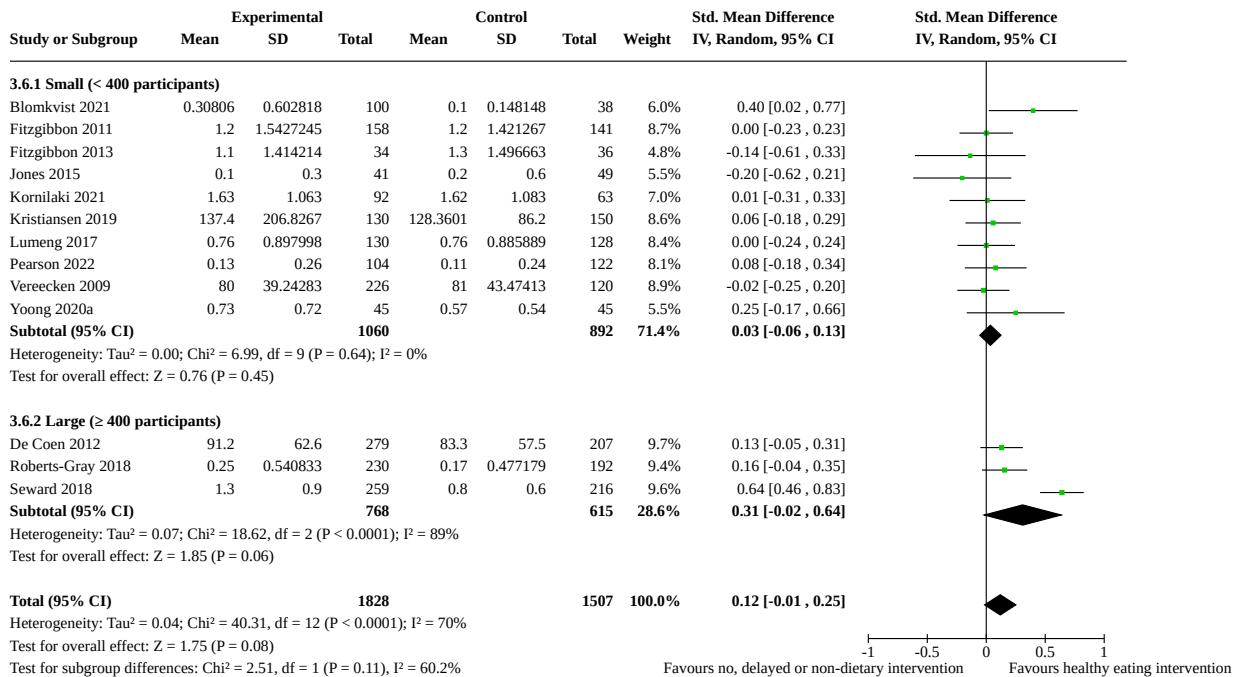
Analysis 3.4. Comparison 3: Vegetable consumption, Outcome 4: Vegetable consumption (Health Promoting Schools: partnerships versus no partnerships)



Analysis 3.5. Comparison 3: Vegetable consumption, Outcome 5: Vegetable consumption (SES: low versus high/unclear)



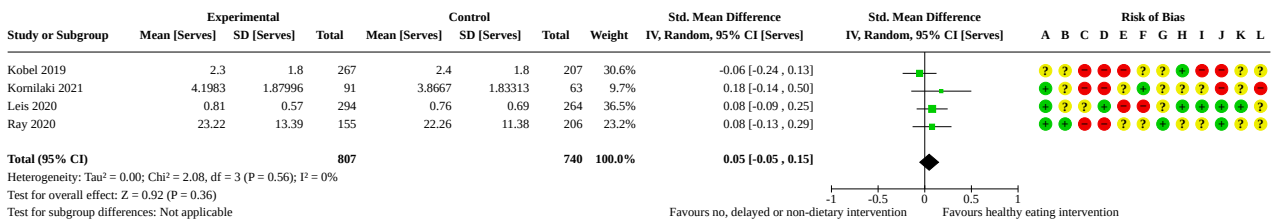
Analysis 3.6. Comparison 3: Vegetable consumption, Outcome 6: Vegetable consumption (study size: small (< 400 participants) versus large (≥ 400 participants))



Comparison 4. Fruit and vegetable consumption

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Fruit and vegetable consumption	4	1547	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.05, 0.15]
4.2 Fruit and vegetable consumption (sensitivity: studies at low overall risk of bias)	2	919	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.05, 0.21]

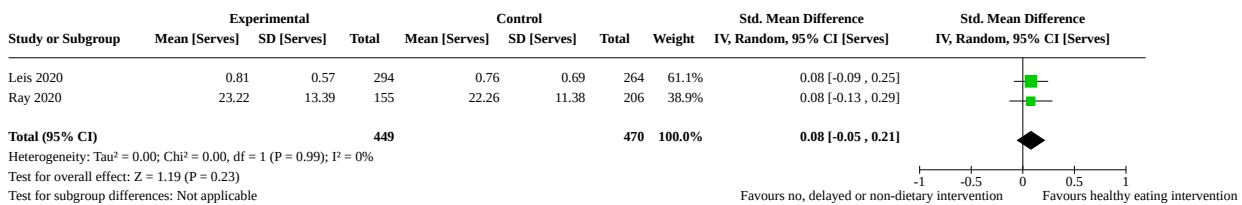
Analysis 4.1. Comparison 4: Fruit and vegetable consumption, Outcome 1: Fruit and vegetable consumption



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Diet outcomes
- (D) Blinding of outcome assessment (detection bias): Diet outcomes
- (E) Incomplete outcome data (attrition bias): Diet outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

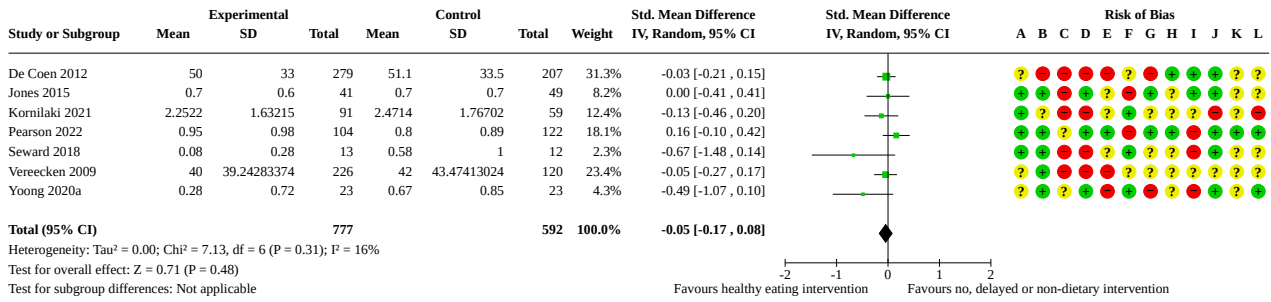
Analysis 4.2. Comparison 4: Fruit and vegetable consumption, Outcome 2: Fruit and vegetable consumption (sensitivity: studies at low overall risk of bias)



Comparison 5. Non-core foods consumption

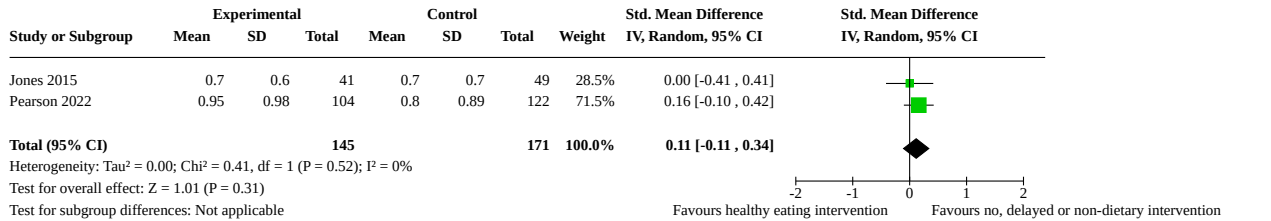
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Non-core foods (i.e. less healthy/discretionary) consumption	7	1369	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.17, 0.08]
5.2 Non-core foods (i.e. less healthy/discretionary) consumption (sensitivity: studies at low overall risk of bias)	2	316	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.11, 0.34]
5.3 Non-core foods (i.e. less healthy/discretionary) consumption (Health Promoting Schools: curriculum versus no curriculum)	7	1369	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.17, 0.08]
5.3.1 Curriculum	3	982	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.18, 0.08]
5.3.2 No curriculum	4	387	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.48, 0.22]

Analysis 5.1. Comparison 5: Non-core foods consumption, Outcome 1: Non-core foods (i.e. less healthy/discretionary) consumption

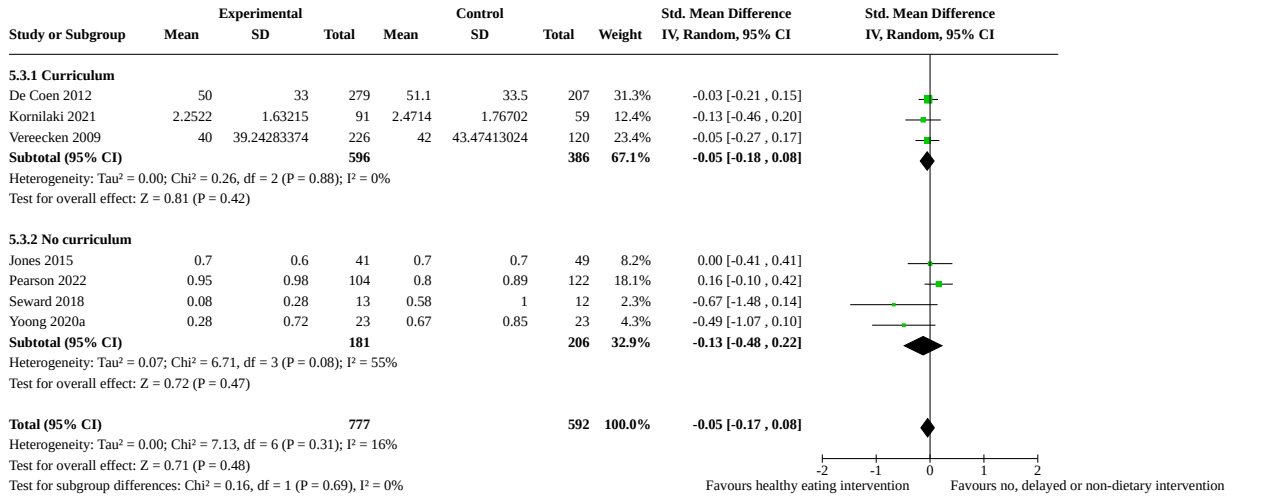


Risk of bias legend
 (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias): Diet outcomes
 (D) Blinding of outcome assessment (detection bias): Diet outcomes
 (E) Incomplete outcome data (attrition bias): Diet outcomes
 (F) Selective reporting (reporting bias)
 (G) Recruitment bias
 (H) Baseline imbalance
 (I) Loss of clusters
 (J) Incorrect analysis
 (K) Contamination
 (L) Other bias

Analysis 5.2. Comparison 5: Non-core foods consumption, Outcome 2: Non-core foods (i.e. less healthy/discretionary) consumption (sensitivity: studies at low overall risk of bias)



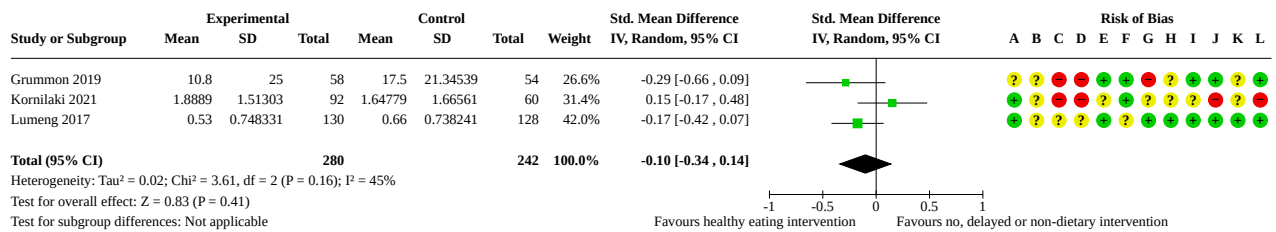
Analysis 5.3. Comparison 5: Non-core foods consumption, Outcome 3: Non-core foods (i.e. less healthy/discretionary) consumption (Health Promoting Schools: curriculum versus no curriculum)



Comparison 6. Sugar-sweetened beverage consumption

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Sugar-sweetened beverage consumption	3	522	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.34, 0.14]

Analysis 6.1. Comparison 6: Sugar-sweetened beverage consumption, Outcome 1: Sugar-sweetened beverage consumption



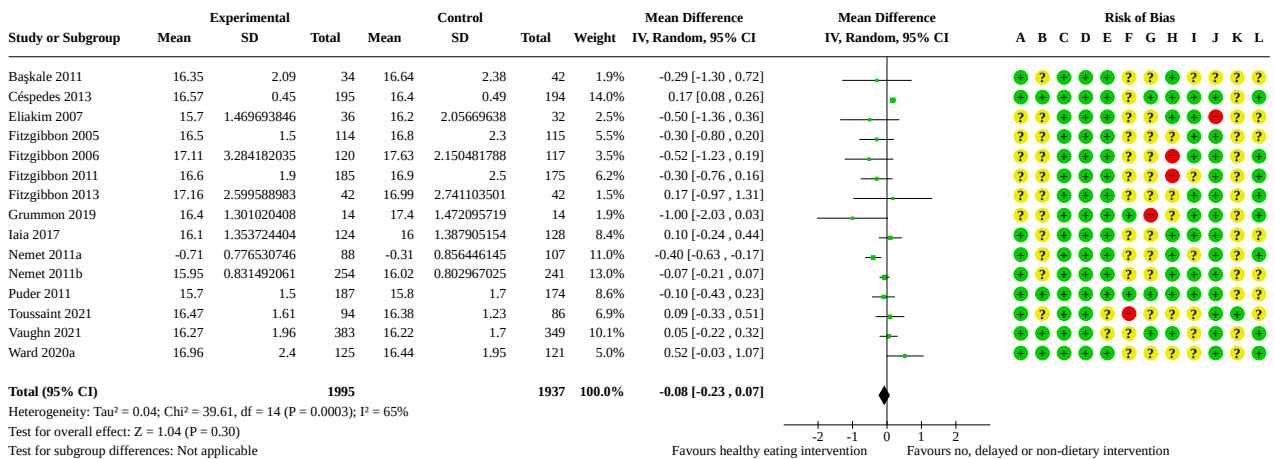
Risk of bias legend
 (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias): Diet outcomes
 (D) Blinding of outcome assessment (detection bias): Diet outcomes
 (E) Incomplete outcome data (attrition bias): Diet outcomes
 (F) Selective reporting (reporting bias)
 (G) Recruitment bias
 (H) Baseline imbalance
 (I) Loss of clusters
 (J) Incorrect analysis
 (K) Contamination
 (L) Other bias

Comparison 7. BMI

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 BMI	15	3932	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.23, 0.07]
7.2 BMI (sensitivity: studies with no industry funding)	13	3319	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.28, 0.07]
7.3 BMI (Health Promoting Schools: curriculum versus no curriculum)	15	3932	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.23, 0.07]
7.3.1 Curriculum	13	3506	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.29, 0.03]
7.3.2 No curriculum	2	426	Mean Difference (IV, Random, 95% CI)	0.27 [-0.15, 0.68]
7.4 BMI (SES: low versus high/unclear)	15	3932	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.23, 0.07]

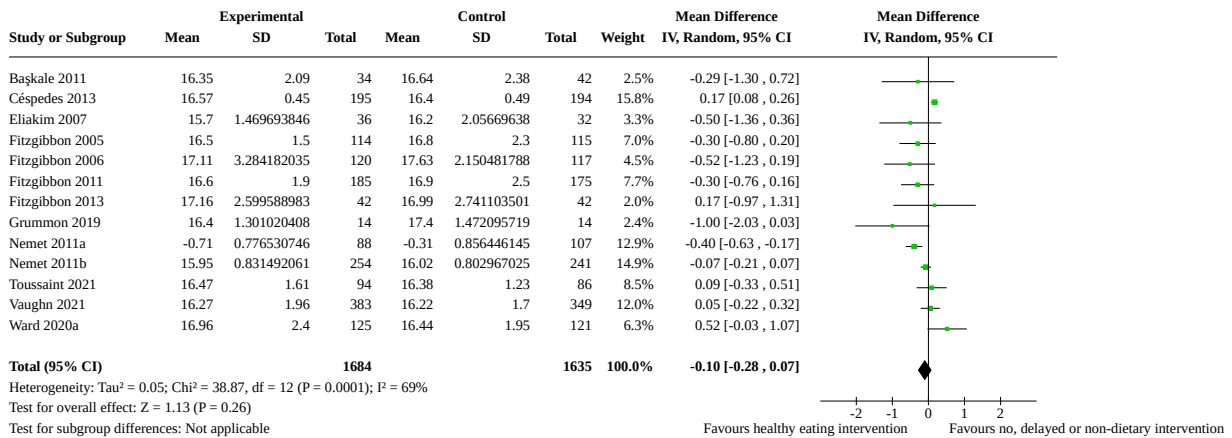
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.4.1 Low	11	2804	Mean Difference (IV, Random, 95% CI)	-0.10 [-0.29, 0.08]
7.4.2 High/unclear	4	1128	Mean Difference (IV, Random, 95% CI)	0.02 [-0.17, 0.22]
7.5 BMI (study size: small (< 400 participants) versus large (≥ 400 participants))	15	3932	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.23, 0.07]
7.5.1 Small (< 400 participants)	13	2705	Mean Difference (IV, Random, 95% CI)	-0.11 [-0.31, 0.09]
7.5.2 Large (≥ 400 participants)	2	1227	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.17, 0.08]

Analysis 7.1. Comparison 7: BMI, Outcome 1: BMI

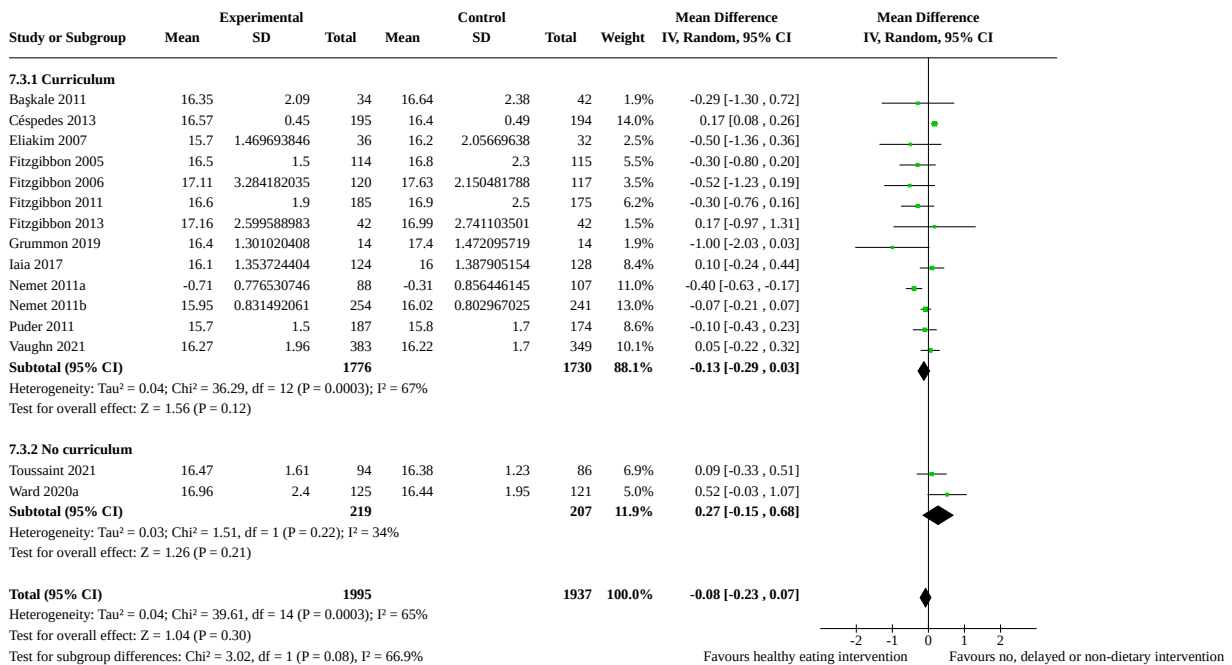


- Risk of bias legend**
- (A) Random sequence generation (selection bias)
 - (B) Allocation concealment (selection bias)
 - (C) Blinding of participants and personnel (performance bias): Physical outcomes
 - (D) Blinding of outcome assessment (detection bias): Physical outcomes
 - (E) Incomplete outcome data (attrition bias): Physical outcomes
 - (F) Selective reporting (reporting bias)
 - (G) Recruitment bias
 - (H) Baseline imbalance
 - (I) Loss of clusters
 - (J) Incorrect analysis
 - (K) Contamination
 - (L) Other bias

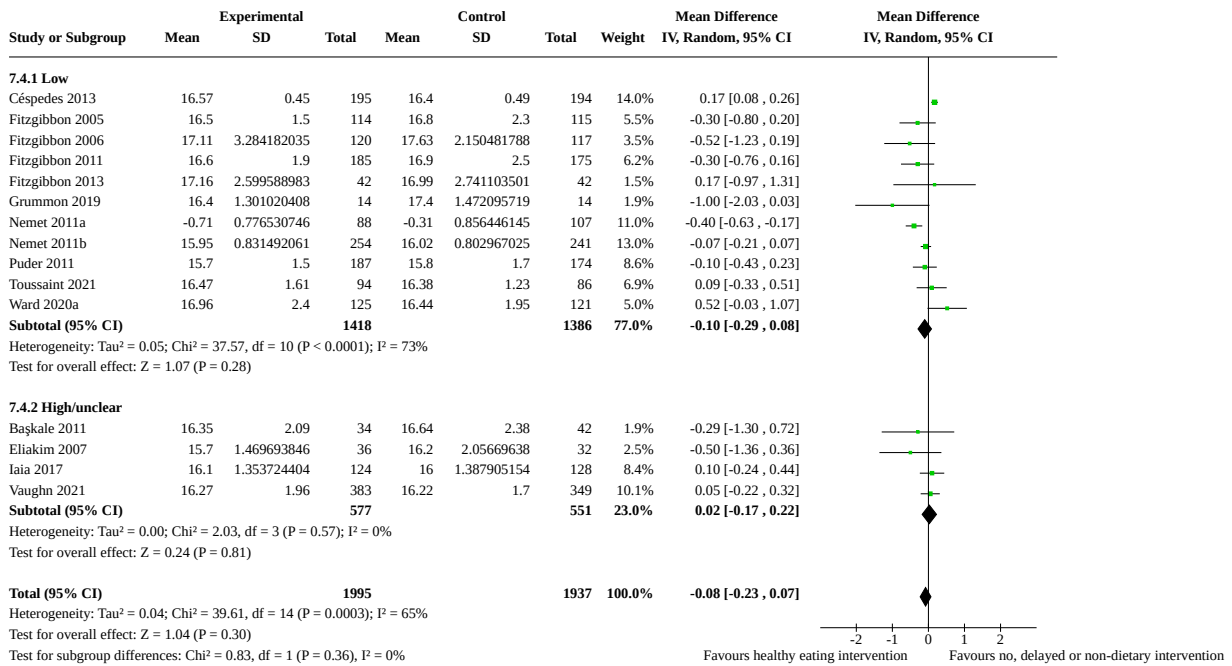
Analysis 7.2. Comparison 7: BMI, Outcome 2: BMI (sensitivity: studies with no industry funding)



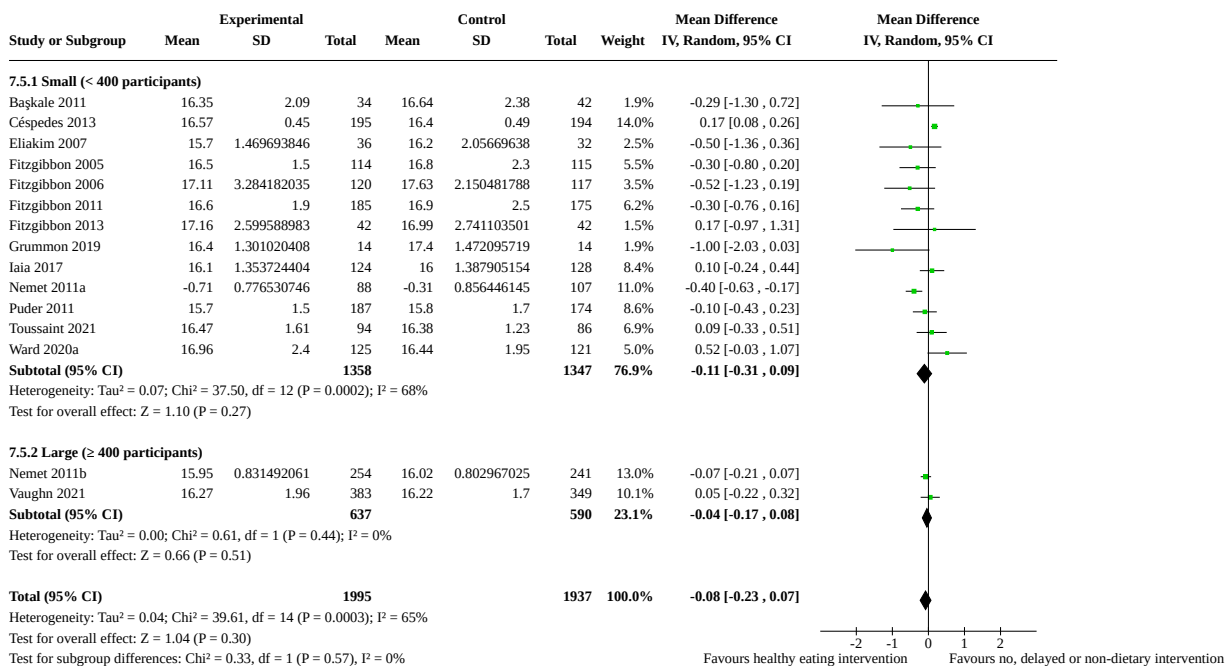
Analysis 7.3. Comparison 7: BMI, Outcome 3: BMI (Health Promoting Schools: curriculum versus no curriculum)



Analysis 7.4. Comparison 7: BMI, Outcome 4: BMI (SES: low versus high/unclear)



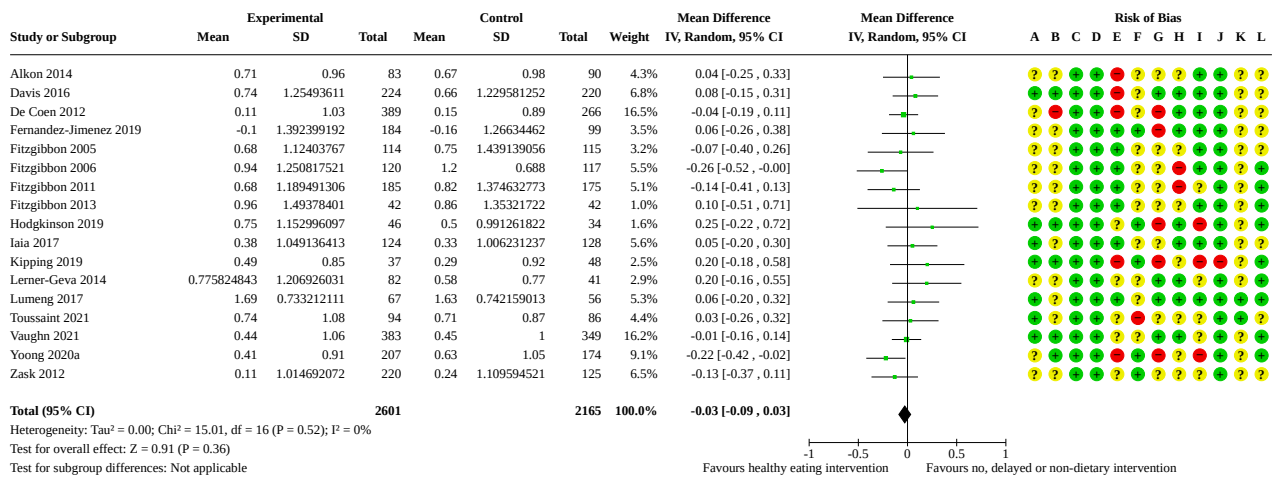
Analysis 7.5. Comparison 7: BMI, Outcome 5: BMI (study size: small (< 400 participants) versus large (≥ 400 participants))



Comparison 8. BMI z-score

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 BMI z-score	17	4766	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.03]
8.2 BMI z-score (sensitivity: studies at low overall risk of bias)	14	3645	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.08, 0.06]
8.3 BMI z-score (Health Promoting Schools: curriculum versus no curriculum)	17	4766	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.03]
8.3.1 Curriculum	12	3867	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.04]
8.3.2 No curriculum	5	899	Mean Difference (IV, Random, 95% CI)	0.00 [-0.17, 0.18]
8.4 BMI z-score (SES: low versus high/unclear)	17	4766	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.03]
8.4.1 Low	10	2193	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.11, 0.08]
8.4.2 High/unclear	7	2573	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.13, 0.06]
8.5 BMI z-score (study size: small (< 400 participants) versus large (≥ 400 participants))	17	4766	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.03]
8.5.1 Small (< 400 participants)	14	2935	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.12, 0.04]
8.5.2 Large (≥ 400 participants)	3	1831	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.10, 0.09]

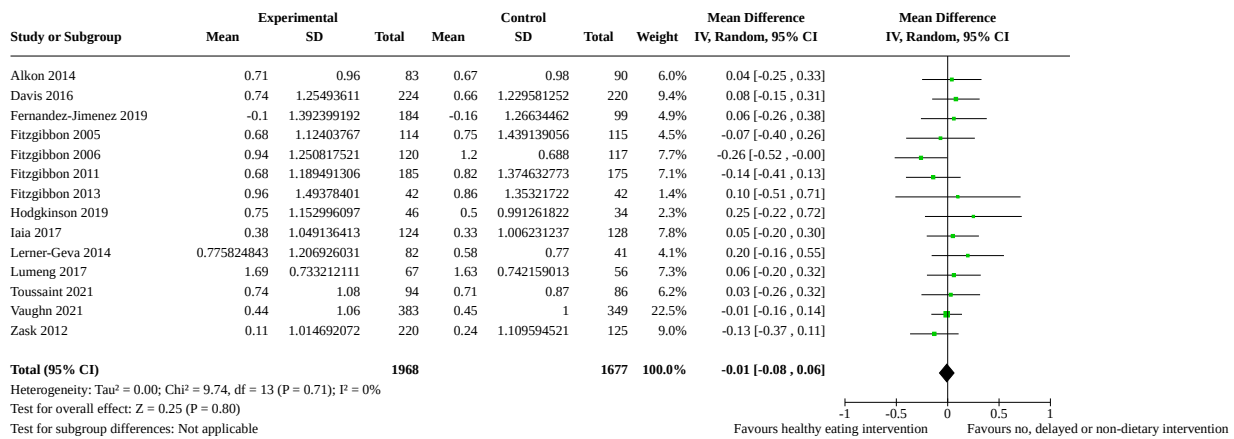
Analysis 8.1. Comparison 8: BMI z-score, Outcome 1: BMI z-score



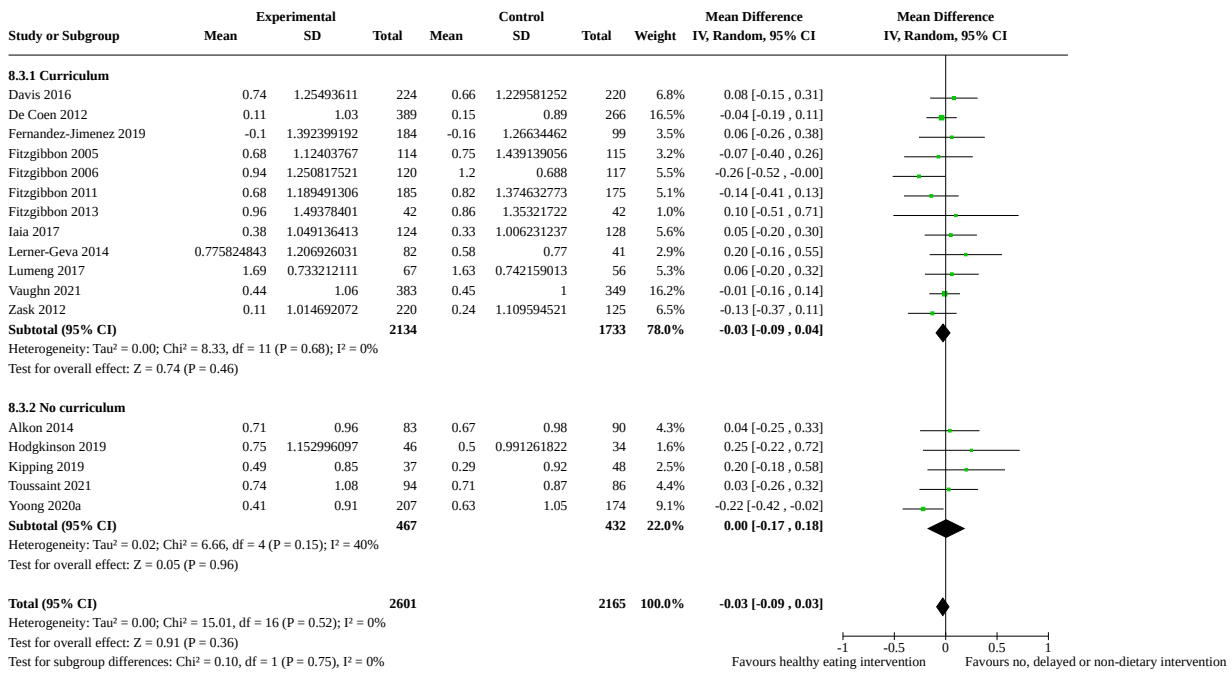
Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Physical outcomes
- (D) Blinding of outcome assessment (detection bias): Physical outcomes
- (E) Incomplete outcome data (attrition bias): Physical outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

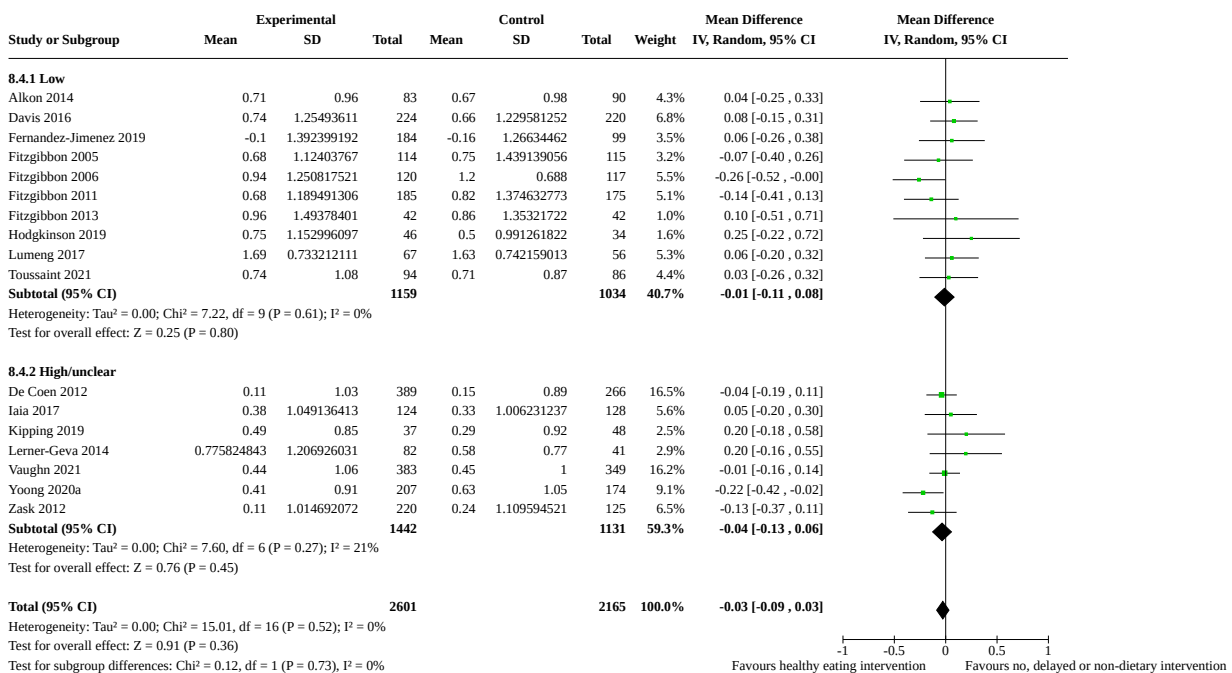
Analysis 8.2. Comparison 8: BMI z-score, Outcome 2: BMI z-score (sensitivity: studies at low overall risk of bias)



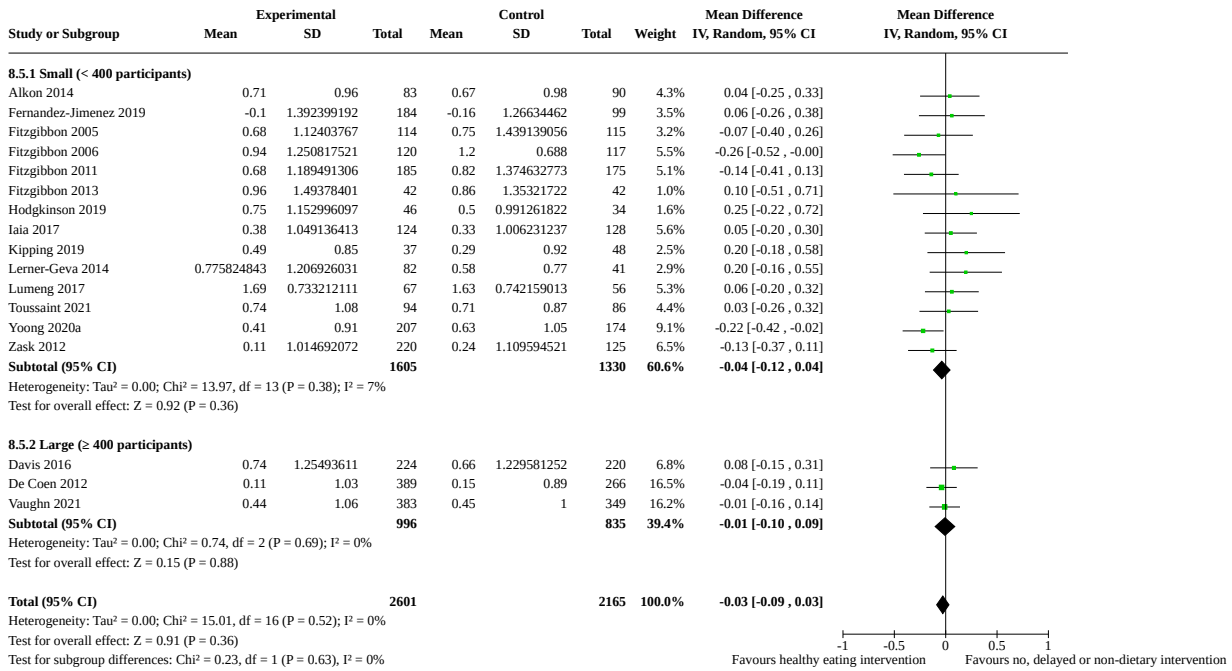
Analysis 8.3. Comparison 8: BMI z-score, Outcome 3: BMI z-score (Health Promoting Schools: curriculum versus no curriculum)



Analysis 8.4. Comparison 8: BMI z-score, Outcome 4: BMI z-score (SES: low versus high/unclear)



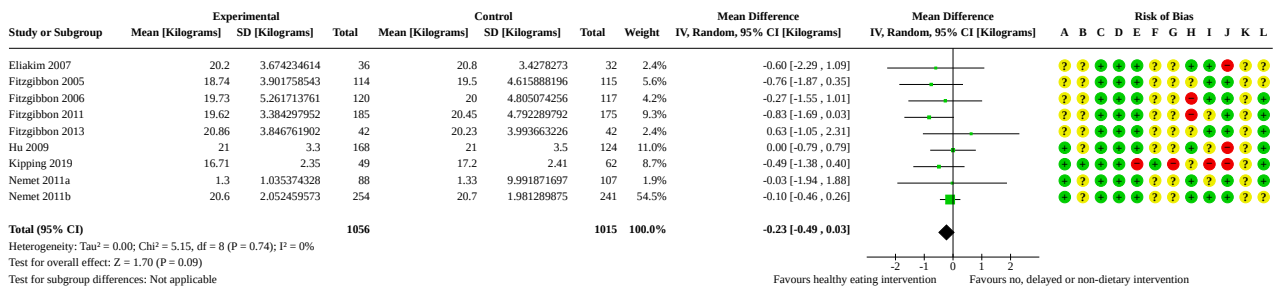
Analysis 8.5. Comparison 8: BMI z-score, Outcome 5: BMI z-score (study size: small (< 400 participants) versus large (≥ 400 participants))



Comparison 9. Absolute weight (kg)

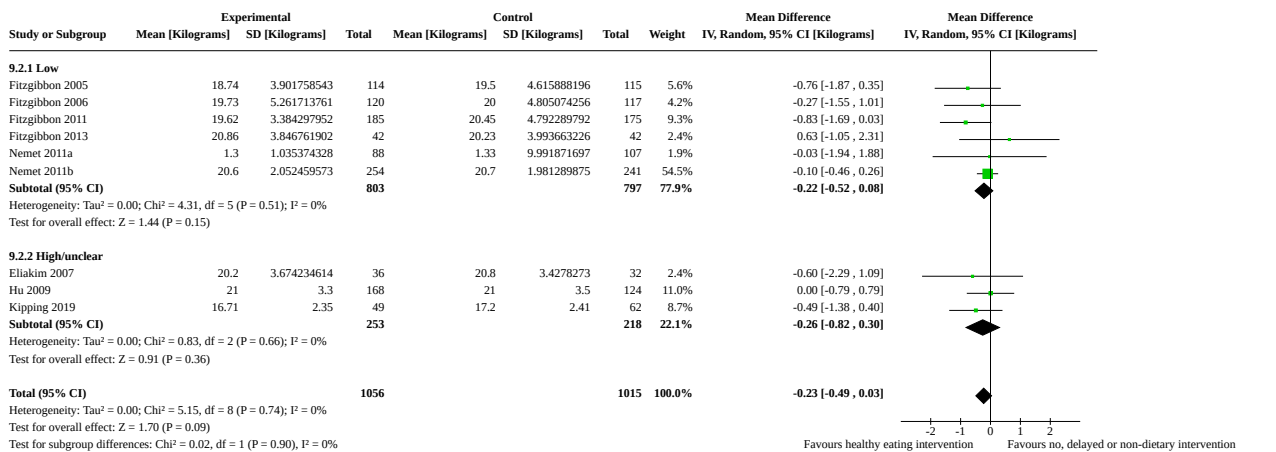
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Absolute weight (kg)	9	2071	Mean Difference (IV, Random, 95% CI)	-0.23 [-0.49, 0.03]
9.2 Absolute weight (kg) (SES: low versus high/unclear)	9	2071	Mean Difference (IV, Random, 95% CI)	-0.23 [-0.49, 0.03]
9.2.1 Low	6	1600	Mean Difference (IV, Random, 95% CI)	-0.22 [-0.52, 0.08]
9.2.2 High/unclear	3	471	Mean Difference (IV, Random, 95% CI)	-0.26 [-0.82, 0.30]

Analysis 9.1. Comparison 9: Absolute weight (kg), Outcome 1: Absolute weight (kg)



Risk of bias legend
 (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias): Physical outcomes
 (D) Blinding of outcome assessment (detection bias): Physical outcomes
 (E) Incomplete outcome data (attrition bias): Physical outcomes
 (F) Selective reporting (reporting bias)
 (G) Recruitment bias
 (H) Baseline imbalance
 (I) Loss of clusters
 (J) Incorrect analysis
 (K) Contamination
 (L) Other bias

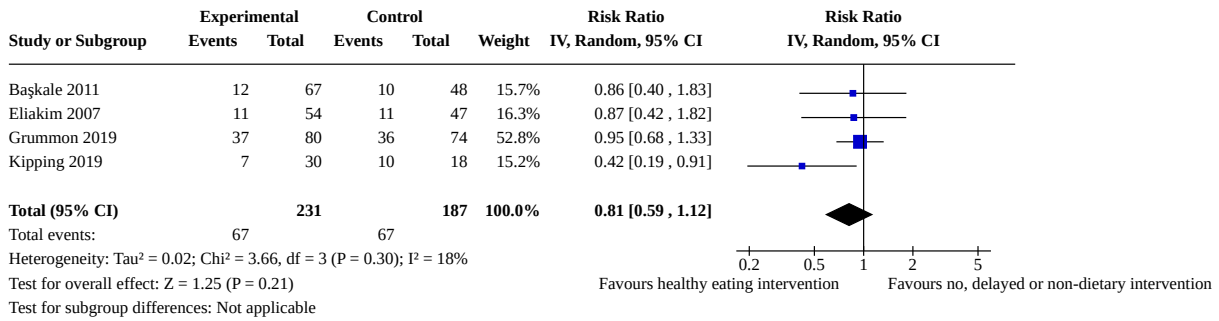
Analysis 9.2. Comparison 9: Absolute weight (kg), Outcome 2: Absolute weight (kg) (SES: low versus high/unclear)



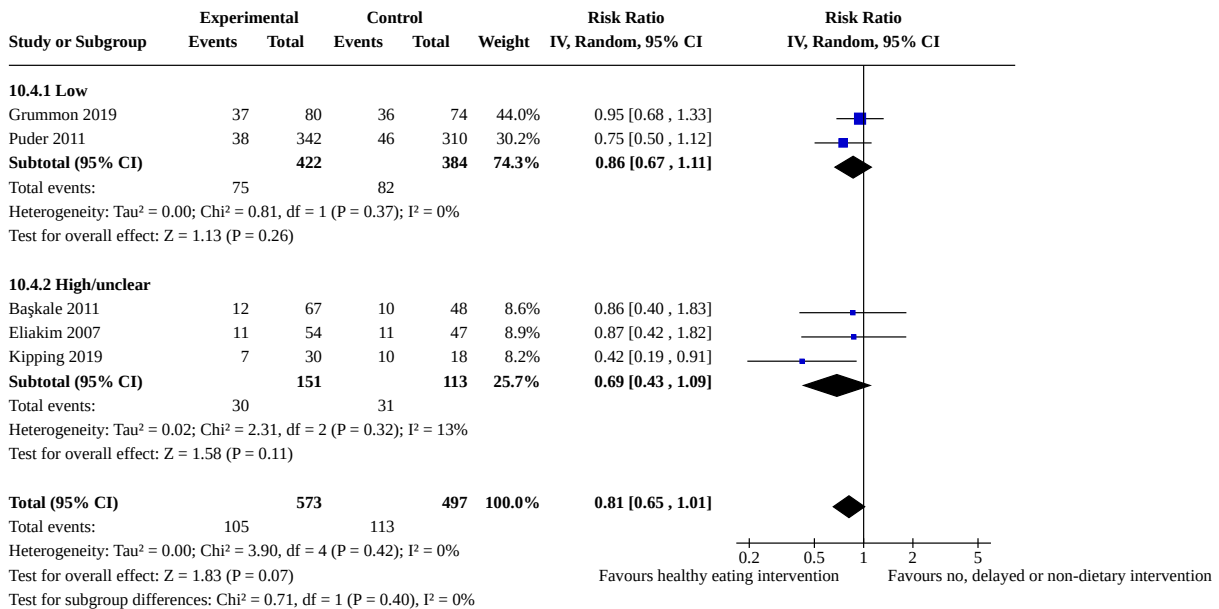
Comparison 10. Overweight and obesity

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Overweight and obesity	5	1070	Risk Ratio (IV, Random, 95% CI)	0.81 [0.65, 1.01]
10.2 Overweight and obesity (sensitivity: studies at low overall risk of bias)	4	1022	Risk Ratio (IV, Random, 95% CI)	0.86 [0.69, 1.09]
10.3 Overweight and obesity (sensitivity: studies with no industry funding)	4	418	Risk Ratio (IV, Random, 95% CI)	0.81 [0.59, 1.12]
10.4 Overweight and obesity (SES: low versus high/unclear)	5	1070	Risk Ratio (IV, Random, 95% CI)	0.81 [0.65, 1.01]

Analysis 10.3. Comparison 10: Overweight and obesity, Outcome 3: Overweight and obesity (sensitivity: studies with no industry funding)



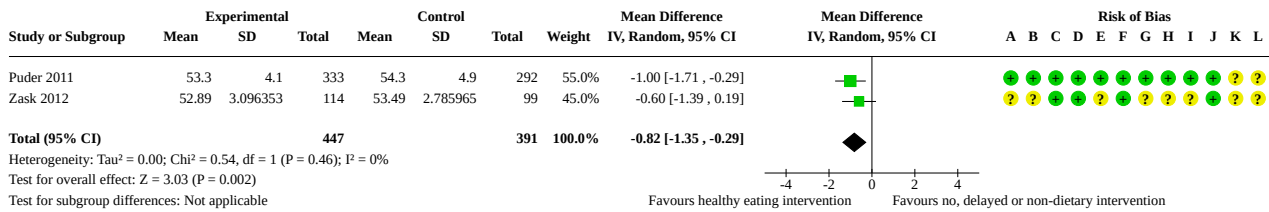
Analysis 10.4. Comparison 10: Overweight and obesity, Outcome 4: Overweight and obesity (SES: low versus high/unclear)



Comparison 11. Waist circumference

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 Waist circumference	2	838	Mean Difference (IV, Random, 95% CI)	-0.82 [-1.35, -0.29]

Analysis 11.1. Comparison 11: Waist circumference, Outcome 1: Waist circumference



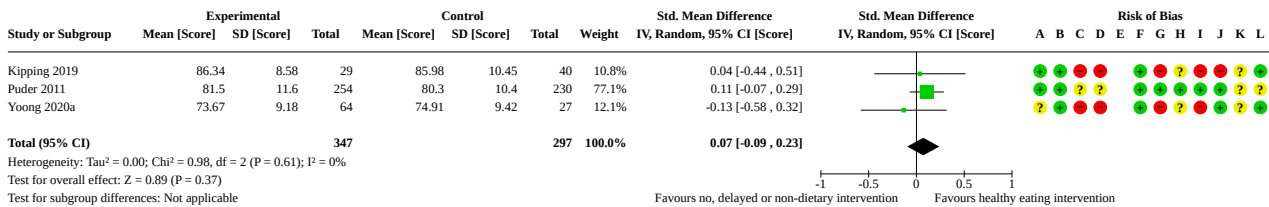
Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Physical outcomes
- (D) Blinding of outcome assessment (detection bias): Physical outcomes
- (E) Incomplete outcome data (attrition bias): Physical outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

Comparison 12. Quality of life

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1 Quality of life	3	644	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.09, 0.23]

Analysis 12.1. Comparison 12: Quality of life, Outcome 1: Quality of life



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias): Quality of life outcomes
- (D) Blinding of outcome assessment (detection bias): Quality of life outcomes
- (E) Incomplete outcome data (attrition bias): Social/emotional outcomes
- (F) Selective reporting (reporting bias)
- (G) Recruitment bias
- (H) Baseline imbalance
- (I) Loss of clusters
- (J) Incorrect analysis
- (K) Contamination
- (L) Other bias

ADDITIONAL TABLES

Table 1. Study findings of primary and secondary outcomes not included in the meta-analysis

Study ID	Outcome	Reason not-meta-analysed	Findings

Table 1. Study findings of primary and secondary outcomes not included in the meta-analysis (Continued)

Fruit consumption			
De Bock 2011	Daily consumption of fruit (g)	Missing data	Positive, participant numbers not available
Morris 2018	Daily consumption of fruit (g)	Missing data	Positive, 201 children
Namenek Brouwer 2013	Daily consumption of fruit (g)	Missing data	Negative, 6 children
Natale 2014b	Rate of fruit consumption (per week)	Different measure	SMD -0.06 (95% CI -0.22 to 0.10), 634 children
Natale 2021	Rate of fruit consumption (per week)	Different measure	SMD 0.02 (95% CI -0.15 to 0.20), 493 children
Pinket 2016	Daily consumption of fruit (g)	Missing data	Negative, 4970 children
Witt 2012	% fruit snack consumed in care	Different measure	Positive, 153
Vegetable consumption			
Başkale 2011	Weekly consumption of vegetables (scale)	Different measure	SMD 0.09 (95% CI -0.21 to 0.39), 172 children
De Bock 2011	Daily consumption of vegetables (g)	Missing data	Positive, participant numbers not available
Morris 2018	Daily consumption of vegetables (g)	Missing data	Positive, 203 children
Namenek Brouwer 2013	Daily consumption of vegetables (g)	Missing data	Positive, 6 children
Natale 2014b	Rate of vegetable consumption (per week)	Different measure	SMD 0.25 (95% CI 0.09 to 0.41), 634 children
Natale 2021	Rate of vegetable consumption (per week)	Different measure	SMD -0.23 (95% CI -0.41 to -0.05), 493 children
Pinket 2016	Daily consumption of vegetables (g)	Missing data	Positive, 4970 children
Witt 2012	% vegetable snack consumed in care	Different measure	Positive, 122 children
Fruit and vegetable consumption combined			
Iaia 2017	% children consuming ≥ 4 servings of fruit and vegetables	Different measure	RR 1.16 (95% CI 0.70 to 1.93), 234 children
Morris 2018	Fruit and vegetables consumed daily (servings)	Missing data	Positive, 200 children
Non-core foods (i.e. less healthy/discretionary) consumption			
Morris 2018	Unhealthy food consumed daily (servings)	Missing data	Positive, 200 children
Natale 2014b	Rate of snack consumption (per week)	Different measure	SMD -0.26 (95% CI -0.42 to -0.11), 634 children
Natale 2021	Rate of snack consumption (per week)	Different measure	SMD 1.19 (95% CI 1.00 to 1.38), 493 children

Table 1. Study findings of primary and secondary outcomes not included in the meta-analysis (Continued)

Sugar-sweetened beverage consumption			
laia 2017	% children not consuming sugar-sweetened beverages daily	Different measure	RR 1.09 (95% CI 1.00 to 1.19), 234 children
Kobel 2019	% children consuming sugar-sweetened beverages daily	Different measure	RR 0.73 (95% CI 0.35 to 1.52), 474 children
Morris 2018	Consumption of sugar-sweetened beverages	Missing data	Negative, 170 children
BMI z-score			
Natale 2014a	BMI z-score	Missing data	Positive, participant numbers not available
Peñalvo 2015	BMI z-score	Missing data	Positive, participant numbers not available
Stookey 2017	Annual change in BMI z-score	Different measure	Positive, 791 children
Waist circumference			
Peñalvo 2015	Waist circumference	No data	Positive, participant numbers not available
Language and cognitive performance			
Puder 2011	Konzentrations-Handlungsverfahren für Vorschulkinder- KHV-VK	Not pooled in meta-analysis	Attention (minutes): SMD -0.06 (95% CI -0.29 to 0.16), 309 children Attention: number of correct cards: SMD 0.02 (95% CI -0.17 to 0.21), 434 children Spatial working memory: SMD 0.12 (95% CI -0.07 to 0.31), 434 children
Ray 2020	Child Social Behaviour Questionnaire	Not pooled in meta-analysis	SMD 0.05 (95% -0.14 to 0.31), 432 children
Social/emotional performance			
Fernandez-Jimenez 2019	Test of Emotional Comprehension	Not pooled in meta-analysis	SMD 0.15 (95% CI -0.09 to 0.40), 282 children
Ray 2020	Child Social Behaviour Questionnaire	Not pooled in meta-analysis	SMD 0.08 (95% CI -0.11 to 0.26), 432 children
BMI: body mass index; CI: confidence interval; RR: risk ratio; SMD: standardised mean difference			

APPENDICES

Appendix 1. Electronic databases search terms

MEDLINE (OVID) search

(Continued)

1	Exp Diet/
2	Nutrition*.mp.
3	(health* adj2 eat*).mp.
4	Child Nutrition Sciences/
5	Exp Fruit/
6	Fruit*.mp.
7	Vegetable/
8	Vegetable*.mp.
9	((Fruit or vegetable) adj2 juice).mp.
10	Canteen.mp.
11	Food Services/
12	Menu*.mp.
13	(Calories or kilocalories or kilojoules).mp.
14	Energy density.mp.
15	Eating/
16	Feeding Behavior?r*.mp.
17	Dietary intake.mp.
18	Food habits/
19	Food/
20	Carbonated beverages/
21	Soft drink*.mp.
22	Soda.mp.
23	Sugar-Sweetened beverages/
24	Dietary fats/
25	Confectionary.mp.
26	(school adj2 (lunch* or meal*)).mp.
27	Menu planning.mp.
28	Feeding program*.mp.

(Continued)

29	Food program*.mp.
30	(nutrition* adj2 program*).mp.
31	Cafeteria*.mp.
32	Nutritional status/
33	Dietary salt.mp.
34	Table salt.mp.
35	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
36	Child, Preschool/
37	Child Day Care Centers/
38	(childcare* or child care*).mp.
39	(daycare* or day care*).mp.
40	Early child*.mp.
41	(nursery or nurseries).mp.
42	Kinder*.mp.
43	(family or home base or homebased or in home).mp.
44	(pre-school* or preschool*).mp
45	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
46	Randomized controlled trial.pt.
47	Controlled clinical trial.pt.
48	Randomized.ab.
49	Trial.ti.
50	Randomly.ab.
51	Clinical Trials as topic.sh.
52	46 or 47 or 48 or 49 or 50 or 51
53	35 and 45 and 52
54	Animals/ not humans/
55	53 not 54

Embase (OVID) search

(Continued)

1	Exp diet/
2	Nutrition*.mp.
3	Nutrition/
4	(health* adj2 eat*).mp.
5	Child nutrition sciences.mp.
6	Nutritional science/
7	Fruit*.mp.
8	Fruit/
9	((fruit or vegetable) adj2 juice).mp.
10	Vegetable*.mp.
11	Vegetable/
12	Canteen*.mp.
13	Food Services.mp.
14	Catering service/
15	Menu*.mp.
16	(calories or kilocalories or kilojoules).mp.
17	Energy intake.mp.
18	Caloric intake/
19	Energy density.mp.
20	Eating/
21	Feeding behaviu?r*.mp.
22	Feeding behaviour/
23	Dietary intake.mp.
24	Dietary intake/
25	Food habit*.mp.
26	Food/
27	Carbonated beverage/
28	Soft drink*.mp.

(Continued)

29	Soft drink/
30	Soda.mp.
31	Sugar-sweetened beverage/
32	Dietary fats.mp.
33	Fat intake/
34	Confectionary.mp.
35	(school adj2(lunch* or meal*)).mp.
36	Menu Planning.mp.
37	Feeding program*.mp.
38	Food program*.mp.
39	(nutrition* adj2 program*).mp.
40	Cafeteria*.mp.
41	Nutritional status/
42	Dietary salt.mp.
43	Table salt.mp.
44	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43
45	Child, Preschool/
46	(pre-school* or preschool*).mp.
47	Day care/
48	Child care/
49	Childcare*.mp.
50	(daycare* or day care*).mp.
51	Early child*.mp.
52	(nursery or nurseries).tw.
53	Kinder*.mp.
54	(family or home based or homebased or "in home").mp.
55	45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54

(Continued)

56	“randomized controlled trial”/
57	“controlled clinical trial”/
58	Randomized.ab.
59	Trial.ti.
60	Randomly.ab.
61	56 or 57 or 58 or 59 or 60
62	44 and 55 and 61
63	Animal experiment/
64	“human experiment”/
65	Human/
66	64 or 65
67	63 not 66
68	62 not 67

PsycINFO (OVID) search

1	Diets/
2	Exp Nutrition/ or Nutrition*.mp.
3	(health* adj2 eat*).mp.
4	Child Nutrition Sciences.mp.
5	Fruit*.mp.
6	((fruit or vegetable) adj2 juice).mp.
7	Vegetable*.mp.
8	Canteen*.mp.
9	Food Services.mp.
10	Menu*.mp.
11	(calories or kilocalories or kilojoules).mp.
12	Food Intake/ or Energy Intake.mp.
13	Energy density.mp.
14	Eating.mp.

(Continued)

15	Eating behaviour/
16	Feeding behavior?r*.mp.
17	Dietary intake.mp.
18	Food/
19	((carbonated or sweetened or soft) adj (drink* or beverage*)).mp.
20	Soda.mp.
21	Dietary fat*.mp.
22	Confectionary.mp.
23	(school adj2 (lunch* or meal*)).mp.
24	Feeding program*.mp.
25	Food program*.mp.
26	(nutrition* adj2 program*).mp.
27	Cafeteria*.mp.
28	Dietary salt.mp.
29	Table salt.mp.
30	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
31	Preschool students/ or nursery school students/
32	(pre-school* or preschool*).mp.
33	Day Care Centers/ or Child Day Care/
34	(childcare* or child care*).mp.
35	(daycare* or day care*).mp.
36	Early child*.mp.
37	(nurseries or nursery).mp.
38	Kindergarten Students/ or Kinder*.mp.
39	(family or home based or homebased).mp.
40	31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41	Randomi?ed controlled trial*.mp.
42	Clinical Trials/

(Continued)

43	Trial.ti.
44	Randomized.ab.
45	Randomly.ab.
46	41 or 42 or 43 or 44 or 45
43	30 and 40 and 46

CINAHL (EBSCO) search^a

S1	(MH "Diet+")
S2	"nutrition*"
S3	(MH "Nutrition")
S4	Health* n2 eat*
S5	(MH "Child Nutrition")
S6	(MH "Vegetables") OR "vegetable*"
S7	Fruit* or ((fruit or vegetable) n2 juice)
S8	"canteen*"
S9	(MH "Food Services")
S10	(MH "Menu Planning") OR "menu*"
S11	Calories or kilocalories or kilojoules
S12	(MH "Energy Intake") OR (MH "Food Intake")
S13	(MH "Energy Density") OR "Energy Density"
S14	"feeding behavior?r*"
S15	(MH "Eating") OR (MH "Eating Behavior")
S16	"dietary intake"
S17	(MH "Food Habits")
S18	(MH "Food")
S19	(MH "Carbonated Beverages") OR "soft drink*"
S20	Soda
S21	"Sweetened drink*"
S22	(MH "Dietary Fats")

(Continued)

S23	“confectionary” OR (MH “candy”)
S24	School n2 (lunch* or meal*)
S25	“feeding program*”
S26	“food program*”
S27	(nutrition* n2 program*)
S28	Cafeteria*
S29	(MH “Nutritional Status”) or "dietary salt" or "table salt"
S30	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29
S31	(MH “Child, Preschool”)
S32	“pre-school*” or preschool*
S33	(MH "Child Day Care") OR (MH "Child Care Providers") OR (MH "Child Care (Saba CCC)") OR (MH "Child Care")
S34	Childcare* or "child care*"
S35	Daycare* or "day care*"
S36	"early child*"
S37	(MH "Schools, Nursery")
S38	Nursery or nurseries
S39	Kinder*
S40	Family or "home based" or homebased or "in home"
S41	S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40
S42	(MH "Randomized Controlled Trials")
S43	(MH "Clinical Trials")
S44	TI trial
S45	AB random*
S46	S42 OR S43 OR S44 OR S45
S47	S30 AND S41 AND S46

CENTRAL search

#1	MeSH descriptor: [Diet] explode all trees
----	---

(Continued)

#2	(nutrition*):ti,ab,kw
#3	((health*near/2 eat*)):ti,ab,kw
#4	MeSH descriptor: [child nutrition sciences] explode all trees
#5	(fruit*):ti,ab,kw
#6	MeSH descriptor: [Fruit] this term only
#7	(vegetable*):ti,ab,kw
#8	MeSH descriptor: [vegetables] this term only
#9	(canteen*):ti,ab,kw
#10	MeSH descriptor: [Fruit and vegetable juices] this term only
#11	((fruit or vegetable) near/2 juice):ti,ab,kw
#12	MeSH descriptor: [Food Services] this term only
#13	(menu*):ti,ab,kw
#14	(calories or kilocalories or kilojoules):ti,ab,kw
#15	("energy density"):ti,ab,kw
#16	MeSH descriptor: [Eating] this term only
#17	MeSH descriptor: [Feeding Behavior] this term only
#18	("feeding behavio*"):ti,ab,kw
#19	("dietary intake"):ti,ab,kw
#20	MeSH descriptor: [Food] this term only
#21	MeSH descriptor: [Carbonated Beverages] this term only
#22	("soft drink"):ti,ab,kw
#23	(soda):ti,ab,kw
#24	("sweetened drink*"):ti,ab,kw
#25	MeSH descriptor: [Dietary Fats] this term only
#26	(confectionary):ti,ab,kw
#27	(school near/2 (lunch* or meal*)):ti,ab,kw
#28	MeSH descriptor: [Menu Planning] this term only
#29	("feeding program*"):ti,ab,kw

(Continued)

#30	("food program*"):ti,ab,kw
#31	(nutrition* near/2 program*):ti,ab,kw
#32	(cafeteria*):ti,ab,kw
#33	MeSH descriptor: [Nutritional Status] this term only
#34	{or #1-#33}
#35	MeSH descriptor: [child, preschool] this term only
#36	("pre-school*" or preschool*):ti,ab,kw
#37	MeSH descriptor: [Child Day Care Centers] this term only
#38	(childcare* or "child care*"):ti,ab,kw
#39	(daycare* or "day care*"):ti,ab,kw
#40	("early child*"):ti,ab,kw
#41	(nursery or nurseries):ti,ab,kw
#42	(Kinder):ti,ab,kw
#43	Family or homebased or "home based" or "in home"
#44	or #35-#43
#45	and #34, #44

SPORTDiscus (EBSCO) search^b

S46	S30 AND S40 AND S45
S45	S41 OR S42 OR S43 OR S44
S44	AB trial* or random*
S43	TI trial*
S42	"clinical trials"
S41	Randomised controlled trial or randomized controlled trial
S40	S31 or S32 or S33 or S34 or S35 or S36 or S38 or S39
S39	Family or "home based" or homebased or "in home"
S38	Kinder* or preschool or early childhood education
S37	Nursery or nurseries
S36	"early child*"

(Continued)

S35	Daycare* or “day care”
S34	Childcare*
S33	“child day care” or “child care providers” or “child care (saba CCC)” or “child care”
S32	“pre-school*” or preschool*
S31	AB child, preschool
S30	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29
S29	(AB “Nutritional Status”) OR “dietary salt” OR “table salt”
S28	Cafeteria*
S27	(nutrition* n2 program*)
S26	”food program*”
S25	“feeding program*”
S24	School n2 (lunch* or meal*)
S23	“confectionary” OR (AB “candy”)
S22	(AB “Dietary Fats”)
S21	“Sweetened drink*”
S20	Soda
S19	(AB “Carbonated beverages” OR “Soft drink*”)
S18	(AB “Food”)
S17	(AB “food habits”)
S16	“dietary intake”
S15	(AB “Eating”) OR (AB “Eating Behaviour”)
S14	“feeding behavio?r*”
S13	(AB “Energy density”) OR “Energy density”
S12	(AB “Energy Intake”) OR (AB “Food Intake”)
S11	Calories or kilocalories or kilojoules
S10	(AB “Menu Planning”) OR “menu*”
S9	(AB “Food Services”)
S8	“canteen*”

(Continued)

S7	Fruit* OR ((fruit OR vegetable) n2 juice)
S6	(AB "vegetables" OR "vegetable**")
S5	(AB "Child nutrition")
S4	Health* n2 eat*
S3	(AB "Nutrition")
S2	"nutrition**"
S1	"Diet"

ERIC (Proquest) search

(Diet OR nutrition* OR (health* AND eat*) OR ("child nutrition") OR fruit* OR vegetable* OR ((fruit or vegetable) n/2 juice) OR canteen* OR menu* OR calories OR kilocalories OR kilojoules OR "energy intake" OR "energy density" OR eating OR ("feeding behavior" OR "feeding behaviors" OR "feeding behaviour") OR "dietary intake" OR food OR ((carbonated OR sweetened OR soft) n/2 (drink* or beverage*)) OR soda OR ("dietary fat" OR "dietary fats") OR confectionary OR (school n/2 (lunch* OR meal*)) OR ("feeding program" OR "feeding programme" OR "feeding programmes" OR "feeding programs") OR cafeteria* OR "dietary salt" OR "table salt")

AND ("pre-school**" OR preschool* OR childcare* OR "child care" OR daycare* OR ("day care" OR "day career" OR "day cares") OR ("early child" OR "early childcare" OR "early childhood" OR "early children") OR nursery OR nurseries OR kinder* OR family OR home-based OR "home based" OR "in home")

AND (Random* OR trial*)

SCOPUS (Scopus) search

TITLE-ABS (diet OR nutrition* OR (health* W/2 eat*) OR "Child Nutrition*" OR fruit* OR vegetable* OR ((fruit OR vegetable) W/2 juice) OR canteen* OR menu* OR calories OR kilocalories OR kilojoules OR "Energy Intake" OR "energy density" OR eating OR "Feeding Behavior*" OR "dietary intake" OR food OR ((carbonated OR sweetened OR soft) AND (drink* OR beverage*)) OR soda OR "Dietary Fat*" OR confectionary OR (school AND (lunch* OR meal*)) OR "feeding program*" OR cafeteria* OR "dietary salt" OR "table salt") AND

TITLE-ABS ("pre-school**" OR preschool* OR childcare* OR "child care*" OR daycare* OR "day care*" OR "early child*" OR nursery OR nurseries OR kinder*) AND

TITLE-ABS (random* OR trial*) AND (LIMIT-TO (EXACTKEYWORD , "Human") OR LIMIT-TO (EXACTKEYWORD , "Humans"))

^aUnless otherwise specified, the default search was used. This searches across the following fields.

- Title
- Abstract
- Subject headings
- PubMed ID
- DOI
- Author

^bUnless otherwise specified, the default search was used. This searches across the following fields.

- Authors
- Subjects
- Keywords
- Title
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WHAT'S NEW

Date	Event	Description
22 August 2023	Amended	Erratum: Inadvertent omission of statistics consultant, Erin Nolan, in authorship of original publication now corrected.
22 August 2023	New citation required but conclusions have not changed	Erratum: Inadvertent omission of statistics consultant, Erin Nolan, in authorship of original publication now corrected.

HISTORY

Protocol first published: Issue 2, 2021

Review first published: Issue 6, 2023

CONTRIBUTIONS OF AUTHORS

Sze Lin Yoong, Luke Wolfenden and Alice Grady conceived the idea for this review. Sze Lin Yoong, Jacklyn Jackson, Luke Wolfenden, Sam McCrabb, Alix Hall and Alice Grady contributed to the methods for the protocol. Sze Lin Yoong, Melanie Lum, Jacklyn Jackson and Debbie Booth developed the search strategy for the review. Erin Nolan and Alix E Hall contributed to statistical analyses. Melanie Lum and Jannah Z Jones provided support with manuscript drafting and referencing. All authors provided critical comments and final approval for the manuscript.

DECLARATIONS OF INTEREST

Sze Lin Yoong: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review.

Melanie Lum: declares no conflict of interest.

Jacklyn Jackson: declares no conflict of interest.

Luke Wolfenden: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review. Luke Wolfenden is Co-ordinating Editor of Cochrane Public Health and was not involved in any stage of the editorial management or assessment of this review.

Courtney Barnes: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review.

Alix E Hall: is a Methods Editor for Cochrane Public Health and was not involved in any stage of the editorial management or assessment of this review.

Sam McCrabb: is Assistant Managing Editor and Methods Editor and was not involved in any stage of the editorial management or assessment of this review.

Nicole Pearson: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review.

Cassandra Lane: declares no conflict of interest.

Jannah Z Jones: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not

received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review.

Erin Nolan: declares no conflict of interest.

Lauren Dinour: declares no conflict of interest.

Therese McDonnell: declares no conflict of interest.

Debbie Booth: declares no conflict of interest.

Alice Grady: is currently undertaking primary research that may be relevant to the review. Where we included such a study, other authors who were not directly involved in the study completed screening, data extraction and risk of bias assessments. This author has not received any benefit, in cash or kind, any hospitality, or any subsidy derived from any source perceived to have an interest in the outcome of the review.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We specified that we would include all dietary outcomes and anthropometric outcomes in the protocol (Yoong 2021). However, we obtained a large number of dietary and anthropometric outcomes that were highly heterogeneous, only reported by one study, and could not reasonably be synthesised with other outcomes. As such, we undertook a posthoc selection of dietary and anthropometric outcomes consistent with those outlined in a recently published core outcome set of obesity prevention interventions in the early years (Brown 2022). The dietary outcomes selected were also consistent with those specified a priori for the summary of finding tables.

High risk of bias was defined inconsistently in the protocol (defined as scoring high on one or more of any risk of bias domains and scoring high on three or more risk of bias domains). We have chosen to classify overall high risk of bias as scoring high on three or more of the risk of bias criteria, given the challenges with blinding associated with public health interventions and assessment of the primary outcomes (diet).

We specified in the protocol that we would prioritise unadjusted over adjusted estimates. However, given that all included studies were cluster-randomised controlled trials (RCTs), we have prioritised cluster-adjusted estimates.

For cluster-RCTs that did not appropriately account for clustering, we specified that we would calculate a design effect and effective sample size using study data (number of clusters, number of participants analysed) and mean intracluster correlation coefficient (ICC) from the included studies. As the ICC values across studies were skewed, we used the median ICC instead of the mean.

For multi-arm studies, we specified that we would split the control group into two or more groups to form independent comparisons. However, we have combined the separate interventions arms, given that the overall aim was to assess the effectiveness of early childhood education and care-based healthy eating interventions.

We specified that we would undertake pooled analysis by the World Health Organization Health Promoting Schools components by health curriculum only versus usual care/no intervention, ethos and environment only versus usual care/no intervention, and partnerships component only versus usual care/no intervention. As the majority of interventions included two or more Health Promoting Schools' components, we could not undertake a subgroup comparison by discrete components only. Instead, we included multi-component interventions as long as a particular component was addressed relative to control.

NOTES

Erratum: Inadvertent omission of statistics consultant, Erin Nolan, in authorship of original publication corrected August 2023.

INDEX TERMS

Medical Subject Headings (MeSH)

Diet; *Diet, Healthy; Fruit; Obesity; *Overweight; Vegetables

MeSH check words

Child; Child, Preschool; Humans