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# BMJ Open

**A cluster randomised controlled trial of an m-health intervention in centre-based childcare services to reduce the packing of discretionary foods in children's lunchboxes: Study protocol for the "SWAP IT Childcare" trial**

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3 **A cluster randomised controlled trial of an m-health intervention in centre based**  
4 **childcare services to reduce the packing of discretionary foods in children's**  
5 **lunchboxes: Study protocol for the "SWAP IT Childcare" trial**  
6

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## ABSTRACT

**Introduction:** In many developed nations, including Australia, a substantial number of children aged under five years attend centre-based childcare services that require parents to pack food in lunchboxes. These lunchboxes often contain excessive amounts of unhealthy (“discretionary”) foods. This study aims to assess the impact of a mobile health (m-health) intervention on reducing the packing of discretionary foods in children’s childcare lunchboxes.

**Methods and analysis:** A cluster randomised controlled trial will be undertaken with parents from 18 centre-based childcare services in the Hunter New England region of New South Wales, Australia. Services will be randomised to receive either a four month m-health intervention called “SWAP IT Childcare” or usual care. The development of the intervention was informed by Behaviour Change Wheel (BCW) model and will consist primarily of provision of targeted information, lunchbox food guidelines and website links addressing parent barriers to packing healthy lunchboxes delivered through push notifications via an existing app used by childcare services to communicate with parents and carers. The primary outcomes of the trial will be energy (kJ) from discretionary foods packed in lunchboxes and the total energy (kJ), saturated fat (g), sugar (g) and sodium (mg) from all foods packed in lunchboxes. Outcomes will be assessed by weighing and photography of lunchbox food items at baseline and at the end of the intervention.

**Ethics and Dissemination:** The study was approved by the Hunter New England Local Health District Human Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human Research Ethics Committee (H-2008-0343).

**Discussion:** If effective, this intervention has the potential to significantly improve the dietary intake of young children attending centre-based childcare services.

**Trial Registration:** The trial is prospectively registered with the Australian New Zealand clinical trials registry (ACTRN12618000133235p).

## ARTICLE SUMMARY

### Strengths and Limitations of this study

- This RCT is the first to use m-health intervention to reduce packing of unhealthy foods in lunchboxes in centre- based childcare services.
- The study uses rigorous outcome measures consisting of weighed food records, supplemented by food photography.
- The intervention is developed using a systematic theory-based approach to identify strategies to target parental barriers to packing healthy lunchboxes.
- If found to be effective, the intervention has potential to be delivered via other childcare online technology-based communication platforms.
- The intervention is conducted in one region of Australia which may limit generalisability of the findings.

## INTRODUCTION

Poor dietary behaviours are leading modifiable risk factors for the development of chronic disease including Type 2 diabetes, cardiovascular disease and certain cancers.[1, 2] To reduce chronic disease risk it is recommended that intake of discretionary foods (i.e. foods high in energy, saturated fat, sugar and/or sodium) are limited.[1] Excessive intake of discretionary foods in childhood is linked to conditions such as dental caries,[3] altered lipid profiles,[4] and unhealthy weight gain.[5] Given that dietary preferences established in childhood track into adulthood,[6] efforts to decrease consumption of discretionary foods in early childhood are recommended to reduce the burden of chronic disease.[1]

National dietary guidelines recommended that children up to 8 years old consume no more than 0.5 serves of discretionary food per day.[7] Despite this, population studies indicate that child consumption typically exceeds these recommendations [8-10]. Specifically, in Australia children aged 4-8 years consumed an average of 41% of their daily energy intake from discretionary foods or approximately 4.5 serves.[8]

Centre-based childcare services, such as preschools and long day care centres, have been identified as priority settings for interventions to improve child diet.[11-13] These services provide access to a significant number of children, with upwards of 80% attending in the year before school in Australia, the United Kingdom (U.K.) and United States (U.S.) [14-16] As children can consume between a third to two thirds of their daily food intake whilst in centre-

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3 based childcare,[17] achieving even modest dietary improvements in this setting is likely to  
4 have considerable potential to improve child health.  
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7 In Australia, the U.K. and the U.S. it is estimated that between 30% -50% of centre-based  
8 childcare services require parents to pack food in a lunchbox for their children to consume in  
9 care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain excessive  
10 amounts of discretionary foods. For example, a study of Australian children from 29 centre-  
11 based childcare services found that 38% of lunchboxes contained more than one serve of  
12 discretionary food and lacked vegetables, fruit or a healthy main meal.[19] A study in 30  
13 centre-based care services in Texas US (607 children) similarly found a disproportionate  
14 amount of discretionary foods packed in lunchboxes with contents exceeding  
15 recommendations for saturated fat, sugar and sodium.[20]  
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21 Despite the potential to improve child diet via interventions to reduce packing of discretionary  
22 foods in lunchboxes of children attending centre-based childcare, to our knowledge just  
23 three randomised trials have been conducted,[21-23] with only one reporting impact on child  
24 dietary intake.[24] Two of these trials utilised multi-component service based strategies  
25 including staff nutrition training and child education, alongside parent targeted strategies  
26 (including workshops, and parent activity stations).[21, 22] Both trials reported significant  
27 improvements in packing of discretionary foods. The remaining trial involved training of  
28 childcare staff without any direct parent strategies. This trial was ineffective in reducing  
29 packing of discretionary foods.[23] While these findings suggest that interventions targeting  
30 parents are more likely to have an impact, previous approaches have been time and  
31 resource intensive, requiring parents to attend face to face sessions. These strategies have  
32 been reported to have limited reach [25] and reduce potential for intervention delivery at a  
33 population level.  
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41 Utilising mobile technology to directly reach parents has been suggested as a potentially  
42 effective strategy to overcome the limited reach of previous parent targeted  
43 interventions.[26, 27] Evidence demonstrates mobile health (m-health) interventions can be  
44 effective in changing dietary behaviours in both adults [28] and children.[28, 29] The use of  
45 mobile phone apps has been identified as highly acceptable to parents as a preferred health  
46 engagement tool,[30] and has potential to successfully reach the large majority (over 86%)  
47 of parents who are estimated to now own a smart phone.[31] Embedding interventions within  
48 existing childcare service mobile phone apps may also overcome previously reported  
49 barriers related to reach and engagement via their ability to reach parents at any place or  
50 time, deliver education materials and provide reminders or prompts targeting specific  
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3 behaviours.[27] Using an existing school communication app for the purpose of delivering  
4 healthy lunchbox information to parents was found to be highly feasible and acceptable by  
5 principals in primary school setting in the HNE area,[32] and the results of a healthy  
6 lunchbox pilot study utilising this model showed promising effects on the nutritional quality of  
7 children's lunchbox contents [unpublished data from a randomized controlled trial to assess  
8 the effectiveness, feasibility and acceptability of an m-health intervention 'SWAP IT',  
9 provided by RS, 2018]. Utilising a similar approach in the centre-based care setting to  
10 reduce packing of discretionary foods in lunchboxes therefore appears highly feasible.  
11 Despite this, to the author's knowledge no such m-health intervention has yet been  
12 conducted in this setting.  
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## 18 **STUDY AIMS**

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20 The primary aim of the trial is to assess the efficacy of an m-health intervention, embedded  
21 within an existing childcare parent communication app to reduce: i) the mean energy (kJ)  
22 from discretionary foods and drinks packed in children's lunchboxes, and ii) the mean energy  
23 (kJ), saturated fat (g), sugar (mg) and sodium (g) from all foods and drinks packed in  
24 lunchboxes. We will also assess the impact of the intervention on child dietary consumption  
25 of: i) mean energy (kJ) from discretionary foods packed in the lunchbox; ii) mean energy  
26 (kJ), mean saturated fat (g), sodium (mg) and sugar (g) from all foods and drinks packed in  
27 the lunchbox; iii) serves of lunchbox discretionary foods and drinks packed and consumed;  
28 and the iv) usual serves of discretionary foods consumed over 24 hours. Parent and service  
29 acceptability and feasibility and potential adverse effects of the intervention will also be  
30 assessed.  
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## 40 **METHODS AND ANALYSIS**

### 41 **Setting and Design**

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43 The study will utilise a cluster randomised controlled trial design, and will be conducted with  
44 parents and children attending centre-based childcare services in the Hunter New England  
45 (HNE) Local Health District of New South Wales (NSW), Australia (see Fig 1). Allocation will  
46 be at the unit of the childcare service. Approximately 819 814 people reside in the HNE area,  
47 of which 51 900 are children aged 0 to 4 years.[33] The area encompasses major  
48 metropolitan centres and inner regional communities, with a small percentage (14%) of  
49 people located in remote communities.[34]  
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3 Following baseline data collection, services will be randomly allocated to receive the four  
4 month intervention or to a usual care control group. The trial outcome measures will be  
5 assessed in the same child cohort within both groups at baseline and at approximately four  
6 months (post intervention) following baseline. The study will follow the CONSORT reporting  
7 guidelines.[35]  
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13 **Figure 1: CONSORT diagram estimating the progress of centre based childcare**  
14 **services and children through the trial**

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16 *Insert Figure 1*  
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20 **Participants and eligibility**

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22 **Sample**

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24 A list of all centre-based childcare services (including long day care and preschool services)  
25 in the study region will be accessed via the NSW Ministry of Health. Approximately 211  
26 (54%) services require parents pack foods (referred to as lunchbox services) and will serve  
27 as the sampling frame. Within NSW, long day care services can provide centre-based care  
28 for children from 6 weeks, to under 6 years of age for eight or more hours per day.  
29 Preschools typically enrol children between 3 and 6 years of age and provide care for 6-8  
30 hours per day.[36]  
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37 **Eligibility**

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39 To be eligible to participate, lunchbox services must cater for children 3-6 years of age, and  
40 be either existing users of the designated parent communication app (Skoolbag),[37] or have  
41 a willingness to commence using the app. Services will be excluded if they are, participating  
42 in any other trial related to improving child nutrition, cater exclusively for children with special  
43 needs or are a Department of Education community run service (as they are not covered  
44 within the existing ethics arrangement). Parents or carers (hereafter referred to as “parents”)  
45 of children aged 3-6 years will be eligible to participate if their child attends during the days  
46 of data collection period and if they indicated willingness to download or use the app.  
47 Children will be excluded if they have special dietary requirements or allergies that would  
48 necessitate specialised tailoring of their diet.  
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## Recruitment procedures

### Services

Initial recruitment will target eligible services currently using Skoolbag (n = 13), after which services that do not use any app (as identified via a telephone survey undertaken by the research team) will be randomly approached (n=112) until 18 services are enrolled. Services commencing using the app for the purpose of the trial will be able to use the app free of charge for the duration of the intervention.

Service managers of eligible services will be posted and emailed information statements and consent forms detailing the study and requesting participation. Written consent will be provided by the manager on behalf of services.

### Children

Centre-based care staff will distribute hard copies of information statements and consent forms to parents approximately two weeks prior to baseline data collection. To maximise consents, research assistants will also be present at the service for two days (based on highest child attendance) during drop off and pick up times to speak with eligible parents and promote participation in the trial. If more than one child is eligible per family, only the oldest will be included in the trial to reduce participant burden.

## Random allocation of childcare services

Consenting services will be randomly allocated to the intervention or usual care control group in a 1:1 ratio using a computerised random number generator. Randomisation of services will be undertaken following baseline data collection by a statistician who will otherwise have no involvement in the study. Based on evidence of associations for family socio-economic status and rurality with child dietary intake,[38, 39] randomisation will be stratified by the socio-economic area of the childcare service and by rural location. As part of ensuring equity of access to the intervention, services will also be stratified by those with high numbers of Aboriginal child enrolments defined as those with >10% Aboriginal children enrolled. This level of stratification was deemed appropriate for the sample size.[40]

This trial will be conducted as an open trial due to the nature of the intervention. Services and parents will be notified of their allocation prior however outcome assessors will remain blinded to service allocation.

### Sample size and power calculations

The study aims to recruit approximately 390 children from 18 childcare services. Given a 15% attrition rate at follow up, this will allow detection of a mean difference of 123kJ in the primary outcome, with an alpha of 0.01 (adjusting for multiple outcomes), and an estimated ICC of 0.1,[41] with 80% power and a standard deviation of 200 kJ. Approximately 123 KJ difference in energy was considered clinically significant based on an estimate of the energy deficit required to reduce the prevalence of childhood obesity (420KJ) [42] and proportionally adjusted to the amount of time children spend in care (approximately 1/3 of the day). Such an energy reduction could be expected to result in the detection of approximately 0.6g less saturated fat, 2.2g less sugar and 44 mg less sodium.[8]

### Intervention

“SWAP IT Childcare” is an adapted version of a previously piloted intervention conducted with primary school children aged 5-12 years. The program is embedded in an existing parent communication app used in both schools and centre-based childcare services and aims to assist parents to “swap in” healthy foods and “swap out” discretionary foods when packing lunchboxes. Services use this communication app to provide information to parents regarding their child’s daily activities, newsletters and other service related information. The app has the capacity to deliver content in the form of text, images and media (videos) and house static information.

The program was co-produced by a team of behavioural researchers and public health nutritionist, centre-based childcare staff and technology provider “Skoolbag” based on formative evaluations with parents. Key differences between schools and childcare settings as well as parent reported barriers were identified during formative assessments which necessitated amendments to strategy selection, intervention components and content between the two programs. The “SWAP IT Childcare” intervention will specifically target parents of children aged 3-6 years and will be primarily delivered via a series of push notification messages using the service’s communication app. Feedback was sought on the content of the program from parents of childcare-aged children, the research unit’s Aboriginal Health Staff advisory group and from two local Aboriginal centre-based care Service Managers to ensure cultural appropriateness.

### Application of a theoretical framework

The “SWAP It Childcare” intervention content was developed using the Behaviour Change Wheel (BCW).[43] This theoretically driven framework is based on 19 theories of health behaviour and is designed to enable the systematic development of interventions for

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3 supporting behaviour change.[43] For a description of the application of the framework  
4 please refer to supplementary file 1.  
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### 6 **Intervention strategies**

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8 A four month intervention (Table 2) consisting of the following components will be delivered  
9 as part of “SWAP IT Childcare”:  
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- 11  
12 1. Provision of weekly push notifications targeting identified barriers to the packing of  
13 healthier lunchboxes
- 14  
15 2. Provision of “SWAP IT Options” which are centre-based childcare lunchbox  
16 guidelines designed to provide specific information to parents on suitable foods for  
17 the lunchbox.
- 18  
19 3. Centre-based childcare service endorsement of the program in order to support  
20 adoption of the “SWAP IT Options” lunchbox guidelines.  
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23 Further details regarding each strategy and delivery mode are provided in table 2.  
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### 25 **Control Group**

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27 Services allocated to the control group will participate in data collection only. Parents from  
28 these services will receive routine centre-based childcare communication via the app (usual  
29 care) with no access to the lunchbox content.  
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**Table 1 Intervention mapping overview**

1. COM B (source of behaviour)	2. Related barrier/ enabler		3. Components of the intervention (numbers represent barriers in column 2)		4. Behaviour Change techniques (numbers represent barriers in column 2)
Capability	1. A lack of knowledge about appropriate foods and drinks for the lunchbox 2. Lack of ideas for healthy appealing lunchbox foods	➔	Provision of weekly push notifications targeting identified barriers to packing of healthier lunchboxes (1, 2, 3, 4, 5, 6, 7, 8)	➔	4.1 Instruction on how to perform a behaviour (1,5,6,7)
Opportunity	3. Perception that it takes longer to prepare and/ or shop for healthy foods for the lunchbox.	➔		➔	5.1 Information about health consequences (8)
	4. Perception that it costs more to pack a healthy lunchbox	➔		➔	6.1 Demonstration of the behaviour (3, 4, 6, 7)
	5. Child is a fussy eater (ie will not accept new foods packed in the lunchbox)	➔		➔	7.1 Prompts/cues (8)
Motivation	6. Reluctance to pack healthy food options in order to avoid: - food going to waste - child going hungry - child complaints	➔	Provision of SWAP IT Lunchbox guidelines (1, 2)	➔	8.2 Behaviour substitution (1, 2, 6, 7)
	7. Parents' lack of awareness of link between nutrition and health outcomes. Belief there is no need to limit less healthy foods the lunchboxes. 8. Lack of motivators or prompts to change lunchbox packing behaviours	➔		➔	11.3 Conserving mental resources (1, 2) 15.1 Verbal persuasion about capability (3, 4, 5, 6)
			Centre-based childcare service support and endorsement of the "SWAP IT in Childcare" program		

**Table 2: Intervention Components, strategies and resources**

Intervention component	Strategy Description	Resources and Delivery Mode
<p><b>1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes</b></p>	<p>Push notifications will alert parents to messages sent via the service’s app for 10 weeks (one per week). The behaviour change techniques designed to influence parent behaviour will be delivered via the content of these messages and images, and through attachments and links to the “SWAP IT Childcare” webpages, videos, fact sheets and other websites. For example, in the message aiming to reduce the perceived barrier of “cost of a healthy lunchbox”, persuasive language will be used in the push message notification explaining that expensive foods doesn’t need to be purchased to provide a healthy lunchbox. An embedded video in the push notification message will provide some examples of inexpensive healthy foods to pack for children, and will demonstrate how healthy items often cost the same as less healthy items in the supermarket. Finally, an attached fact sheet provides practical examples of how to save money and demonstrates cost savings possible over a year. For further information on behaviour change techniques used to address each barrier please refer to table 1.</p>	<p><b>a) “SWAP IT Childcare” push notification topics delivered via the app</b></p> <p>Week 1 (2 messages): Welcome to “SWAP IT” The ultimate list of healthy lunchbox foods</p> <p>Week 2: “Sweet” food ideas for the lunchbox</p> <p>Week 3: Cost saving ideas for the lunchbox</p> <p>Week 4: Common fussy eating concerns</p> <p>Week 5: Healthy savoury snacks that are a hit!</p> <p>Week 6: Why are some lunchbox snacks better than others?</p> <p>Week 7: Is your child drinking enough?</p> <p>Week 8: Top 5 time saving ideas when packing a healthy lunchbox</p> <p>Week 9: Supporting children to try new foods</p> <p>Week 10: Thanks for being part of SWAP IT</p> <p><b>b) Links to fact sheets and videos within messages</b></p> <p>Top time saving tips (fact sheet and video) Money saving tips for the lunchbox (fact sheet and</p>

		<p>video)          Fussy Eating Concerns (fact sheet)          Tips for encouraging new foods (fact sheet and video)          5 Best savoury swaps for the lunchbox (fact sheet)          5 Best sweet swaps for the lunchbox (fact sheet)</p>
<p><b>2. Provision of “SWAP IT Options” Lunchbox Guidelines</b></p>	<p>Parents will be given access to and encouraged to use 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,[7] recommendations outlined in the NSW Ministry of Health nutrition sector specific resource[44] and health and wellbeing requirements outlined in national accreditation standards.[45]</p>	<p><b>a) “SWAP IT Options” Lunchbox Guidelines, provided via links in push notification messages delivered via the app</b></p> <p>SWAP IT Options Savoury          SWAP IT Options Sweet          SWAP IT Options Lunch foods          SWAP IT Options Drinks</p>
<p><b>3. Centre-based childcare service endorsement of the program</b></p>	<p>To support service adoption of the “SWAP IT Choices” lunchbox guidelines, a Health Promotion Officer will conduct 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).The Service Managers will also be 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.</p> <p>Service Managers will be asked to send two communications to parents via the app or other preferred communication methods (e.g. hard copy newsletters). The first communication will be sent prior to the</p>	<p><b>a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.</b></p> <p><b>b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.</b></p>

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	<p>first app push notification message to convey service support for the program, and to endorse the use of the “SWAP IT Options” lunchbox guidelines and the second communication, will be sent approximately mid-intervention. This is designed to provide parents with non-contingent praise and support to continue to access the app and its content and assist with prevention of a drop off in opening messages over time.</p> <p>A record of implementation will be given to Service Managers to enable them to record their delivery of the agreed tasks during the intervention period and to measure implementation fidelity.</p>	<p><b>c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).</b></p> <p><b>d) Provision of a service-completed record of implementation form.</b></p>
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For peer review only

## DATA COLLECTION PROCEDURES AND MEASURES:

### Primary Outcomes

Food packed in lunchboxes

The primary trial outcomes include mean energy (kJ) provided by discretionary foods, and mean energy (kj), saturated fat (g), sugar (g) and sodium (mg) provided by all food and drinks packed in children's lunchboxes. The outcome will be assessed via photography and weighed food records. Weighing is considered one of the most accurate methods of determining portion size and consumption of food and drinks.[46] Research assistants will undertake a one day training session requiring them to practice weighing sample lunchboxes and complete data collection forms with feedback given on their adherence to data collection protocols. Lunchbox measures will be undertaken on one unique day for each child as part of two-day data collection at each service at both baseline and approximately four months follow up. Parents will not be informed of the day that lunchbox data will be collected to minimise reactivity bias. On the days of data collection all packed food and drinks (excluding water) will be weighed, individually where possible, and photographed by a trained research assistant blinded to service allocation. Food will be photographed against paper that includes a metric ruler graphic to aid weight estimations if required. Weight will be recorded in grams by a second trained research assistant using a standardised form developed by the research team. To ensure consistency and quality of data collection, lunchbox photographs and data collection forms will be reviewed by a dietitian once returned for accuracy and compliance with protocols.

The weighed food record data will be verified using photos and entered into a food and nutrient analysis database (Foodworks™)[47] in grams by a trained dietitian. The weights of individual foods weighed as part of a mixed foods (e.g. determining the weight of the cheese and weight of the bread as part of the total grams recorded for a cheese sandwich), will be estimated by using standard weights from Foodworks™ foods if applicable (e.g. a standard weight of a slice of bread) or estimates extrapolated by visual assessment of photographs. A random sample of approximately 20% of lunchbox data entries will be checked for errors by a second dietitian following the same data entry protocols and corrections made as required.

### Secondary Outcomes

Child dietary consumption of foods packed in lunchboxes

Children's consumption of mean energy (kJ) from discretionary foods and mean energy (Kj) saturated fat (g), sugar (g) and sodium (mg) from all foods and calorific drinks packed in



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3 children's lunchboxes will be assessed. As per the packed lunchbox contents, consumption  
4 will be measured on the same unique day for each child at both baseline and approximately  
5 four months follow up. On the day of the lunchbox audits, as part of the data collection  
6 procedure, children will be asked to return all uneaten food and empty packaging to their  
7 lunchbox. After the final meal of the day, food weights, and any packaging included as part  
8 of pre-consumption weights, will be weighed and recorded in grams on the same data  
9 collection form. In order to determine amounts consumed, the total weight of the  
10 foods/drinks post consumption will be subtracted from the total weight of food/drinks pre-  
11 consumption. The same process (as described for the primary outcome measure) will be  
12 undertaken in when entering the amount of food consumed into Foodworks™ for the nutrient  
13 analysis. This method of collecting pre and post consumption weighed food records has  
14 been successfully undertaken by the research team as part of previous trials conducted with  
15 26 childcare services.[48]

22  
23 Serves of lunchbox discretionary foods packed and consumed

24  
25 The number (count of individual items) and serves (600kJ equivalents) of discretionary food  
26 and drinks packed and consumed will be reported. A dietitian will categorise each item as  
27 discretionary or non-discretionary consistent with the Australian Dietary Guidelines.[7]  
28

29  
30 Overall daily usual child intake of discretionary foods

31  
32 Overall daily usual child intake of discretionary foods (serves per day) will be measured via a  
33 sub-group of questions included as part of a 65 item food frequency questionnaire. This  
34 will be completed as part of the online parent survey by both intervention and control parents  
35 at baseline and follow up.  
36

37  
38 The food frequency questions were sourced from the Short Food Survey (SFS), which has  
39 been found to be a valid and reliable tool for Australian children aged 4-11 years with a  
40 significant correlation reported for serves of discretionary foods against 24 hour recalls.[49]  
41 Minor adaptations to the survey were made to capture foods frequently served in the centre-  
42 based care setting.  
43

44  
45 The online parent survey will be emailed to consenting parents after the completion of  
46 baseline data collection and at follow-up. Parents will be asked to complete the survey for  
47 their oldest eligible child only. If not completed, an automated email reminder will be sent  
48 after approximately two weeks. After a further week, non-responders will be offered the  
49 opportunity to complete the survey via phone interview or via paper form.  
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## Other Measures

### Parent and Child Demographics

Parent and child demographics and will be collected as part of the parent online survey and via participant consent form. Specifically, parents will report on child age, gender, post-code of residence, and parental education level, in the consent form, and additional questions on income level, living arrangements and language spoken at home are collected in the online survey.

### Service operational characteristics

Service operational characteristics will be assessed via a Service Manager pen and paper survey distributed to all participating services at baseline on one day of service data collection. Characteristics will include number of years in operation, total number of children enrolled, number of staff employed, and previous staff nutrition training.

### Service Nutrition context (staff behaviours and service nutrition policy and procedures)

The service nutrition context will include assessments of nutrition policies and staff behaviours (e.g. prompting children to eat healthy food, role modelling healthy eating, meal time practices) where there is evidence of potential impact of behaviours on food packed and consumed by children in care. An adapted version of an existing tool, the Environment and Policy Assessment Observation (EPAO) instrument will be used to assess nutrition context.[50] Modified versions of the EPAO have been used previously by the research team in other intervention trials.[51-53] Completion of the EPAO will be undertaken by a third trained research assistant on one of the two days allocated for service-based data collection. A research assistant will observe service staff present in the room/ space where the majority of eligible children are present throughout the day between the core hours of 9am to 3pm. The EPAO tool also includes a short in-person Service Manager interview to collect information and documentation of service nutrition policies and procedures.

### Cost and time

Total grocery cost and average time spent packing lunchboxes will be assessed via items included in the online parent survey at baseline and post intervention for both intervention and control. Change in mean cost of lunchbox contents will be assessed using prices as indicated from online supermarket websites using quantities extracted from weighted lunchbox records at baseline and follow-up.

## Adverse Events

To monitor any adverse parent reaction as a result of the intervention, the average number of parent complaints regarding lunchbox policies at each service will be determined via a question included in the Service Manager pen and paper survey in intervention and control services at both baseline and follow up.

## Intervention acceptability and feasibility

Within the intervention services, parent acceptability (if the intervention is agreeable or satisfactory) will include assessing satisfaction and perceived usefulness of the program content and delivery.[54] Feasibility (suitability for use) will include measuring parent use and engagement with the intervention using app and program website analytics data including; number of message views, frequency of click throughs to linked web-based resources, and number of website page views.[54] Additional information related to parent engagement will be collected in the parent online survey via 25 items assessing satisfaction and usefulness of the program, number of messages opened and number of links accessed. At follow-up service acceptability will include assessment of service managers satisfaction, perceived usefulness, appropriateness, and usefulness of the program measured via a separate 22 item pen and paper survey adapted from an existing questionnaire.[55]

## Intervention fidelity

Intervention fidelity will include assessing whether messages were delivered as intended and quality of message content via researchers directly monitoring the push notifications during the intervention. Parent exposure to the intervention will be assessed via questions included in the parent online survey. Service delivered components of the intervention will be measured via a service completed implementation log. Implementation of other intervention components e.g. site visits conducted as planned, will be recorded as part of the research team's project records. Measuring fidelity across various domains such as these has been recommended as key to informing "real world uptake" of interventions.[56]

## Contamination and co-intervention measures

Contamination will be largely mitigated by centrally controlled access to the intervention (i.e. only parents of the intervention services will receive the messages via the app). Within the post intervention survey, parents will be asked if they accessed the intervention or study website in the last four months. Service and parent receipt of other nutrition interventions separate to the trial during the invention period will be assessed via a question in the EPAO document and in the parent survey at follow up.

## Statistical Analysis

Differences between groups in outcomes will be assessed using hierarchical linear regression models, adjusting for pre-specified prognostic variables associated with the outcome, (service level EPAO scores) as well as clustering, controlling for baseline outcome. A subgroup analyses by child gender and socio economic status will also be undertaken to assess whether there was differential impact by such variables. Using intention to treat principles,[57] missing data from primary and secondary outcomes will be imputed using multiple imputation and will be the main analyses. Findings from the complete case analyses will also be reported. An additional outcome analysis will be conducted whereby only parents who have downloaded the app will be included.

## DISCUSSION

This randomised controlled trial is the first to assess the impact of an m-health intervention targeting the packing of discretionary foods in lunchboxes in the childcare setting. It significantly adds to the limited evidence available for interventions that aim to successfully engage parents and improve centre-based childcare lunchboxes with high potential for delivery at scale. The use of technology to directly support parents packing behaviours represents a highly innovative approach to improve the diets of young children attending centre-based childcare services.

The research also has the potential to significantly improve the health outcomes of young children. The benefits of reducing discretionary foods includes a likely improvement in diet quality, potentially facilitating risk factor reduction for conditions such as Type II Diabetes, cardiovascular disease and certain cancers later in life.[8] If shown to be effective, this intervention has potential to be embedded into other m-health or childcare online technology-based communication platforms providing an opportunity to reach parents nationally to improve the health of young children.

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## DATA STATEMENT

Technical appendix, statistical code and dataset will be made available. Please contact the corresponding author.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

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## **ETHICS AND TRIAL REGISTRATION**

Ethics approval has been provided by the Hunter New England Local Health District Human Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human Research Ethics Committee (H-2008-0343). The trial is prospectively registered with the Australian New Zealand clinical trials registry (ACTRN12618000133235p). Evaluation and process data collected as part of the study will be disseminated peer-reviewed publications and local, national and international presentations, and, and will form part of a PhD student thesis.

## **AUTHOR CONTRIBUTIONS**

First author NP led the development of this manuscript. MF, NP, SY, RS, NN, LW led the development of the intervention, evaluation protocol and research design. All authors contributed to drafting and final approval of the manuscript.

## REFERENCES

1. Joint WHO/FAO Expert Consultation on Diet, Nutrition and the prevention of Chronic Disease. Diet, Nutrition and the Prevention of Chronic Disease: report of a joint WHO/FAO expert consultation, in WHO technical report series; 916. Geneva: 2003.
2. Australian Institute of Health and Welfare. Australia's health 2016. Australia's health series no. 15. Cat. no. AUS 199. 2016. Canberra: AIHW.
3. World Health Organisation. Guideline: Sugars intake for adults and children. Geneva:2015.
4. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. *Pediatrics* 2011;128 (December).
5. Kumar S and Kelly AS. Review of Childhood Obesity: From Epidemiology, Etiology, and Comorbidities to Clinical Assessment and Treatment. *Mayo Clin Proc* 2017;92:251-265.
6. Mura PM, Caton SJ, Vereijken C, et al. How infants and young children learn about food: a systematic review. *Frontiers in Psychology*2017;8:1046.
7. National Health and Medical Research Council. Educator Guide. 2013. National Health and Medical Research Council: Canberra.
8. Johnson BJ, Bell LK, Zarnowiecki D, et al. Contribution of Discretionary Foods and Drinks to Australian Children's Intake of Energy, Saturated Fat, Added Sugars and Salt. *Children (Basel)* 2017;4(12).
9. Public Health England, National Diet and Nutrition Survey. Results from Years 5-6 (combined) of the Rolling Programme (2012/13 – 2013/14). 2016: London.
10. Drewnowski A and Rehm CD. Consumption of added sugars among US children and adults by food purchase location and food source. *Am J Clin Nutr*2014;100(3):901-7.
11. Buscemi J, Odoms-Young A, Stolley ML, et al. Adaptation and dissemination of an evidence-based obesity prevention intervention: design of a comparative effectiveness trial. *Contemp Clin Trials*2014;38(2):355-60.
12. Larson N, Ward DS, Neelon S B et al. What role can child-care settings play in obesity prevention? A review of the evidence and call for research efforts. *J Am Diet Assoc*2011; 111(9):1343-62.
13. Mikkelsen MV, Husby S, Skov LR et al. A systematic review of types of healthy eating interventions in preschools. *Nutr J*2014;13:56.
14. Lucas PJ, Patterson E, Sacks G, et al. Preschool and School Meal Policies: An Overview of What We Know about Regulation, Implementation, and Impact on Diet in the UK, Sweden, and Australia. *Nutrients*2017;9(7).
15. Sweitzer, SJ, Briley ME, and Robert-Gray C R. Do sack lunches provided by parents meet the nutritional needs of young children who attend child care? *J Am Diet Assoc*2009;109(1):141-4.
16. Australian Government Australian Institute of Family Studies. Child care and early childhood education in Australia. 2015 Accessed: 20th September 2018. URL: <https://aifs.gov.au/publications/child-care-and-early-childhood-education-australia>.
17. Soanes, R, Miller M, and A Begley, Nutrient intakes of two- and three-year-old children: a comparison between those attending and not attending long day care centres. *Nutr Diet*2001;58(2):114-120.
18. NSW Ministry of Health, Population Health Information Management System (PHIMS), Healthy Children Initiative. 2018.
19. Kelly B, Hardy L, Howlett S, et al. Opening up Australian preschoolers' lunchboxes. *Aust N Z J Public Health*2010;34(3):288-92.
20. Romo-Palafox MJ, Ranjit N, Sweitzer SJ, et al. Adequacy of Parent-Packed Lunches and Preschooler's Consumption Compared to Dietary Reference Intake Recommendations. *J Am Coll Nutr*2017;36(3)169-176.



21. Roberts-Gray C, Briley ME, Ranjit N, et al. Efficacy of the Lunch is in the Bag intervention to increase parents' packing of healthy bag lunches for young children: a cluster-randomized trial in early care and education centers. *Int J Behav Nutr Phys Act*2016;13:3.
22. Zask A, Adams JK, Brooks LO, et al. Tooty Fruity Veggie: an obesity prevention intervention evaluation in Australian preschools. *Health Promot J Austr*2012;23(1)10-5.
23. Hardy LL, King L, Kelly B, et al. Munch and Move: evaluation of a preschool healthy eating and movement skill program. *Int J Behav Nutr Phys Act*2010;7(1):80.
24. Roberts-Gray C, Ranjit N, Sweitzer, SJ et al. Parent packs, child eats: Surprising results of Lunch is in the Bag's efficacy trial. *Appetite*2018;121:249-262.
25. Roberts-Gray C, Sweitzer SJ, Ranjit N, et al. Structuring Process Evaluation to Forecast Use and Sustainability of an Intervention: Theory and Data From the Efficacy Trial for Lunch Is in the Bag. *Health Educ Behav* 2017;44(4):559-569.
26. Mitchell GL, Farrow C, Haycraft E, et al. Parental influences on children's eating behaviour and characteristics of successful parent-focussed interventions. *Appetite*2013;60(1)85-94.
27. Curtis KE, Lahiri S, and Brown KE. Targeting Parents for Childhood Weight Management: Development of a Theory-Driven and User-Centered Healthy Eating App. *JMIR Mhealth Uhealth*2015;3(2):e69.
28. Schoeppe S, Alley S, Lippevelde W, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *Int J Behav Nutr Phys Act*2016;13(1):127.
29. Rose T, Barker M, Jacob M, et al. A Systematic Review of Digital Interventions for Improving the Diet and Physical Activity Behaviors of Adolescents. *J Adolesc Health* 2017;61(6)669-677.
30. Fjeldsoe BS, Miller YD, O'Brien JL, et al. Iterative development of MobileMums: a physical activity intervention for women with young children. *Int J Behav Nutr Phys Act*2012;9:151.
31. Yellow Social Media Report 2018 Consumers. Yellow Social Media Report 2018- Consumers. June 2018: Melbourne, Australia.
32. Reynolds R, Sutherland R, Nathan, N, et al. Feasibility and principal acceptability of school-based mobile communication applications to disseminate healthy lunchbox messages to parents. *Health Promot J Austr*Published Online First: 12 March 2018. doi:10.1002/hpja.57
33. Australian Bureau of Statistics. Census of Population Health and Housing-Community Profiles. 2016. Accessed Sept 2018. URL: <http://www.abs.gov.au/websitedbs/D3310114.nsf/Home/2016%20Census%20Community%20Profiles>.
34. NSW Health website. Accessed August 2018. URL: <https://www.health.nsw.gov.au/lhd/pages/hnelhd.aspx>.
35. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*2010;63(8)834-40.
36. Australian Bureau of Statistics. *4240.0 Preschool Education*, Australia. 2006: Canberra.
37. Skoolbag PTY LTD, MOQ group of companies. *Skoolbag*. 2018.
38. Burns CM, Gibbon P, Boak RL, et al. Food cost and availability in a rural setting in Australia. *Rural Remote Health*2004;4(4)311.
39. Ward PR, Coveney J, Verity F, et al. Cost and affordability of healthy food in rural South Australia. *Rural Remote Health*2012;12:1938.
40. Kang M, Ragan BG, and Park JH. Issues in outcomes research: an overview of randomization techniques for clinical trials. *J Athl Train*2008;43(2)215-21.
41. Jones J, Wyse R, Finch M, et al. Effectiveness of an intervention to facilitate the implementation of health eating and physical activity policies and practices in childcare services: a randomised control trial. *Implement Sci*2015;10:147.
42. Cochrane T, Davey R, and de Castella FR. Estimates of the energy deficit required to reverse the trend in childhood obesity in Australian schoolchildren. *Aust N Z J Public Health*2016; 40(1):62-7.



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2  
3 43. Michie S, van Stralen MM, and West R. The behaviour change wheel: a new method for  
4 characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.  
5 44. NSW Ministry of Health. Caring for Children birth to 5 years. 2014: Sydney:NSW  
6 Government.  
7 45. Australian Children's Education and Care Quality Authority. What is the NQF? Accessed  
8 August 2018. URL: <https://www.acecqa.gov.au/nqf/about>.  
9 46. Ward S, Blanger M, Donovan D, et al. Association between childcare educators' practices  
10 and preschoolers' physical activity and dietary intake: a cross-sectional analysis. *BMJ Open*  
11 2017;7(5):e013657.  
12 47. Xyris software. *Foodworks*. 2017: High Gate Hill, QLD.  
13 48. Seward K, Wolfenden L, Finch M. et al, Multistrategy childcare-based intervention to  
14 improve compliance with nutrition guidelines versus usual care in long day care services: a  
15 study protocol for a randomised controlled trial. *BMJ Open*2016;6(6):e010786.  
16 49. Hendrie GA, Viner Smith E, and Golley RK. The reliability and relative validity of a diet index  
17 score for 4-11-year-old children derived from a parent-reported short food survey. *Public*  
18 *Health Nutr*2014;17(7)1486-97.  
19 50. Ward D, Hales D, Haverly K. An instrument to assess the obesogenic environment of child  
20 care centers. *Am J Health Beha*2008;32(4)380-6.  
21 51. Finch M, Wolfenden L, Falkiner M, et al. Impact of a population based intervention to  
22 increase the adoption of multiple physical activity practices in centre based childcare  
23 services: a quasi experimental, effectiveness study. *Int J Behav Nutr Phys Act*2012;9:101.  
24 52. Razak LA, Yoong SL, Wiggers J, et al. Impact of scheduling multiple outdoor free-play periods  
25 in childcare on child moderate-to-vigorous physical activity: a cluster randomised trial. *Int J*  
26 *Behav Nutr Phys Act*2018;15(1):34.  
27 53. Bell AC, Davies L, Finch M, et al., An implementation intervention to encourage healthy  
28 eating in centre-based child-care services: impact of the Good for Kids Good for Life  
29 programme. *Public Health Nutrition*2014;18(9)1610-1619.  
30 54. Weiner BJ, Lewis CC, Stanick C, et al., Psychometric assessment of three newly developed  
31 implementation outcome measures. *Implement Sci*2017;12(1):108.  
32 55. Taki S, Lymer S, Russell, CG, et al. Assessing User Engagement of an mHealth Intervention:  
33 Development and Implementation of the Growing Healthy App Engagement Index. *JMIR*  
34 *Mhealth Uhealth*2017;5(6):e89.  
35 56. Breitenstein SM, Fogg L, Garvey C, et al. Measuring implementation fidelity in a  
36 community-based parenting intervention. *Nurs Res*2010;59(3)158-65.  
37 57. White IR, Horton NJ, Carpenter J, et al. Strategy for intention to treat analysis in randomised  
38 trials with missing outcome data. *BMJ*2011;342:d40.  
39 58. Atkins L and Michie S. Conference on 'Changing dietary behaviour: physiology through to  
40 practice'. Symposium 4: Changing diet and behaviour – putting theory into practice.  
41 *Proceedings of the Nutrition Society*2015;74:164-170.  
42 59. Michie S, Wood CE, Johnston M, et al. Behaviour change techniques: the development and  
43 evaluation of a taxonomic method for reporting and describing behaviour change  
44 interventions (a suite of five studies involving consensus methods, randomised controlled  
45 trials and analysis of qualitative data). *Health Technol Assess*2015;19(99):1-188.  
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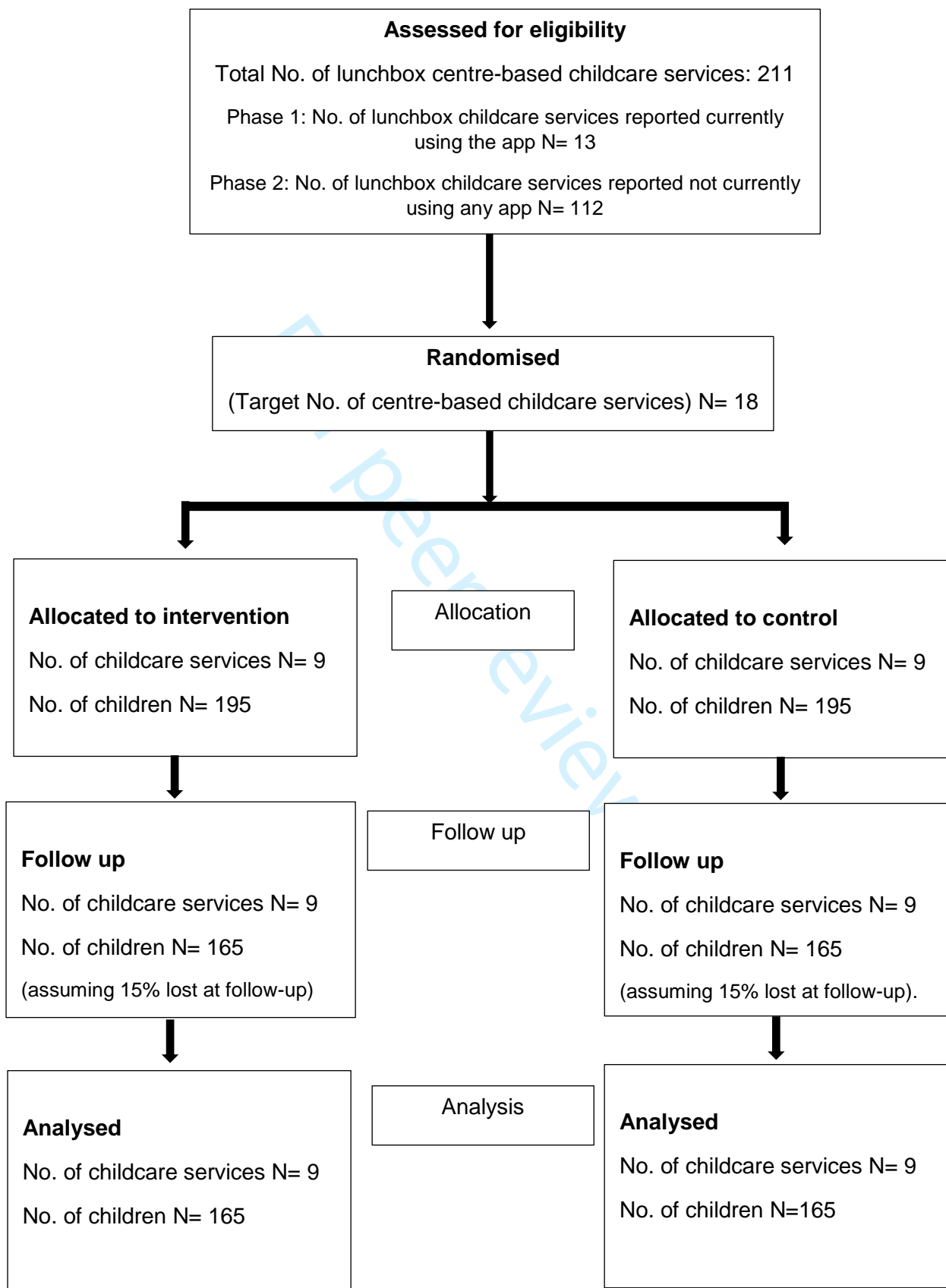


Figure 1 CONSORT flow diagram estimating the progress of preschools and parents through the trial

### **Supplementary file 1: Application of a theoretical framework: Behaviour Change Wheel**

The “SWAP It Childcare” intervention content was been developed using the Behaviour Change Wheel (BCW).[43] Based on a similar process described by behavioural researchers for designing an intervention to change diet behaviours using the BCW,[58] a three-step approach was utilised to apply the framework.

Step one included identification of the target behaviour (ie to pack less discretionary foods in lunchboxes) and formative work to assessing barriers and facilitators to packing healthy foods in children’s through literature reviews and semi-structured interviews with a convenience sample of parents (n= 28). A behavioural analysis, mapping barriers to the COM B components of the BCW was undertaken with the purpose of ensuring our behavioural diagnosis was comprehensive (ie we had sufficient information to gain understanding of the behaviour in respect to all components of the COM B model).

Step two involved identifying intervention options using the BCW. The intervention functions (the means by which an intervention may change behaviour) of education, persuasion, modelling and environmental restructuring were identified using the COM B/ intervention function matrix (ref) and the APEASE (Acceptability, Practicability, Effectiveness/ cost-effectiveness, Affordability, Safety/ side effects, Equity) criteria.[58] Policy categories were then considered to determine the delivery method of the intervention functions. The pre-determined mode of delivery (use of an app to deliver the intervention), fitted the category of “service provision” and was our only identified policy category.

Step three involved identifying the content and delivery options for the intervention. Behaviour change techniques most likely to bring about the desired change were mapped to the identified barriers (with reference to their COM B classifications) using the Behaviour Change Technique taxonomy.[59] A summary of the identified barriers, their COM B classification and the selected behaviour change techniques can be found in table 1. The resulting intervention consists of three key components which address nine identified barriers incorporating eight behaviour change techniques (See table 1).

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	<a href="#">#3</a>	Date and version identifier	1
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	20
Roles and responsibilities:	<a href="#">#5b</a>	Name and contact information for the trial sponsor	NA

1	sponsor contact			
2	information			
3				
4	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	NA
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
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12	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	NA
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
17				
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20	Background and	<a href="#">#6a</a>	Description of research question and justification for	3
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
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27	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	6
28	rationale: choice of			
29	comparators			
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32	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	5
33				
34				
35	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	5
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
39				
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41				
42	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	5
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
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48	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable,	6
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
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54	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8
55	description		replication, including how and when they will be	
56			administered	
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1	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	NA
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
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7	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols,	17
8	adherence		and any procedures for monitoring adherence (eg, drug	
9			tablet return; laboratory tests)	
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13	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	NA
14	concomitant care		permitted or prohibited during the trial	
15				
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17	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	14
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
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28	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any	6
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
32				
33				
34				
35	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study	7
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
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41				
42	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to	7
43			reach target sample size	
44				
45				
46	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,	7
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
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57	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg,	7
58	concealment		central telephone; sequentially numbered, opaque, sealed	
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1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
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4	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol	7
5	implementation		participants, and who will assign participants to	
6			interventions	
7				
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9	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg,	7
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is	NA
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
17				
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19				
20	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline,	14
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
27				
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30				
31	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-	13
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
35				
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38	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including	19
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
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46	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary	18
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
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51				
52	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and	18
53	analyses		adjusted analyses)	
54				
55				
56	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	18
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
59				
60				



1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary	NA
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
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11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	NA
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
14				
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16	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	17
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
19				
20				
21	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any,	NA
22			and whether the process will be independent from	
23			investigators and the sponsor	
24				
25				
26				
27	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional	20
28	approval		review board (REC / IRB) approval	
29				
30				
31	Protocol	<a href="#">#25</a>	Plans for communicating important protocol modifications	NA
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
35				
36				
37	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential	6
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
40				
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42				
43	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	NA
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
46				
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48	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	14
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
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55	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal	19
56	interests		investigators for the overall trial and each study site	
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59	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset,	NA
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and disclosure of contractual agreements that limit such access for investigators

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4	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for
5	trial care		compensation to those who suffer harm from trial
6			participation
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8			
9	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial
10	trial results		results to participants, healthcare professionals, the public,
11			and other relevant groups (eg, via publication, reporting in
12			results databases, or other data sharing arrangements),
13			including any publication restrictions
14			
15			
16			
17	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of
18	authorship		professional writers
19			
20			
21	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol,
22	reproducible		participant-level dataset, and statistical code
23	research		
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26			
27	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given
28	materials		to participants and authorised surrogates
29			
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31	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of
32			biological specimens for genetic or molecular analysis in the
33			current trial and for future use in ancillary studies, if
34			applicable
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 38 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made  
 39 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

**A cluster randomised controlled trial of an m-health intervention in centre-based childcare services to reduce the packing of discretionary foods in children's lunchboxes: Study protocol for the "SWAP IT Childcare" trial**

Journal:	<i>BMJ Open</i>
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Keywords:	lunchbox, discretionary foods, m-health, childcare

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Manuscripts

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3 **A cluster randomised controlled trial of an m-health intervention in centre based**  
4 **childcare services to reduce the packing of discretionary foods in children's**  
5 **lunchboxes: Study protocol for the "SWAP IT Childcare" trial**  
6

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44 Keywords: lunchbox, discretionary foods, m-health, childcare

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46 Date: 4<sup>th</sup> December 2018

47 Protocol version: revision 2  
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## ABSTRACT

**Introduction:** In many developed nations, including Australia, a substantial number of children aged under five years attend centre-based childcare services that require parents to pack food in lunchboxes. These lunchboxes often contain excessive amounts of unhealthy (“discretionary”) foods. This study aims to assess the impact of a mobile health (m-health) intervention on reducing the packing of discretionary foods in children’s childcare lunchboxes.

**Methods and analysis:** A cluster randomised controlled trial will be undertaken with parents from 18 centre-based childcare services in the Hunter New England region of New South Wales, Australia. Services will be randomised to receive either a four month m-health intervention called “SWAP IT Childcare” or usual care. The development of the intervention was informed by the Behaviour Change Wheel model and will consist primarily of the provision of targeted information, lunchbox food guidelines and website links addressing parent-barriers to packing healthy lunchboxes delivered through push notifications via an existing app used by childcare services to communicate with parents and carers. The primary outcomes of the trial will be energy (kilojoules) from discretionary foods packed in lunchboxes and the total energy (kilojoules), saturated fat (grams), total and added sugars (grams) and sodium (milligrams) from all foods packed in lunchboxes. Outcomes will be assessed by weighing and photographing all lunchbox food items at baseline and at the end of the intervention.

**Ethics and Dissemination:** The study was approved by the Hunter New England Local Health District Human Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human Research Ethics Committee (H-2008-0343). Evaluation and process data collected as part of the study will be disseminated in peer-reviewed publications and local, national and international presentations and will form part of PhD student theses.

**Trial registration:** The trial is prospectively registered with the Australian New Zealand clinical trials registry (ACTRN12618000133235).

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This randomised controlled trial is the first to use a m-health intervention to reduce packing of unhealthy foods in lunchboxes in centre- based childcare services.
- The study uses rigorous outcome measures consisting of weighed food records, supplemented by food photography.
- The intervention is developed using a systematic theory-based approach to identify strategies to target parental barriers to packing healthy lunchboxes.
- If found to be effective, the intervention has potential to be delivered via other childcare online technology-based communication platforms.
- The intervention is conducted in one region of Australia which may limit the generalisability of the study findings.

### INTRODUCTION

Poor dietary behaviours are leading modifiable risk factors for the development of future chronic disease including Type 2 diabetes, cardiovascular disease and certain cancers.[1, 2] To reduce chronic disease risk it is recommended that the intake of discretionary foods (i.e. foods high in energy, saturated fat, sugar and/or sodium) is limited.[1] Excessive intake of discretionary foods in childhood is linked to conditions such as dental caries,[3] altered lipid profiles,[4] and unhealthy weight gain.[5] Given that dietary preferences established in childhood are known to track into adulthood,[6] efforts to decrease the consumption of discretionary foods in the early childhood years is recommended to reduce the burden of chronic disease.[1]

National dietary guidelines recommended that children up to eight years of age consume no more than 0.5 serves of discretionary foods per day unless the child is taller or more active where they may consume up to 2 serves per day (i.e. no more than 300- 1200 kJ per day from discretionary foods).[7] Despite this, population studies indicate that child consumption typically exceeds these recommendations [8-10]. Specifically, in Australia children aged four to eight years consumed an average of 41% of their daily energy intake from discretionary foods, the equivalent to approximately 4.5 serves.[8]

Centre-based childcare services, such as preschools and long day care centres, have been identified as priority settings for interventions to improve child diet.[11-13] Such services provide access to a significant number of children, with upwards of 80% of children attending

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3 some form of centre-based care in the year prior to compulsory schooling in Australia, the  
4 United Kingdom (U.K.) and United States (U.S.). [14-16] As children can consume between  
5 one third to two thirds of their daily food intake whilst in centre- based childcare,[17] achieving  
6 even modest dietary improvements in this setting is likely to have considerable potential to  
7 improve child health.  
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11  
12 In Australia, the U.K. and the U.S. it is estimated that between 30% and 50% of centre-based  
13 childcare services require parents to pack food in a lunchbox for their children to consume  
14 while in care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain  
15 excessive amounts of discretionary foods. For example, a study of Australian children  
16 attending 29 centre-based childcare services found that 60% of lunchboxes contained more  
17 than one serve of discretionary food, with an average of two serves of discretionary foods  
18 provided per lunchbox. In addition, 38% of lunchboxes were considered poorly balanced  
19 containing more than one serve of discretionary food and lacked vegetables, fruit or a healthy  
20 main meal. [19] An additional study conducted in 30 centre-based childcare services in Texas  
21 U.S., (607 children) similarly found a disproportionate amount of discretionary foods packed  
22 in lunchboxes with contents exceeding recommendations for saturated fat, sugar and  
23 sodium.[20]  
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32 Despite the potential to improve child diet via interventions to reduce packing of discretionary  
33 foods in lunchboxes of children attending centre-based childcare, to our knowledge just three  
34 randomised trials have been conducted,[21-23] with only one reporting on impact on child  
35 dietary intake.[24] Two of these trials utilised multi-component service based strategies  
36 including staff nutrition training and child education, alongside parent targeted strategies  
37 (including workshops, and parent activity stations).[21,22] Both trials reported significant  
38 improvements in the packing of discretionary foods. The remaining trial involved training of  
39 childcare staff without any direct parent strategies. This trial was ineffective in reducing  
40 packing of discretionary foods.[23] While these findings suggest that interventions targeting  
41 parents are more likely to have an impact, previous approaches have been time and resource  
42 intensive, requiring parents to attend face to face educational sessions. Such strategies have  
43 been reported to have limited reach,[25] and reduce the potential for intervention delivery at a  
44 population level.  
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54 Utilising mobile technology to directly reach parents has been suggested as a potentially  
55 effective strategy to overcome the limited reach of previous parent targeted  
56 interventions.[26,27] Evidence demonstrates that mobile health (m-health) interventions can  
57 be effective in changing dietary behaviours in both adults [28] and children.[28,29] The use of  
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3 mobile phone applications (apps) has been identified as highly acceptable to parents as a  
4 preferred health engagement tool,[30] and has the potential to successfully reach the large  
5 majority (over 86%) of parents who are estimated to now own a smart phone.[31] Embedding  
6 interventions within existing childcare service mobile phone apps may also overcome  
7 previously reported barriers related to reach and engagement via their ability to reach parents  
8 at any place or time, deliver education materials and provide reminders or prompts targeting  
9 specific behaviours.[27] Using an existing school communication app for the purpose of  
10 delivering healthy lunchbox information to parents was found to be highly feasible and  
11 acceptable by principals in the primary school setting within the Hunter New England region  
12 of NSW,[32] and the results of a healthy lunchbox pilot study utilising this model showed  
13 promising effects on the nutritional quality of children's lunchbox contents [unpublished data  
14 from a randomised controlled trial to assess the effectiveness, feasibility and acceptability of  
15 an m-health intervention 'SWAP IT', provided by author RS, 2018]. Utilising a similar approach  
16 in the centre-based childcare setting to reduce the packing of discretionary foods in  
17 lunchboxes therefore appears highly feasible. Despite this, to the author's knowledge no such  
18 m-health intervention has been conducted in this setting.

## 29 **STUDY AIMS**

31 The primary aim of the trial is to assess the efficacy of an m-health intervention, embedded  
32 within an existing childcare parent communication app to reduce: i) the mean energy (kilojoule  
33 (kJ)) from discretionary foods and drinks packed in children's lunchboxes, and ii) the mean  
34 energy (kilojoule (kJ)), saturated fat (grams (g)), total and added sugar (grams (g)) and sodium  
35 (grams (g)) from all foods and drinks packed in lunchboxes. We will also assess the impact of  
36 the intervention on child dietary consumption of: i) mean energy (kJ) from discretionary foods  
37 packed in the lunchbox; ii) mean energy (kJ), mean saturated fat (g), sodium (mg) and total  
38 and added sugars (g) from all foods and drinks packed in the lunchbox; iii) serves of lunchbox  
39 discretionary foods and drinks packed and consumed; and iv) usual serves of discretionary  
40 foods consumed over 24 hours. Parent and service acceptability and feasibility and potential  
41 adverse effects of the intervention will also be assessed.

## 51 **METHODS AND ANALYSIS**

### 52 **Settings and Design**

53 The study will utilise a cluster randomised controlled trial design, and will be conducted with  
54 parents and children attending centre-based childcare services located in the Hunter New  
55 England (HNE) Local Health District of New South Wales (NSW), Australia (see Figure 1).



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3 Allocation will be at the unit of the childcare service. In 2016, approximately 819 814 people  
4 were reported to reside in the HNE area, of which 51 900 were children aged 0 to 4 years.[33]  
5 The area encompasses major metropolitan centres and inner regional communities, with a  
6 small percentage (14%) of people located in remote communities.[34]  
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10 The trial will run between March 2018 and January 2019. Following baseline data collection  
11 services will be randomly allocated to receive the approximately four month intervention or to  
12 a usual care control group. The trial outcome measures will be assessed in the same child  
13 cohort within both groups at baseline and post intervention. The study will follow the  
14 CONSORT reporting guidelines.[35]  
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### 21 **Figure 1: CONSORT diagram estimating the progress of centre based childcare** 22 **services and children through the trial**

23  
24 *Insert Figure 1*  
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### 28 **Participants and eligibility**

#### 29 **Sample**

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31 A list of all centre-based childcare services (including long day care and preschool services)  
32 located in the study region will be accessed via the NSW Ministry of Health. Approximately  
33 211 (54%) services in the study region require parents to pack foods (referred to as lunchbox  
34 services) and will serve as the sampling frame. Within NSW, long day care services can  
35 provide centre-based care for children from six weeks, to under six years of age for eight or  
36 more hours per day. Preschools typically enrol children between three and six years of age  
37 and provide care for six and eight hours per day.[36]  
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#### 46 **Eligibility**

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48 To be eligible to participate, lunchbox services must cater for children three to six years of  
49 age, and be either existing users of the designated parent communication app (Skoolbag),[37]  
50 or have a willingness to commence using the app. Services will be excluded if they are;  
51 participating in any other trial related to improving child nutrition, cater exclusively for children  
52 with special needs or are a Department of Education community run service (as they are not  
53 covered within the existing ethics arrangement). Parents or carers (hereafter referred to as  
54 “parents”) of children aged 3-6 years will be eligible to participate if their child attends during  
55 the days of data collection period and if they indicated willingness to download or use the app.  
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3 Children will be excluded if they have special dietary requirements or allergies that would  
4 necessitate specialised tailoring of their diet.  
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## 9 **Recruitment procedures**

### 10 **Services**

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12 Initial recruitment will target eligible services currently using Skoolbag (n = 13), after which  
13 services that do not use any app (as identified via a telephone survey undertaken by the  
14 research team) will be randomly approached (n=112) until 18 services are enrolled in the trial.  
15 Services commencing using the app for the purpose of the trial will be able to use the app free  
16 of charge for the duration of the intervention.  
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21 Service managers of eligible services will be posted and emailed information statements and  
22 consent forms detailing the study and requesting participation. Written consent to participate  
23 in the trial will be provided by the manager on behalf of the services.  
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### 27 **Children**

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29 Centre-based childcare staff will distribute hard copies of information statements and consent  
30 forms to parents approximately two weeks prior to baseline data collection. To maximise  
31 consent rates, research assistants will also be present at the service for two days (based on  
32 highest child attendance) during drop off and pick up times to speak with eligible parents and  
33 promote participation in the trial. If more than one child is eligible per family, only the oldest  
34 will be included in the trial to reduce participant burden.  
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## 42 **Random allocation of childcare services**

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44 Consenting services will be randomly allocated to the intervention or usual care control group  
45 in a 1:1 ratio using a computerised random number generator. Randomisation of services will  
46 be undertaken following baseline data collection by a statistician who will otherwise have no  
47 involvement in the study. Based on evidence of associations for family socio-economic status  
48 and rurality with child dietary intake,[38,39] randomisation will be stratified by the socio-  
49 economic area of the childcare service and by rural location. As part of ensuring equity of  
50 access to the intervention, services will also be stratified by those with high numbers of  
51 Aboriginal child enrolments defined as those with >10% Aboriginal children enrolled. This level  
52 of stratification was deemed appropriate for the sample size.[40]  
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3 This trial will be conducted as an open trial due to the nature of the intervention. Services and  
4 parents will be notified of their allocation following baseline data collection however outcome  
5 assessors will remain blinded to service allocation.  
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### 10 **Sample size and power calculations**

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12 The study aims to recruit approximately 390 children from 18 childcare services. Given a 15%  
13 attrition rate at follow up, this will allow detection of a mean difference of 123 kJ in the primary  
14 outcome, with an alpha of 0.01 (adjusting for multiple outcomes), and an estimated ICC of 0.1,  
15 with 80% power [41,42] and a standard deviation of 200 kJ. The ICC applied is based on  
16 internal and unpublished pilot data undertaken with a smaller number of lunchboxes. As  
17 children are recruited from childcare centres which may have existing lunchbox policies that  
18 may impact on provision of food, we anticipate that an ICC of 0.1 may be a conservative  
19 estimate of clustering. Approximately 123 kJ difference in energy was considered clinically  
20 significant based on an estimate of the energy deficit required to reduce the prevalence of  
21 childhood obesity (420KJ)[43] and proportionally adjusted to the amount of time children  
22 spend in care (approximately one third of the day). Such an energy reduction could be  
23 expected to result in the detection of approximately 0.6g less saturated fat, 2.2g less sugar  
24 and 44 mg less sodium.[8]  
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### 36 **Intervention**

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38 “SWAP IT Childcare” is an adapted version of a previously piloted intervention conducted with  
39 primary school children aged 5-12 years. The program is embedded in an existing parent  
40 communication app used in both schools and centre-based childcare services and aims to  
41 assist parents to “swap in” healthy foods and “swap out” discretionary foods when packing  
42 lunchboxes. Services use this communication app to provide information to parents regarding  
43 their child’s daily activities, newsletters and other service related information. The app has the  
44 capacity to deliver content in the form of text, images and media (videos) and store information  
45 available for permanent access.  
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51 The program was co-produced by a team of behavioural researchers, public health nutritionist,  
52 centre-based childcare staff and the technology provider “Skoolbag” and was based on  
53 formative evaluations with parents. Key differences between the primary schools and  
54 childcare settings as well as parent reported barriers were identified during formative  
55 assessments which necessitated amendments to strategy selection, intervention components  
56 and content between the two programs. The “SWAP IT Childcare” intervention will specifically  
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3 target parents of children aged three to six years and will be primarily delivered via a series of  
4 push notification messages using the service's communication app. Feedback was sought on  
5 the content of the program from parents of childcare-aged children, the research unit's  
6 Aboriginal Health Staff advisory group and from two local Aboriginal centre-based childcare  
7 service managers to ensure cultural appropriateness.  
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#### 11 Application of a theoretical framework

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14 The "SWAP It Childcare" intervention content was developed using the Behaviour Change  
15 Wheel (BCW).[44] This theoretically driven framework is based on 19 theories of health  
16 behaviour and is designed to enable the systematic development of interventions for  
17 supporting behaviour change.[44] For a description of the application of the framework please  
18 refer to supplementary file 1. An overview of the intervention mapping process is provided in  
19 Table 1.  
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#### 27 **Intervention strategies**

28 A four month intervention (Table 2) consisting of the following components will be delivered  
29 as part of "SWAP IT Childcare":  
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- 32 1. Provision of weekly push notifications targeting identified barriers to the packing of  
33 healthier lunchboxes
- 34 2. Provision of "SWAP IT Options" which are centre-based childcare lunchbox guidelines  
35 designed to provide specific information to parents on suitable foods for the lunchbox.
- 36 3. Centre-based childcare service endorsement of the program in order to support  
37 adoption of the "SWAP IT Options" lunchbox guidelines.  
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43 Further details regarding each strategy and delivery mode are provided in table 2.  
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#### 45 **Control Group**

46 Services allocated to the control group will participate in data collection only. Parents from  
47 these services will receive routine centre-based childcare communication via the app (usual  
48 care) with no access to the lunchbox content.  
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#### 53 **Patient and Public Involvement**

54 The research question and intervention was co-designed together with the local health  
55 promotion unit (Hunter New England Population Health) responsible for supporting childcare  
56 services to support parents with packing healthier lunchboxes. As described in the methods,  
57 intervention design and content was informed in part, by the results of a survey of parents  
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3 (n= 29) from a convenience sample of local childcare services and consultation with two  
4 local Aboriginal centre based childcare service managers. Service managers were also  
5 consulted about the acceptability of app technology for delivering the intervention to parents.  
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7 The participating parents were not involved in the design, recruitment or conduct of the study  
8 however childcare staff will support recruitment via assistance with distribution and collection  
9 of consent forms and assistance with the data collection process by identifying lunchboxes  
10 for weighing. Participant burden to engaging with the intervention will be assessed as part of  
11 a follow up survey with parents assessing acceptability and time and cost of changing  
12 behaviours. A summary of the results will be provided to participating services to distribute to  
13 parents and a copy of the summary will be available on the research unit's website or upon  
14 individual request from parents.  
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Table 1 Intervention mapping overview

1. COM B (source of behaviour)	2. Related barrier/ enabler		3. Components of the Intervention (numbers represent barriers in column 2)		4. Behaviour Change techniques (numbers represent barriers in column 2)
Capability	1. A lack of knowledge about appropriate foods and drinks for the lunchbox	➔	Provision of weekly push notifications targeting identified barriers to packing of healthier lunchboxes (1, 2, 3, 4, 5, 6, 7, 8)	➔	4.1 Instruction on how to perform a behaviour (1,5,6,7)
	2. Lack of ideas for healthy appealing lunchbox foods				5.1 Information about health consequences (8)
Opportunity	3. Perception that it takes longer to prepare and/ or shop for healthy foods for the lunchbox.	➔		➔	6.1 Demonstration of the behaviour (3, 4, 6, 7)
	4. Perception that it costs more to pack a healthy lunchbox	➔			7.1 Prompts/cues (8)
	5. Child is a fussy eater (i.e. will not accept new foods packed in the lunchbox)	➔			8.2 Behaviour substitution (1, 2, 6, 7)
	6. Reluctance to pack healthy food options in order to avoid: <ul style="list-style-type: none"> <li>- food going to waste</li> <li>- child going hungry</li> <li>- child complaints</li> </ul>	➔	Provision of SWAP IT Lunchbox guidelines (1, 2)	➔	11.3 Conserving mental resources (1, 2)
Motivation	7. Parents' lack of awareness of link between nutrition and health outcomes. Belief there is no need to limit less healthy foods the lunchboxes.	➔			15.1 Verbal persuasion about capability (3, 4, 5, 6)
	8. Lack of motivators or prompts to change lunchbox packing behaviours	➔	Centre-based childcare service support and endorsement of the "SWAP IT in Childcare" program		

Table 2: Intervention components, strategies and resources

Intervention component	Strategy Description	Resources and Delivery Mode
<p><b>1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes</b></p>	<p>Push notifications will alert parents to messages sent via the service's app for 10 weeks (one per week). The behaviour change techniques designed to influence parent behaviour will be delivered via the content of these messages and images, and through attachments and links to the "SWAP IT Childcare" webpages, videos, fact sheets and other websites. Graphics of recommended "swaps" will be included in various messages, for example a graphic recommending a swap from a popular high saturated fat, high sodium savoury cracker to low saturated fat, lower sodium cracker, a swap from a cheese flavoured biscuit to vegetables sticks and dip and a swap from chocolate biscuit snacks to wholegrain cereal snacks. As an example of a push notification message, the message aiming to reduce the perceived barrier of "cost of a healthy lunchbox", includes persuasive language explaining that expensive foods doesn't need to be purchased to provide a healthy lunchbox. It also includes an embedded video in the push notification message that provides examples of inexpensive healthy foods to pack for children, and will demonstrate how healthy items often cost the same as less healthy items in the supermarket. Finally, an attached fact sheet provides practical examples of how to save money and demonstrates cost savings possible over a year. For</p>	<p><b>a) "SWAP IT Childcare" push notification topics delivered via the app</b></p> <p>Week 1 (2 messages): Welcome to "SWAP IT" The ultimate list of healthy lunchbox foods</p> <p>Week 2: "Sweet" food ideas for the lunchbox</p> <p>Week 3: Cost saving ideas for the lunchbox</p> <p>Week 4: Common fussy eating concerns</p> <p>Week 5: Healthy savoury snacks that are a hit!</p> <p>Week 6: Why are some lunchbox snacks better than others?</p> <p>Week 7: Is your child drinking enough?</p> <p>Week 8: Top 5 time saving ideas when packing a healthy lunchbox</p> <p>Week 9: Supporting children to try new foods</p> <p>Week 10: Thanks for being part of SWAP IT</p> <p><b>b) Links to fact sheets and videos within messages</b></p> <p>Top time saving tips (fact sheet and video)</p>

	<p>further information on behaviour change techniques used to address each barrier please refer to Table 1.</p>	<p>Money saving tips for the lunchbox (fact sheet and video)          Fussy Eating Concerns (fact sheet)          Tips for encouraging new foods (fact sheet and video)          5 Best savoury swaps for the lunchbox (fact sheet)          5 Best sweet swaps for the lunchbox (fact sheet)</p>
<p><b>2. Provision of “SWAP IT Options” Lunchbox Guidelines</b></p>	<p>Parents will be given access to and encouraged to use 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,[7] recommendations outlined in the NSW Ministry of Health nutrition sector specific resource [45] and health and wellbeing requirements outlined in national accreditation standards.[46]</p>	<p><b>a) “SWAP IT Options” Lunchbox Guidelines, provided via links in push notification messages delivered via the app</b></p> <p>SWAP IT Options Savoury          SWAP IT Options Sweet          SWAP IT Options Lunch foods          SWAP IT Options Drinks</p>
<p><b>3. Centre-based childcare service endorsement of the program</b></p>	<p>To support service adoption of the “SWAP IT Choices” lunchbox guidelines, a Health Promotion Officer will conduct 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).The Service Managers will also be 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.</p>	<p><b>a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.</b></p>

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	<p>Service managers will be asked to send two communications to parents via the app or other preferred communication methods (e.g. hard copy newsletters). The first communication will be sent prior to the first app push notification message to convey service support for the program, and to endorse the use of the “SWAP IT Options” lunchbox guidelines and the second communication, will be sent approximately mid-intervention. This is designed to provide parents with non-contingent praise and support to continue to access the app and its content and assist with prevention of a drop off in opening messages over time.</p> <p>A record of implementation will be given to service managers to enable them to record their delivery of the agreed tasks during the intervention period and to measure implementation fidelity.</p>	<p><b>b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.</b></p> <p><b>c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).</b></p> <p><b>d) Provision of a service-completed record of implementation form.</b></p>
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## DATA COLLECTION PROCEDURES AND MEASURES:

### Primary Outcomes

Food packed in lunchboxes

The primary trial outcomes include mean energy (kJ) provided by discretionary foods, and mean energy (kJ), saturated fat (g), total and added sugars (g) and sodium (mg) provided by all food and drinks packed in children's lunchboxes. The outcome will be assessed via photography and weighed food records. Weighing is considered one of the most accurate methods of determining portion size and consumption of food and drinks.[47] Research assistants will undertake a one day training session requiring them to practice weighing sample lunchboxes and complete data collection forms with feedback given on their adherence to data collection protocols. Lunchbox measures will be undertaken on one unique day for each child as part of two-day data collection at each service at both baseline and approximately four months follow up. The days of the week on which data will be collected may be different for each service. Parents will not be informed of the day that lunchbox data will be collected to minimise reactivity bias. On the days of data collection all packed food and drinks (excluding water) will be weighed, individually where possible, and photographed by a trained research assistant blinded to service allocation. Food will be photographed against paper that includes a metric ruler graphic to aid weight estimations if required. Weight will be recorded in grams by a second trained research assistant using a standardised form developed by the research team. To ensure consistency and quality of data collection, lunchbox photographs and data collection forms will be reviewed by a dietitian once returned for accuracy and compliance with protocols.

The weighed food record data will be verified using photos and entered into a food and nutrient analysis database (Foodworks™)[48] in grams by a trained dietitian. The weights of individual foods weighed as part of a mixed foods (e.g. determining the weight of the cheese and weight of the bread as part of the total grams recorded for a cheese sandwich), will be estimated by using standard weights from Foodworks™ foods if applicable (e.g. a standard weight of a slice of bread) or estimates extrapolated by visual assessment of photographs. Where foods are home-made, an appropriate standard recipe will be sourced from within the Foodworks™ database. Where a suitable recipe is not available, Dietitians within the research team will reach a consensus on an appropriate alternate source for the recipe. When commercial foods are not in their packages, photographs will be used in conjunction with the research team's consensus on the most likely product fit and these assumptions will be recorded. A random sample of approximately 20% of lunchbox data entries will be checked for errors by a second dietitian following the same data entry protocols and corrections made as required.

## Secondary Outcomes

### Child dietary consumption of foods packed in lunchboxes

Children's consumption of mean energy (kJ) from discretionary foods, and mean energy (kJ) saturated fat (g), total and added sugars (g) and sodium (mg) from all foods and calorific drinks packed in children's lunchboxes will be assessed. As per the packed lunchbox contents, consumption will be measured on the same unique day for each child at both baseline and approximately four months follow up. On the day of the lunchbox audits, as part of the data collection procedure, children will be asked to return all uneaten food and empty packaging to their lunchbox. After the final meal of the day, food weights, and any packaging included as part of pre-consumption weights, will be weighed and recorded in grams on the same data collection form. In order to determine amounts consumed, the total weight of the foods/drinks post consumption will be subtracted from the total weight of food/drinks pre-consumption. The same process (as described for the primary outcome measure) will be undertaken when entering the amount of food consumed into Foodworks™ for the nutrient analysis. This method of collecting pre and post consumption weighed food records has been successfully undertaken by the research team as part of a previous trial conducted with 26 childcare services.[49]

### Serves of lunchbox discretionary foods packed and consumed

The number (count of individual items) and serves (600 kJ equivalents) of discretionary food and drinks packed and consumed will be reported. A dietitian will categorise each item as discretionary or non-discretionary consistent with the Australian Dietary Guidelines.[7]

### Overall daily usual child intake of discretionary foods

Overall daily usual child intake of discretionary foods (serves per day) will be measured via a sub-group of questions included as part of a 65 item food frequency questionnaire. This will be completed as part of the online parent survey by both intervention and control parents at baseline and follow up.

The food frequency questions were sourced from the Short Food Survey (SFS), which has been found to be a valid and reliable tool for Australian children aged 4-11 years with a significant correlation ( $r=0.43-0.44$ ,  $P<0.01$ ) reported for serves of discretionary foods against 24 hour recalls.[50] Minor adaptations to the survey were made to capture foods frequently served in the centre-based childcare setting.

The online parent survey will be emailed to consenting parents after the completion of service-level baseline data collection and again at follow-up. Parents will be asked to complete the

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3 survey for their oldest eligible child only. If not completed, an automated email reminder will  
4 be sent after approximately two weeks. After a further week, non-responders will be offered  
5 the opportunity to complete the survey via phone interview or via paper form.  
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## 9 10 **Other Measures**

### 11 Parent and child demographics

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14 Parent and child demographic information will be collected as part of the parent online survey  
15 and via participant consent form. Specifically, parents will report on child age, gender, post-  
16 code of residence, and parental education level, as part of the consent form, and additional  
17 questions on income level, living arrangements and language spoken at home will be collected  
18 via the online survey.  
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### 23 Service operational characteristics

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26 Service operational characteristics will be assessed via a pen and paper survey completed by  
27 the service manager at all participating services at baseline on one day of service data  
28 collection. Characteristics will include number of years in operation, total number of children  
29 enrolled, number of staff employed, and previous staff nutrition training.  
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### 33 Service nutrition context (staff behaviours and service nutrition policy and procedures)

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36 The service nutrition context will include assessments of nutrition policies and staff behaviours  
37 (e.g. prompting children to eat healthy food, role modelling healthy eating, meal time practices)  
38 where there is evidence of potential impact of behaviours on food packed and consumed by  
39 children in care. An adapted version of an existing tool, the Environment and Policy  
40 Assessment Observation (EPAO) instrument will be used to assess nutrition context.[51]  
41 Modified versions of the EPAO have been used previously by the research team in other  
42 intervention trials.[52-54] Completion of the EPAO will be undertaken by a third trained  
43 research assistant on one of the two days allocated for service-level data collection. A  
44 research assistant will observe service staff present in the room/ space where the majority of  
45 eligible children are present throughout the day between the core hours of 9am to 3pm. The  
46 EPAO tool also includes a short in-person service manager interview to collect information  
47 and documentation of service nutrition policies and procedures.  
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### Cost and time

Total grocery cost and average time spent packing lunchboxes will be assessed via items included in the online parent survey at baseline and post intervention for both intervention and control groups. Change in mean cost of lunchbox contents will be assessed using prices as indicated from online supermarket websites using quantities extracted from weighted lunchbox records at baseline and follow-up.

### Adverse events

To monitor any adverse parent reaction as a result of the intervention, the average number of parent complaints regarding lunchbox policies at each service will be determined via a question included in the service manager pen and paper survey in intervention and control services at both baseline and follow up.

### Intervention acceptability and feasibility

Within the intervention services, parent acceptability (i.e. an assessment as to whether the intervention is agreeable or satisfactory) will include assessing satisfaction and perceived usefulness of the program content and delivery via items included within the parent survey.[55] Feasibility (i.e. suitability for use) will include measuring parent use and engagement with the intervention, through the use of app and program website analytics data including: number of message views, frequency of click throughs to linked web-based resources, and number of website page views.[55] Additional information related to parent engagement will be collected in the parent online survey via 25 items assessing use of the app and features such as the push notification alerts, satisfaction and usefulness of the program, number of messages opened, number of links accessed and any barriers to accessing or using the technology. At follow-up service acceptability will include assessment of service managers satisfaction, perceived usefulness, and appropriateness of the program measured via a separate 22 item pen and paper survey adapted from an existing questionnaire.[56]

### Intervention fidelity

Intervention fidelity will include assessing whether messages were delivered as intended and quality of message content via researchers directly monitoring the push notifications during the intervention. Parent exposure to the intervention will be assessed via questions included in the parent online survey. Service delivered components of the intervention will be measured via a service completed implementation log. Implementation of other intervention components e.g. site visits conducted as planned, will be recorded as part of the research team's project

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3 records. Measuring fidelity across various domains such as these has been recommended as  
4 key to informing “real world uptake” of interventions.[57]  
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#### 6 Contamination and co-intervention measures

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8 Contamination will be largely mitigated by centrally controlled access to the intervention (i.e.  
9 only parents of the intervention services will receive the messages via the app). Within the  
10 post intervention survey, parents will be asked if they accessed the intervention or study  
11 website in the last four months. Service and parent receipt of other nutrition interventions  
12 separate to the trial during the invention period will be assessed via questions included within  
13 the EPAO document and within the parent survey at follow up.  
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#### 22 **Statistical Analysis**

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24 All statistical analysis will be performed with SAS (V.9.4) statistical software by an experienced  
25 statistician independent to the study. Differences in outcomes between groups will be  
26 assessed using hierarchical linear regression models, adjusting for pre-specified prognostic  
27 variables associated with the outcome, (service level EPAO scores) as well as clustering,  
28 controlling for baseline outcome. A subgroup analyses by child gender and socio economic  
29 status will also be undertaken to assess whether there was a differential impact according to  
30 such variables. Using intention to treat principles,[58] missing data from primary and  
31 secondary outcomes at follow-up due to attrition, will be imputed using multiple imputation[58]  
32 through the SAS MI and MIANALYZE Procedure and will be the main analyses. Findings from  
33 the complete case analyses will also be reported. An additional outcome analysis will be  
34 conducted whereby only parents who have downloaded the app will be included.  
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#### 45 **DISCUSSION**

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47 This randomised controlled trial is the first to assess the impact of an m-health intervention  
48 targeting the packing of discretionary foods in lunchboxes in the childcare setting. It  
49 significantly adds to the limited evidence available for interventions that aim to successfully  
50 engage parents and improve centre-based childcare lunchboxes with high potential for  
51 delivery at scale. The use of technology to directly support parents packing behaviours  
52 represents a highly innovative approach to improve the diets of young children attending  
53 centre-based childcare services.  
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3 The research also has the potential to significantly improve the health outcomes of young  
4 children. The benefits of reducing discretionary foods includes a likely improvement in diet  
5 quality, potentially facilitating risk factor reduction for conditions such as Type II diabetes,  
6 cardiovascular disease and certain cancers later in life.[8] If shown to be effective, this  
7 intervention has the potential to be embedded into other m-health or childcare online  
8 technology-based communication platforms providing an opportunity to reach parents  
9 nationally to improve the health of young children.  
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22 of participating centre- based childcare services.  
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## 29 **DATA STATEMENT**

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31 Technical appendix, statistical code and dataset will be made available. Please contact the  
32 corresponding author.  
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## 37 **COMPETING INTERESTS**

38  
39 The authors declare that they have no competing interests.  
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7 NHMRC.  
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## 11 **ETHICS AND DISSEMINATION**

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14 Ethics approval has been provided by the Hunter New England Local Health District Human  
15 Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human  
16 Research Ethics Committee (H-2008-0343). The trial is prospectively registered with the  
17 Australian New Zealand clinical trials registry (ACTRN12618000133235p). Evaluation and  
18 process data collected as part of the study will be disseminated peer-reviewed publications  
19 and local, national and international presentations, and will form part of a PhD student thesis.  
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## 24 **AUTHOR CONTRIBUTIONS**

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26  
27 First author Nicole Pond led the development of this manuscript. Meghan Finch, Nicole Pond,  
28 Sze Lin Yoong, Rachel Sutherland, Nicole Nathan, Luke Wolfenden and Vanessa Herrmann  
29 led the development of the intervention, Meghan Finch, Nicole Pond, Sze Lin Yoong, Rachel  
30 Sutherland, Nicole Nathan, Alice Grady, Melanie Kingsland, Karen Gillham contributed to the  
31 evaluation protocol and research design. Meghan Finch, Nicole Pond, Sze Lin Yoong, Rachel  
32 Sutherland, Nicole Nathan, Luke Wolfenden, Alice Grady, Melanie Kingsland, Karen Gillham  
33 and Vanessa Herrmann contributed to drafting and final approval of the manuscript.  
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## REFERENCES

1. Joint WHO/FAO Expert Consultation on Diet, Nutrition and the prevention of Chronic Disease. Diet, Nutrition and the Prevention of Chronic Disease: report of a joint WHO/FAO expert consultation, in WHO technical report series; 916. Geneva: 2003.
2. Australian Institute of Health and Welfare. Australia's health 2016. Australia's health series no. 15. Cat. no. AUS 199. 2016. Canberra: AIHW.
3. World Health Organisation. Guideline: Sugars intake for adults and children. Geneva:2015.
4. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. *Pediatrics* 2011;128 (December).
5. Kumar S and Kelly AS. Review of Childhood Obesity: From Epidemiology, Etiology, and Comorbidities to Clinical Assessment and Treatment. *Mayo Clin Proc* 2017;92:251-265.
6. Mura PM, Caton SJ, Vereijken C, et al. How infants and young children learn about food: a systematic review. *Frontiers in Psychology*2017;8:1046.
7. National Health and Medical Research Council. Educator Guide, p22. 2013. National Health and Medical Research Council: Canberra.
8. Johnson BJ, Bell LK, Zarnowiecki D, et al. Contribution of Discretionary Foods and Drinks to Australian Children's Intake of Energy, Saturated Fat, Added Sugars and Salt. *Children (Basel)* 2017;4(12).
9. Public Health England, National Diet and Nutrition Survey. Results from Years 5-6 (combined) of the Rolling Programme (2012/13 – 2013/14). 2016: London.
10. Drewnowski A and Rehm CD. Consumption of added sugars among US children and adults by food purchase location and food source. *Am J Clin Nutr*2014;100(3):901-7.
11. Buscemi J, Odoms-Young A, Stolley ML, et al. Adaptation and dissemination of an evidence-based obesity prevention intervention: design of a comparative effectiveness trial. *Contemp Clin Trials*2014;38(2):355-60.
12. Larson N, Ward DS, Neelon S B et al. What role can child-care settings play in obesity prevention? A review of the evidence and call for research efforts. *J Am Diet Assoc*2011; 111(9):1343-62.
13. Mikkelsen MV, Husby S, Skov LR et al. A systematic review of types of healthy eating interventions in preschools. *Nutr J*2014;13:56.
14. Lucas PJ, Patterson E, Sacks G, et al. Preschool and School Meal Policies: An Overview of What We Know about Regulation, Implementation, and Impact on Diet in the UK, Sweden, and Australia. *Nutrients*2017;9(7).
15. Sweitzer, SJ, Briley ME, and Robert-Gray C R. Do sack lunches provided by parents meet the nutritional needs of young children who attend child care? *J Am Diet Assoc*2009;109(1):141-4.
16. Australian Government Australian Institute of Family Studies. Child care and early childhood education in Australia. 2015 Accessed: 20th September 2018. URL: <https://aifs.gov.au/publications/child-care-and-early-childhood-education-australia>.
17. Soanes, R, Miller M, and A Begley, Nutrient intakes of two- and three-year-old children: a comparison between those attending and not attending long day care centres. *Nutr Diet*2001;58(2):114-120.
18. NSW Ministry of Health, Population Health Information Management System (PHIMS), Healthy Children Initiative. 2018.
19. Kelly B, Hardy L, Howlett S, et al. Opening up Australian preschoolers' lunchboxes. *Aust N Z J Public Health*2010;34(3):288-92.



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20. Romo-Palafox MJ, Ranjit N, Sweitzer SJ, et al. Adequacy of Parent-Packed Lunches and Preschooler's Consumption Compared to Dietary Reference Intake Recommendations. *J Am Coll Nutr*2017;36(3)169-176.
21. Roberts-Gray C, Briley ME, Ranjit N, et al. Efficacy of the Lunch is in the Bag intervention to increase parents' packing of healthy bag lunches for young children: a cluster-randomized trial in early care and education centers. *Int J Behav Nutr Phys Act*2016;13:3.
22. Zask A, Adams JK, Brooks LO, et al. Tooty Fruity Veggie: an obesity prevention intervention evaluation in Australian preschools. *Health Promot J Austr*2012;23(1)10-5.
23. Hardy LL, King L, Kelly B, et al. Munch and Move: evaluation of a preschool healthy eating and movement skill program. *Int J Behav Nutr Phys Act*2010;7(1):80.
24. Roberts-Gray C, Ranjit N, Sweitzer, SJ et al. Parent packs, child eats: Surprising results of Lunch is in the Bag's efficacy trial. *Appetite*2018;121:249-262.
25. Roberts-Gray C, Sweitzer SJ, Ranjit N, et al. Structuring Process Evaluation to Forecast Use and Sustainability of an Intervention: Theory and Data From the Efficacy Trial for Lunch Is in the Bag. *Health Educ Behav* 2017;44(4):559-569.
26. Mitchell GL, Farrow C, Haycraft E, et al. Parental influences on children's eating behaviour and characteristics of successful parent-focussed interventions. *Appetite*2013;60(1)85-94.
27. Curtis KE, Lahiri S, and Brown KE. Targeting Parents for Childhood Weight Management: Development of a Theory-Driven and User-Centered Healthy Eating App. *JMIR Mhealth Uhealth*2015;3(2):e69.
28. Schoeppe S, Alley S, Lippevelde W, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *Int J Behav Nutr Phys Act*2016;13(1):127.
29. Rose T, Barker M, Jacob M, et al. A Systematic Review of Digital Interventions for Improving the Diet and Physical Activity Behaviors of Adolescents. *J Adolesc Health* 2017;61(6)669-677.
30. Fjeldsoe BS, Miller YD, O'Brien JL, et al. Iterative development of MobileMums: a physical activity intervention for women with young children. *Int J Behav Nutr Phys Act*2012;9:151.
31. Yellow Social Media Report 2018 Consumers. Yellow Social Media Report 2018- Consumers. June 2018: Melbourne, Australia.
32. Reynolds R, Sutherland R, Nathan, N, et al. Feasibility and principal acceptability of school-based mobile communication applications to disseminate healthy lunchbox messages to parents. *Health Promot J Austr*Published Online First: 12 March 2018. doi:10.1002/hpja.57
33. Australian Bureau of Statistics. Census of Population Health and Housing-Community Profiles. 2016. Accessed Sept 2018. URL: <http://www.abs.gov.au/websitedbs/D3310114.nsf/Home/2016%20Census%20Community%20Profiles>.
34. NSW Health website. Accessed August 2018. URL: <https://www.health.nsw.gov.au/lhd/pages/hnelhd.aspx>.
35. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*2010;63(8)834-40.
36. Australian Bureau of Statistics. *4240.0 Preschool Education, Australia*. 2006: Canberra.
37. Skoolbag PTY LTD, MOQ group of companies. *Skoolbag*. 2018.
38. Burns CM, Gibbon P, Boak RL, et al. Food cost and availability in a rural setting in Australia. *Rural Remote Health*2004;4(4)311.
39. Ward PR, Coveney J, Verity F, et al. Cost and affordability of healthy food in rural South Australia. *Rural Remote Health*2012;12:1938.
40. Kang M, Ragan BG, and Park JH. Issues in outcomes research: an overview of randomization techniques for clinical trials. *J Athl Train*2008;43(2)215-21.
41. Delaney T, Wyse R, Yoong SL, et al. Cluster randomized controlled trial of a consumer behavior intervention to improve healthy food purchases from online canteens. *Am J Clin Nutr*2017;106(5):1311-1320.

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42. Yoong SL, Grady A, Wiggers J et al. A randomised controlled trial of an online menu planning intervention to improve childcare service adherence to dietary guidelines: a study protocol. *BMJ Open*2017;7:e017498. doi:10.1136/bmjopen-2017-017498
  43. Cochrane T, Davey R, and de Castella FR. Estimates of the energy deficit required to reverse the trend in childhood obesity in Australian schoolchildren. *Aust N Z J Public Health*2016; 40(1):62-7.
  44. Michie S, van Stralen MM, and West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
  45. NSW Ministry of Health. Caring for Children birth to 5 years. 2014: Sydney:NSW Government.
  46. Australian Children's Education and Care Quality Authority. What is the NQF? Accessed August 2018. URL: <https://www.acecqa.gov.au/nqf/about>.
  47. Ward S, Blanger M, Donovan D, et al. Association between childcare educators' practices and preschoolers' physical activity and dietary intake: a cross-sectional analysis. *BMJ Open* 2017;7(5):e013657.
  48. Xyris software. *Foodworks*. 2017: High Gate Hill, QLD.
  49. Seward K, Wolfenden L, Finch M. et al, Multistrategy childcare-based intervention to improve compliance with nutrition guidelines versus usual care in long day care services: a study protocol for a randomised controlled trial. *BMJ Open*2016;6(6):e010786.
  50. Hendrie GA, Viner Smith E, and Golley RK. The reliability and relative validity of a diet index score for 4-11-year-old children derived from a parent-reported short food survey. *Public Health Nutr*2014;17(7)1486-97.
  51. Ward D, Hales D, Haverly K. An instrument to assess the obesogenic environment of child care centers. *Am J Health Beha*2008;32(4)380-6.
  52. Finch M, Wolfenden L, Falkiner M, et al. Impact of a population based intervention to increase the adoption of multiple physical activity practices in centre based childcare services: a quasi experimental, effectiveness study. *Int J Behav Nutr Phys Act*2012;9:101.
  53. Razak LA, Yoong SL, Wiggers J, et al. Impact of scheduling multiple outdoor free-play periods in childcare on child moderate-to-vigorous physical activity: a cluster randomised trial. *Int J Behav Nutr Phys Act*2018;15(1):34.
  54. Bell AC, Davies L, Finch M, et al., An implementation intervention to encourage healthy eating in centre-based child-care services: impact of the Good for Kids Good for Life programme. *Public Health Nutrition*2014;18(9)1610-1619.
  55. Weiner BJ, Lewis CC, Stanick C, et al., Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci*2017;12(1):108.
  56. Taki S, Lymer S, Russell, CG, et al. Assessing User Engagement of an mHealth Intervention: Development and Implementation of the Growing Healthy App Engagement Index. *JMIR Mhealth Uhealth*2017;5(6):e89.
  57. Breitenstein SM, Fogg L, Garvey C, et al. Measuring implementation fidelity in a community-based parenting intervention. *Nurs Res*2010;59(3)158-65.
  58. White IR, Horton NJ, Carpenter J, et al. Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ*2011;342:d40.

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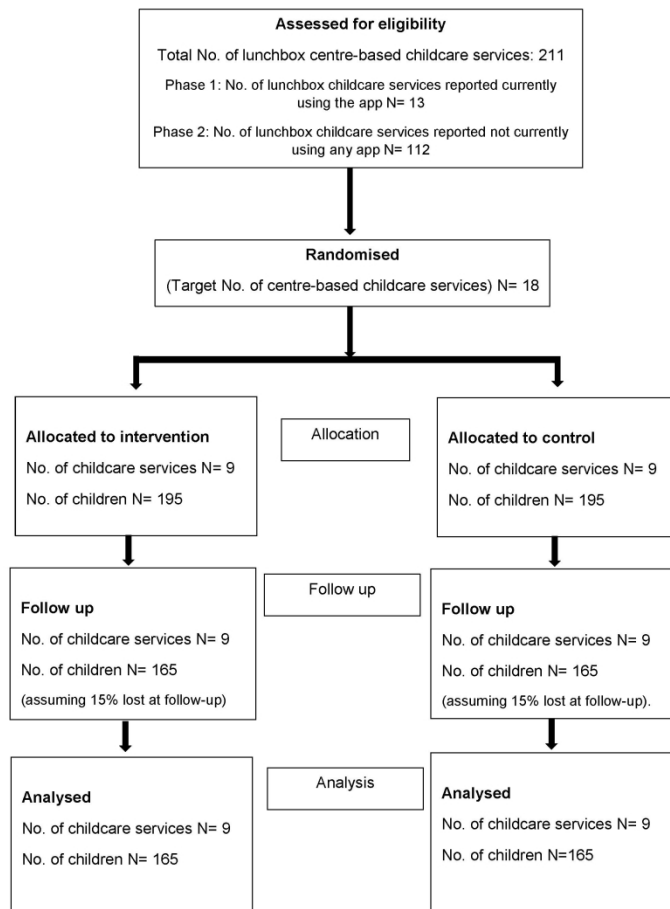


Figure 1 CONSORT flow diagram estimating the progress of preschools and parents through the trial

210x297mm (300 x 300 DPI)

### **Supplementary file 1: Application of a theoretical framework: Behaviour Change Wheel**

The “SWAP It Childcare” intervention content was developed using the Behaviour Change Wheel (BCW).<sup>1</sup> Based on a similar process described by behavioural researchers for designing an intervention to change diet behaviours using the BCW,<sup>2</sup> a three-step approach was used to apply the framework.

Step one included the identification of the target behaviour (ie to pack less discretionary foods in lunchboxes) and formative work to assess barriers and facilitators to packing healthy foods in children’s lunchboxes through literature reviews and semi-structured interviews with a convenience sample of parents (n= 28). A behavioural analysis, involving mapping of barriers to the COM B components of the BCW was undertaken with the purpose of ensuring the behavioural diagnosis was comprehensive.

Step two involved identifying intervention options using the BCW. The intervention functions (the means by which an intervention may change behaviour) of education, persuasion, and modelling were identified using the COM B/ intervention function matrix and the APEASE (Acceptability, Practicability, Effectiveness/ cost-effectiveness, Affordability, Safety/ side effects, Equity) criteria.<sup>2</sup> Policy categories were then considered to determine the delivery method of the intervention functions. The pre-determined mode of delivery (use of an app to deliver the intervention), fitted the category of “service provision” and was our only identified policy category.

Step three involved identifying the content and delivery options for the intervention. Behaviour change techniques most likely to bring about the desired change were mapped to the identified barriers (with reference to their COM B classifications) using the Behaviour Change Technique taxonomy.<sup>3</sup> A summary of the identified barriers, their COM B classification and the selected behaviour change techniques can be found in table 1. The resulting intervention consists of three key components which address nine identified barriers incorporating eight behaviour change techniques (See table 1 in main text).

<sup>1</sup>. Michie S, van Stralen MM, and West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.

<sup>2</sup>. Atkins L and Michie S. Conference on ‘Changing dietary behaviour: physiology through to practice’. Symposium 4: Changing diet and behaviour – putting theory into practice. *Proceedings of the Nutrition Society*2015;74:164-170.

<sup>3</sup>. Michie S, Wood CE, Johnston M, et al. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technol Assess*2015;19(99):1-188.

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	<a href="#">#3</a>	Date and version identifier	1
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	20
Roles and responsibilities:	<a href="#">#5b</a>	Name and contact information for the trial sponsor	NA

1	sponsor contact			
2	information			
3				
4	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	NA
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
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12	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	NA
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
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20	Background and	<a href="#">#6a</a>	Description of research question and justification for	3
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
24				
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27	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	6
28	rationale: choice of			
29	comparators			
30				
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32	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	5
33				
34				
35	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	5
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
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42	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	5
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
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48	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable,	6
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
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54	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8
55	description		replication, including how and when they will be	
56			administered	
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1	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	NA
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
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7	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols,	17
8	adherence		and any procedures for monitoring adherence (eg, drug	
9			tablet return; laboratory tests)	
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13	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	NA
14	concomitant care		permitted or prohibited during the trial	
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17	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	14
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
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28	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any	6
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
32				
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35	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study	7
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
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42	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to	7
43			reach target sample size	
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46	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,	7
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
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57	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg,	7
58	concealment		central telephone; sequentially numbered, opaque, sealed	
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1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
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4	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol	7
5	implementation		participants, and who will assign participants to	
6			interventions	
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9	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg,	7
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is	NA
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
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20	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline,	14
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
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31	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-	13
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
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38	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including	19
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
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46	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary	18
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
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52	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and	18
53	analyses		adjusted analyses)	
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55				
56	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	18
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
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1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary	NA
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
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11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	NA
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
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16	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	17
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
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21	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any,	NA
22			and whether the process will be independent from	
23			investigators and the sponsor	
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27	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional	20
28	approval		review board (REC / IRB) approval	
29				
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31	Protocol	<a href="#">#25</a>	Plans for communicating important protocol modifications	NA
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
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37	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential	6
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
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43	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	NA
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
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48	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	14
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
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55	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal	19
56	interests		investigators for the overall trial and each study site	
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59	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset,	NA
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and disclosure of contractual agreements that limit such access for investigators

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4	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for
5	trial care		compensation to those who suffer harm from trial
6			participation
7			
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9	Dissemination policy:	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial
10	trial results		results to participants, healthcare professionals, the public,
11			and other relevant groups (eg, via publication, reporting in
12			results databases, or other data sharing arrangements),
13			including any publication restrictions
14			
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17	Dissemination policy:	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of
18	authorship		professional writers
19			
20			
21	Dissemination policy:	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol,
22	reproducible		participant-level dataset, and statistical code
23	research		
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27	Informed consent	<a href="#">#32</a>	Model consent form and other related documentation given
28	materials		to participants and authorised surrogates
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31	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of
32			biological specimens for genetic or molecular analysis in the
33			current trial and for future use in ancillary studies, if
34			applicable
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 38 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made  
 39 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

**A cluster randomised controlled trial of an m-health intervention in centre-based childcare services to reduce the packing of discretionary foods in children's lunchboxes: Study protocol for the "SWAP IT Childcare" trial**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-026829.R2
Article Type:	Protocol
Date Submitted by the Author:	09-Jan-2019
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<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	lunchbox, discretionary foods, m-health, childcare

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Manuscripts

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3 **A cluster randomised controlled trial of an m-health intervention in centre based**  
4 **childcare services to reduce the packing of discretionary foods in children's**  
5 **lunchboxes: Study protocol for the "SWAP IT Childcare" trial**  
6

7 Nicole Pond<sup>1</sup>, Meghan Finch<sup>1,2,3,4</sup>, Rachel Sutherland<sup>1,2,3,4</sup>, Luke Wolfenden<sup>1,2,3,4</sup>, Nicole  
8 Nathan<sup>1,2,3,4</sup>, Melanie Kingsland<sup>1,2,3,4</sup>, Alice Grady<sup>1,2,3</sup>, Karen Gillham<sup>1</sup>, Vanessa Herrmann<sup>1</sup>,  
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44 Keywords: lunchbox, discretionary foods, m-health, childcare

45 Word count: 4879 (suggested word count 4000)

46 Date: 10<sup>th</sup> January 2019

47 Protocol version: revision 3  
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## ABSTRACT

**Introduction:** In many developed nations, including Australia, a substantial number of children aged under five years attend centre-based childcare services that require parents to pack food in lunchboxes. These lunchboxes often contain excessive amounts of unhealthy (“discretionary”) foods. This study aims to assess the impact of a mobile health (m-health) intervention on reducing the packing of discretionary foods in children’s childcare lunchboxes.

**Methods and analysis:** A cluster randomised controlled trial will be undertaken with parents from 18 centre-based childcare services in the Hunter New England region of New South Wales, Australia. Services will be randomised to receive either a four month m-health intervention called “SWAP IT Childcare” or usual care. The development of the intervention was informed by the Behaviour Change Wheel model and will consist primarily of the provision of targeted information, lunchbox food guidelines and website links addressing parent-barriers to packing healthy lunchboxes delivered through push notifications via an existing app used by childcare services to communicate with parents and carers. The primary outcomes of the trial will be energy (kilojoules) from discretionary foods packed in lunchboxes and the total energy (kilojoules), saturated fat (grams), total and added sugars (grams) and sodium (milligrams) from all foods packed in lunchboxes. Outcomes will be assessed by weighing and photographing all lunchbox food items at baseline and at the end of the intervention.

**Ethics and Dissemination:** The study was approved by the Hunter New England Local Health District Human Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human Research Ethics Committee (H-2008-0343). Evaluation and process data collected as part of the study will be disseminated in peer-reviewed publications and local, national and international presentations and will form part of PhD student theses.

**Trial registration:** The trial is prospectively registered with the Australian New Zealand clinical trials registry (ACTRN12618000133235).

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This randomised controlled trial is the first to use a m-health intervention to reduce packing of unhealthy foods in lunchboxes in centre- based childcare services.
- The study uses rigorous outcome measures consisting of weighed food records, supplemented by food photography.
- The intervention is developed using a systematic theory-based approach to identify strategies to target parental barriers to packing healthy lunchboxes.
- If found to be effective, the intervention has potential to be delivered via other childcare online technology-based communication platforms.
- The intervention is conducted in one region of Australia which may limit the generalisability of the study findings.

### INTRODUCTION

Poor dietary behaviours are leading modifiable risk factors for the development of future chronic disease including Type 2 diabetes, cardiovascular disease and certain cancers.[1, 2] To reduce chronic disease risk it is recommended that the intake of discretionary foods (i.e. foods high in energy, saturated fat, sugar and/or sodium) is limited.[1] Excessive intake of discretionary foods in childhood is linked to conditions such as dental caries,[3] altered lipid profiles,[4] and unhealthy weight gain.[5] Given that dietary preferences established in childhood are known to track into adulthood,[6] efforts to decrease the consumption of discretionary foods in the early childhood years is recommended to reduce the burden of chronic disease.[1]

National dietary guidelines recommended that children up to eight years of age consume no more than 0.5 serves of discretionary foods per day unless the child is taller or more active where they may consume up to 2 serves per day (i.e. no more than 300- 1200 kJ per day from discretionary foods).[7] Despite this, population studies indicate that child consumption typically exceeds these recommendations [8-10]. Specifically, in Australia children aged four to eight years consumed an average of 41% of their daily energy intake from discretionary foods, the equivalent to approximately 4.5 serves.[8]

Centre-based childcare services, such as preschools and long day care centres, have been identified as priority settings for interventions to improve child diet.[11-13] Such services provide access to a significant number of children, with upwards of 80% of children attending

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3 some form of centre-based care in the year prior to compulsory schooling in Australia, the  
4 United Kingdom (U.K.) and United States (U.S.). [14-16] As children can consume between  
5 one third to two thirds of their daily food intake whilst in centre- based childcare,[17] achieving  
6 even modest dietary improvements in this setting is likely to have considerable potential to  
7 improve child health.  
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12 In Australia, the U.K. and the U.S. it is estimated that between 30% and 50% of centre-based  
13 childcare services require parents to pack food in a lunchbox for their children to consume  
14 while in care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain  
15 excessive amounts of discretionary foods. For example, a study of Australian children  
16 attending 29 centre-based childcare services found that 60% of lunchboxes contained more  
17 than one serve of discretionary food, with an average of two serves of discretionary foods  
18 provided per lunchbox. In addition, 38% of lunchboxes were considered poorly balanced  
19 containing more than one serve of discretionary food and lacked vegetables, fruit or a healthy  
20 main meal. [19] An additional study conducted in 30 centre-based childcare services in Texas  
21 U.S., (607 children) similarly found a disproportionate amount of discretionary foods packed  
22 in lunchboxes with contents exceeding recommendations for saturated fat, sugar and  
23 sodium.[20]  
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32 Despite the potential to improve child diet via interventions to reduce packing of discretionary  
33 foods in lunchboxes of children attending centre-based childcare, to our knowledge just three  
34 randomised trials have been conducted,[21-23] with only one reporting on impact on child  
35 dietary intake.[24] Two of these trials utilised multi-component service based strategies  
36 including staff nutrition training and child education, alongside parent targeted strategies  
37 (including workshops, and parent activity stations).[21,22] Both trials reported significant  
38 improvements in the packing of discretionary foods. The remaining trial involved training of  
39 childcare staff without any direct parent strategies. This trial was ineffective in reducing  
40 packing of discretionary foods.[23] While these findings suggest that interventions targeting  
41 parents are more likely to have an impact, previous approaches have been time and resource  
42 intensive, requiring parents to attend face to face educational sessions. Such strategies have  
43 been reported to have limited reach,[25] and reduce the potential for intervention delivery at a  
44 population level.  
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54 Utilising mobile technology to directly reach parents has been suggested as a potentially  
55 effective strategy to overcome the limited reach of previous parent targeted  
56 interventions.[26,27] Evidence demonstrates that mobile health (m-health) interventions can  
57 be effective in changing dietary behaviours in both adults [28] and children.[28,29] The use of  
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3 mobile phone applications (apps) has been identified as highly acceptable to parents as a  
4 preferred health engagement tool,[30] and has the potential to successfully reach the large  
5 majority (over 86%) of parents who are estimated to now own a smart phone.[31] Embedding  
6 interventions within existing childcare service mobile phone apps may also overcome  
7 previously reported barriers related to reach and engagement via their ability to reach parents  
8 at any place or time, deliver education materials and provide reminders or prompts targeting  
9 specific behaviours.[27] Using an existing school communication app for the purpose of  
10 delivering healthy lunchbox information to parents was found to be highly feasible and  
11 acceptable by principals in the primary school setting within the Hunter New England region  
12 of NSW,[32] and the results of a healthy lunchbox pilot study utilising this model showed  
13 promising effects on the nutritional quality of children's lunchbox contents [unpublished data  
14 from a randomised controlled trial to assess the effectiveness, feasibility and acceptability of  
15 an m-health intervention 'SWAP IT', provided by author RS, 2018]. Utilising a similar approach  
16 in the centre-based childcare setting to reduce the packing of discretionary foods in  
17 lunchboxes therefore appears highly feasible. Despite this, to the author's knowledge no such  
18 m-health intervention has been conducted in this setting.

## 29 **STUDY AIMS**

31 The primary aim of the trial is to assess the efficacy of a m-health intervention, embedded  
32 within an existing childcare parent communication app to reduce: i) the mean energy (kilojoule  
33 (kJ)) from discretionary foods and drinks packed in children's lunchboxes, and ii) the mean  
34 energy (kilojoule (kJ)), saturated fat (grams (g)), total and added sugars (grams (g)) and  
35 sodium (milligrams (mg)) from all foods and drinks packed in lunchboxes. We will also assess  
36 the impact of the intervention on child dietary consumption of: i) mean energy (kJ) from  
37 discretionary foods packed in the lunchbox; ii) mean energy (kJ), mean saturated fat (g),  
38 sodium (mg) and total and added sugars (g) from all foods and drinks packed in the lunchbox;  
39 iii) serves of lunchbox discretionary foods and drinks packed and consumed; and iv) usual  
40 serves of discretionary foods consumed over 24 hours. Parent and service acceptability and  
41 feasibility and potential adverse effects of the intervention will also be assessed.

## 51 **METHODS AND ANALYSIS**

### 52 **Settings and Design**

53 The study will utilise a cluster randomised controlled trial design, and will be conducted with  
54 parents and children attending centre-based childcare services located in the Hunter New  
55 England (HNE) Local Health District of New South Wales (NSW), Australia (see Figure 1).



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3 Allocation will be at the unit of the childcare service. In 2016, approximately 819 814 people  
4 were reported to reside in the HNE area, of which 51 900 were children aged 0 to 4 years.[33]  
5 The area encompasses major metropolitan centres and inner regional communities, with a  
6 small percentage (14%) of people located in remote communities.[34]  
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10 The trial will run between March 2018 and January 2019. Following baseline data collection  
11 services will be randomly allocated to receive the approximately four month intervention or to  
12 a usual care control group. The trial outcome measures will be assessed in the same child  
13 cohort within both groups at baseline and post intervention. The study will follow the  
14 CONSORT reporting guidelines.[35]  
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### 21 **Figure 1: CONSORT diagram estimating the progress of centre-based childcare** 22 **services and children through the trial**

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24 *Insert Figure 1*  
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### 28 **Participants and eligibility**

#### 29 **Sample**

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31 A list of all centre-based childcare services (including long day care and preschool services)  
32 located in the study region will be accessed via the NSW Ministry of Health. Approximately  
33 211 (54%) services in the study region require parents to pack foods (referred to as lunchbox  
34 services) and will serve as the sampling frame. Within NSW, long day care services can  
35 provide centre-based care for children from six weeks, to under six years of age for eight or  
36 more hours per day. Preschools typically enrol children between three and six years of age  
37 and provide care for six and eight hours per day.[36]  
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#### 46 **Eligibility**

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48 To be eligible to participate, lunchbox services must cater for children three to six years of  
49 age, and be either existing users of the designated parent communication app (Skoolbag),[37]  
50 or have a willingness to commence using the app. Services will be excluded if they are;  
51 participating in any other trial related to improving child nutrition, cater exclusively for children  
52 with special needs or are a Department of Education community run service (as they are not  
53 covered within the existing ethics arrangement). Parents or carers (hereafter referred to as  
54 “parents”) of children aged 3-6 years will be eligible to participate if their child attends during  
55 the days of data collection period and if they indicated willingness to download or use the app.  
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3 Children will be excluded if they have special dietary requirements or allergies that would  
4 necessitate specialised tailoring of their diet.  
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## 9 **Recruitment procedures**

### 10 **Services**

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12 Initial recruitment will target eligible services currently using Skoolbag (n = 13), after which  
13 services that do not use any app (as identified via a telephone survey undertaken by the  
14 research team) will be randomly approached (n=112) until 18 services are enrolled in the trial.  
15 Services commencing using the app for the purpose of the trial will be able to use the app free  
16 of charge for the duration of the intervention.  
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21 Service managers of eligible services will be posted and emailed information statements and  
22 consent forms detailing the study and requesting participation. Written consent to participate  
23 in the trial will be provided by the manager on behalf of the services.  
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### 27 **Children**

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29 Centre-based childcare staff will distribute hard copies of information statements and consent  
30 forms to parents approximately two weeks prior to baseline data collection. To maximise  
31 consent rates, research assistants will also be present at the service for two days (based on  
32 highest child attendance) during drop off and pick up times to speak with eligible parents and  
33 promote participation in the trial. If more than one child is eligible per family, only the oldest  
34 will be included in the trial to reduce participant burden.  
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## 42 **Random allocation of childcare services**

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44 Consenting services will be randomly allocated to the intervention or usual care control group  
45 in a 1:1 ratio using a computerised random number generator. Randomisation of services will  
46 be undertaken following baseline data collection by a statistician who will otherwise have no  
47 involvement in the study. Based on evidence of associations for family socio-economic status  
48 and rurality with child dietary intake,[38,39] randomisation will be stratified by the socio-  
49 economic area of the childcare service and by rural location. As part of ensuring equity of  
50 access to the intervention, services will also be stratified by those with high numbers of  
51 Aboriginal child enrolments defined as those with >10% Aboriginal children enrolled. This level  
52 of stratification was deemed appropriate for the sample size.[40]  
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3 This trial will be conducted as an open trial due to the nature of the intervention. Services and  
4 parents will be notified of their allocation following baseline data collection however outcome  
5 assessors will remain blinded to service allocation.  
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### 10 **Sample size and power calculations**

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12 The study aims to recruit approximately 390 children from 18 childcare services. Given a 15%  
13 attrition rate at follow up, this will allow detection of a mean difference of 123 kJ in the primary  
14 outcome, with an alpha of 0.01 (adjusting for multiple outcomes), and an estimated ICC of 0.1,  
15 with 80% power [41,42] and a standard deviation of 200 kJ. The ICC applied is based on  
16 internal and unpublished pilot data undertaken with a smaller number of lunchboxes. As  
17 children are recruited from childcare centres which may have existing lunchbox policies that  
18 may impact on provision of food, we anticipate that an ICC of 0.1 may be a conservative  
19 estimate of clustering. Approximately 123 kJ difference in energy was considered clinically  
20 significant based on an estimate of the energy deficit required to reduce the prevalence of  
21 childhood obesity (420KJ)[43] and proportionally adjusted to the amount of time children  
22 spend in care (approximately one third of the day). Such an energy reduction could be  
23 expected to result in the detection of approximately 0.6g less saturated fat, 2.2g less sugar  
24 and 44 mg less sodium.[8]  
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### 36 **Intervention**

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38 “SWAP IT Childcare” is an adapted version of a previously piloted intervention conducted with  
39 primary school children aged 5-12 years. The program is embedded in an existing parent  
40 communication app used in both schools and centre-based childcare services and aims to  
41 assist parents to “swap in” healthy foods and “swap out” discretionary foods when packing  
42 lunchboxes. Services use this communication app to provide information to parents regarding  
43 their child’s daily activities, newsletters and other service related information. The app has the  
44 capacity to deliver content in the form of text, images and media (videos) and store information  
45 available for permanent access.  
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51 The program was co-produced by a team of behavioural researchers, public health nutritionist,  
52 centre-based childcare staff and the technology provider “Skoolbag” and was based on  
53 formative evaluations with parents. Key differences between the primary schools and  
54 childcare settings as well as parent reported barriers were identified during formative  
55 assessments which necessitated amendments to strategy selection, intervention components  
56 and content between the two programs. The “SWAP IT Childcare” intervention will specifically  
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3 target parents of children aged three to six years and will be primarily delivered via a series of  
4 push notification messages using the service's communication app. Feedback was sought on  
5 the content of the program from parents of childcare-aged children, the research unit's  
6 Aboriginal Health Staff advisory group and from two local Aboriginal centre-based childcare  
7 service managers to ensure cultural appropriateness.  
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#### 11 Application of a theoretical framework

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14 The "SWAP It Childcare" intervention content was developed using the Behaviour Change  
15 Wheel (BCW).[44] This theoretically driven framework is based on 19 theories of health  
16 behaviour and is designed to enable the systematic development of interventions for  
17 supporting behaviour change.[44] For a description of the application of the framework please  
18 refer to supplementary file 1. An overview of the intervention mapping process is provided in  
19 Table 1.  
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#### 27 **Intervention strategies**

28 A four month intervention (Table 2) consisting of the following components will be delivered  
29 as part of "SWAP IT Childcare":  
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- 32 1. Provision of weekly push notifications targeting identified barriers to the packing of  
33 healthier lunchboxes
- 34 2. Provision of "SWAP IT Options" which are centre-based childcare lunchbox guidelines  
35 designed to provide specific information to parents on suitable foods for the lunchbox.
- 36 3. Centre-based childcare service endorsement of the program in order to support  
37 adoption of the "SWAP IT Options" lunchbox guidelines.  
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43 Further details regarding each strategy and delivery mode are provided in table 2.  
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#### 45 **Control Group**

46 Services allocated to the control group will participate in data collection only. Parents from  
47 these services will receive routine centre-based childcare communication via the app (usual  
48 care) with no access to the lunchbox content.  
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#### 53 **Patient and Public Involvement**

54 The research question and intervention was co-designed together with the local health  
55 promotion unit (Hunter New England Population Health) responsible for supporting childcare  
56 services to support parents with packing healthier lunchboxes. As described in the methods,  
57 intervention design and content was informed in part, by the results of a survey of parents  
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3 (n= 29) from a convenience sample of local childcare services and consultation with two  
4 local Aboriginal centre-based childcare service managers. Service managers were also  
5 consulted about the acceptability of app technology for delivering the intervention to parents.  
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7 The participating parents were not involved in the design, recruitment or conduct of the study  
8 however childcare staff will support recruitment via assistance with distribution and collection  
9 of consent forms and assistance with the data collection process by identifying lunchboxes  
10 for weighing. Participant burden to engaging with the intervention will be assessed as part of  
11 a follow up survey with parents assessing acceptability and time and cost of changing  
12 behaviours. A summary of the results will be provided to participating services to distribute to  
13 parents and a copy of the summary will be available on the research unit's website or upon  
14 individual request from parents.  
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Table 1 Intervention mapping overview

1. COM B (source of behaviour)	2. Related barrier/ enabler		3. Components of the Intervention (numbers represent barriers in column 2)		4. Behaviour Change techniques (numbers represent barriers in column 2)
Capability	1. A lack of knowledge about appropriate foods and drinks for the lunchbox	➔	Provision of weekly push notifications targeting identified barriers to packing of healthier lunchboxes (1, 2, 3, 4, 5, 6, 7, 8)	➔	4.1 Instruction on how to perform a behaviour (1,5,6,7)
	2. Lack of ideas for healthy appealing lunchbox foods	➔		➔	5.1 Information about health consequences (8)
Opportunity	3. Perception that it takes longer to prepare and/ or shop for healthy foods for the lunchbox.	➔		➔	6.1 Demonstration of the behaviour (3, 4, 6, 7)
	4. Perception that it costs more to pack a healthy lunchbox	➔		➔	7.1 Prompts/cues (8)
	5. Child is a fussy eater (i.e. will not accept new foods packed in the lunchbox)	➔	Provision of SWAP IT Lunchbox guidelines (1, 2)	➔	8.2 Behaviour substitution (1, 2, 6, 7)
	6. Reluctance to pack healthy food options in order to avoid: - food going to waste - child going hungry - child complaints	➔		➔	11.3 Conserving mental resources (1, 2)
Motivation	7. Parents' lack of awareness of link between nutrition and health outcomes. Belief there is no need to limit less healthy foods the lunchboxes.	➔		➔	15.1 Verbal persuasion about capability (3, 4, 5, 6)
	8. Lack of motivators or prompts to change lunchbox packing behaviours	➔	Centre-based childcare service support and endorsement of the "SWAP IT in Childcare" program		

Table 2: Intervention components, strategies and resources

Intervention component	Strategy Description	Resources and Delivery Mode
<p><b>1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes</b></p>	<p>Push notifications will alert parents to messages sent via the service's app for 10 weeks (one per week). The behaviour change techniques designed to influence parent behaviour will be delivered via the content of these messages and images, and through attachments and links to the "SWAP IT Childcare" webpages, videos, fact sheets and other websites. Graphics of recommended "swaps" will be included in various messages, for example a graphic recommending a swap from a popular high saturated fat, high sodium savoury cracker to low saturated fat, lower sodium cracker, a swap from a cheese flavoured biscuit to vegetables sticks and dip and a swap from chocolate biscuit snacks to wholegrain cereal snacks. As an example of a push notification message, the message aiming to reduce the perceived barrier of "cost of a healthy lunchbox", includes persuasive language explaining that expensive foods doesn't need to be purchased to provide a healthy lunchbox. It also includes an embedded video in the push notification message that provides examples of inexpensive healthy foods to pack for children, and will demonstrate how healthy items often cost the same as less healthy items in the supermarket. Finally, an attached fact sheet provides practical examples of how to save money and demonstrates cost savings possible over a year. For</p>	<p><b>a) "SWAP IT Childcare" push notification topics delivered via the app</b></p> <p>Week 1 (2 messages): Welcome to "SWAP IT" The ultimate list of healthy lunchbox foods</p> <p>Week 2: "Sweet" food ideas for the lunchbox</p> <p>Week 3: Cost saving ideas for the lunchbox</p> <p>Week 4: Common fussy eating concerns</p> <p>Week 5: Healthy savoury snacks that are a hit!</p> <p>Week 6: Why are some lunchbox snacks better than others?</p> <p>Week 7: Is your child drinking enough?</p> <p>Week 8: Top 5 time saving ideas when packing a healthy lunchbox</p> <p>Week 9: Supporting children to try new foods</p> <p>Week 10: Thanks for being part of SWAP IT</p> <p><b>b) Links to fact sheets and videos within messages</b></p> <p>Top time saving tips (fact sheet and video)</p>



	<p>further information on behaviour change techniques used to address each barrier please refer to Table 1.</p>	<p>Money saving tips for the lunchbox (fact sheet and video)          Fussy Eating Concerns (fact sheet)          Tips for encouraging new foods (fact sheet and video)          5 Best savoury swaps for the lunchbox (fact sheet)          5 Best sweet swaps for the lunchbox (fact sheet)</p>
<p><b>2. Provision of “SWAP IT Options” Lunchbox Guidelines</b></p>	<p>Parents will be given access to and encouraged to use 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,[7] recommendations outlined in the NSW Ministry of Health nutrition sector specific resource [45] and health and wellbeing requirements outlined in national accreditation standards.[46]</p>	<p><b>a) “SWAP IT Options” Lunchbox Guidelines, provided via links in push notification messages delivered via the app</b></p> <p>SWAP IT Options Savoury          SWAP IT Options Sweet          SWAP IT Options Lunch foods          SWAP IT Options Drinks</p>
<p><b>3. Centre-based childcare service endorsement of the program</b></p>	<p>To support service adoption of the “SWAP IT Choices” lunchbox guidelines, a Health Promotion Officer will conduct 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).The Service Managers will also be 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.</p>	<p><b>a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.</b></p>

	<p>Service managers will be asked to send two communications to parents via the app or other preferred communication methods (e.g. hard copy newsletters). The first communication will be sent prior to the first app push notification message to convey service support for the program, and to endorse the use of the “SWAP IT Options” lunchbox guidelines and the second communication, will be sent approximately mid-intervention. This is designed to provide parents with non-contingent praise and support to continue to access the app and its content and assist with prevention of a drop off in opening messages over time.</p> <p>A record of implementation will be given to service managers to enable them to record their delivery of the agreed tasks during the intervention period and to measure implementation fidelity.</p>	<p><b>b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.</b></p> <p><b>c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).</b></p> <p><b>d) Provision of a service-completed record of implementation form.</b></p>
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## DATA COLLECTION PROCEDURES AND MEASURES:

### Primary Outcomes

Food packed in lunchboxes

The primary trial outcomes include mean energy (kJ) provided by discretionary foods, and mean energy (kJ), saturated fat (g), total and added sugars (g) and sodium (mg) provided by all food and drinks packed in children's lunchboxes. The outcome will be assessed via photography and weighed food records. Weighing is considered one of the most accurate methods of determining portion size and consumption of food and drinks.[47] Research assistants will undertake a one day training session requiring them to practice weighing sample lunchboxes and complete data collection forms with feedback given on their adherence to data collection protocols. Lunchbox measures will be undertaken on one unique day for each child as part of two-day data collection at each service at both baseline and approximately four months follow up. The days of the week on which data will be collected may be different for each service. Parents will not be informed of the day that lunchbox data will be collected to minimise reactivity bias. On the days of data collection all packed food and drinks (excluding water) will be weighed, individually where possible, and photographed by a trained research assistant blinded to service allocation. Food will be photographed against paper that includes a metric ruler graphic to aid weight estimations if required. Weight will be recorded in grams by a second trained research assistant using a standardised form developed by the research team. To ensure consistency and quality of data collection, lunchbox photographs and data collection forms will be reviewed by a dietitian once returned for accuracy and compliance with protocols.

The weighed food record data will be verified using photos and entered into a food and nutrient analysis database (Foodworks™)[48] in grams by a trained dietitian. The weights of individual foods weighed as part of a mixed foods (e.g. determining the weight of the cheese and weight of the bread as part of the total grams recorded for a cheese sandwich), will be estimated by using standard weights from Foodworks™ foods if applicable (e.g. a standard weight of a slice of bread) or estimates extrapolated by visual assessment of photographs. Where foods are home-made, an appropriate standard recipe will be sourced from within the Foodworks™ database. Where a suitable recipe is not available, Dietitians within the research team will reach a consensus on an appropriate alternate source for the recipe. When commercial foods are not in their packages, photographs will be used in conjunction with the research team's consensus on the most likely product fit and these assumptions will be recorded. A random sample of approximately 20% of lunchbox data entries will be checked for errors by a second dietitian following the same data entry protocols and corrections made as required.

## Secondary Outcomes

### Child dietary consumption of foods packed in lunchboxes

Children's consumption of mean energy (kJ) from discretionary foods, and mean energy (kJ) saturated fat (g), total and added sugars (g) and sodium (mg) from all foods and calorific drinks packed in children's lunchboxes will be assessed. As per the packed lunchbox contents, consumption will be measured on the same unique day for each child at both baseline and approximately four months follow up. On the day of the lunchbox audits, as part of the data collection procedure, children will be asked to return all uneaten food and empty packaging to their lunchbox. After the final meal of the day, food weights, and any packaging included as part of pre-consumption weights, will be weighed and recorded in grams on the same data collection form. In order to determine amounts consumed, the total weight of the foods/drinks post consumption will be subtracted from the total weight of food/drinks pre-consumption. The same process (as described for the primary outcome measure) will be undertaken when entering the amount of food consumed into Foodworks™ for the nutrient analysis. This method of collecting pre and post consumption weighed food records has been successfully undertaken by the research team as part of a previous trial conducted with 26 childcare services.[49]

### Serves of lunchbox discretionary foods packed and consumed

The number (count of individual items) and serves (600 kJ equivalents) of discretionary food and drinks packed and consumed will be reported. A dietitian will categorise each item as discretionary or non-discretionary consistent with the Australian Dietary Guidelines.[7]

### Overall daily usual child intake of discretionary foods

Overall daily usual child intake of discretionary foods (serves per day) will be measured via a sub-group of questions included as part of a 65 item food frequency questionnaire. This will be completed as part of the online parent survey by both intervention and control parents at baseline and follow up.

The food frequency questions were sourced from the Short Food Survey (SFS), which has been found to be a valid and reliable tool for Australian children aged 4-11 years with a significant correlation ( $r=0.43-0.44$ ,  $P<0.01$ ) reported for serves of discretionary foods against 24 hour recalls.[50] Minor adaptations to the survey were made to capture foods frequently served in the centre-based childcare setting.

The online parent survey will be emailed to consenting parents after the completion of service-level baseline data collection and again at follow-up. Parents will be asked to complete the

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3 survey for their oldest eligible child only. If not completed, an automated email reminder will  
4 be sent after approximately two weeks. After a further week, non-responders will be offered  
5 the opportunity to complete the survey via phone interview or via paper form.  
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## 9 10 **Other Measures**

### 11 Parent and child demographics

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14 Parent and child demographic information will be collected as part of the parent online survey  
15 and via participant consent form. Specifically, parents will report on child age, gender, post-  
16 code of residence, and parental education level, as part of the consent form, and additional  
17 questions on income level, living arrangements and language spoken at home will be collected  
18 via the online survey.  
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### 23 Service operational characteristics

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26 Service operational characteristics will be assessed via a pen and paper survey completed by  
27 the service manager at all participating services at baseline on one day of service data  
28 collection. Characteristics will include number of years in operation, total number of children  
29 enrolled, number of staff employed, and previous staff nutrition training.  
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### 33 Service nutrition context (staff behaviours and service nutrition policy and procedures)

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36 The service nutrition context will include assessments of nutrition policies and staff behaviours  
37 (e.g. prompting children to eat healthy food, role modelling healthy eating, meal time practices)  
38 where there is evidence of potential impact of behaviours on food packed and consumed by  
39 children in care. An adapted version of an existing tool, the Environment and Policy  
40 Assessment Observation (EPAO) instrument will be used to assess nutrition context.[51]  
41 Modified versions of the EPAO have been used previously by the research team in other  
42 intervention trials.[52-54] Completion of the EPAO will be undertaken by a third trained  
43 research assistant on one of the two days allocated for service-level data collection. A  
44 research assistant will observe service staff present in the room/ space where the majority of  
45 eligible children are present throughout the day between the core hours of 9am to 3pm. The  
46 EPAO tool also includes a short in-person service manager interview to collect information  
47 and documentation of service nutrition policies and procedures.  
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### Cost and time

Total grocery cost and average time spent packing lunchboxes will be assessed via items included in the online parent survey at baseline and post intervention for both intervention and control groups. Change in mean cost of lunchbox contents will be assessed using prices as indicated from online supermarket websites using quantities extracted from weighted lunchbox records at baseline and follow-up.

### Adverse events

To monitor any adverse parent reaction as a result of the intervention, the average number of parent complaints regarding lunchbox policies at each service will be determined via a question included in the service manager pen and paper survey in intervention and control services at both baseline and follow up.

### Intervention acceptability and feasibility

Within the intervention services, parent acceptability (i.e. an assessment as to whether the intervention is agreeable or satisfactory) will include assessing satisfaction and perceived usefulness of the program content and delivery via items included within the parent survey.[55] Feasibility (i.e. suitability for use) will include measuring parent use and engagement with the intervention, through the use of app and program website analytics data including: number of message views, frequency of click throughs to linked web-based resources, and number of website page views.[55] Additional information related to parent engagement will be collected in the parent online survey via 25 items assessing use of the app and features such as the push notification alerts, satisfaction and usefulness of the program, number of messages opened, number of links accessed and any barriers to accessing or using the technology. At follow-up service acceptability will include assessment of service managers satisfaction, perceived usefulness, and appropriateness of the program measured via a separate 22 item pen and paper survey adapted from an existing questionnaire.[56]

### Intervention fidelity

Intervention fidelity will include assessing whether messages were delivered as intended and quality of message content via researchers directly monitoring the push notifications during the intervention. Parent exposure to the intervention will be assessed via questions included in the parent online survey. Service delivered components of the intervention will be measured via a service completed implementation log. Implementation of other intervention components e.g. site visits conducted as planned, will be recorded as part of the research team's project

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3 records. Measuring fidelity across various domains such as these has been recommended as  
4 key to informing “real world uptake” of interventions.[57]  
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#### 6 7 Contamination and co-intervention measures 8

9 Contamination will be largely mitigated by centrally controlled access to the intervention (i.e.  
10 only parents of the intervention services will receive the messages via the app). Within the  
11 post intervention survey, parents will be asked if they accessed the intervention or study  
12 website in the last four months. Service and parent receipt of other nutrition interventions  
13 separate to the trial during the invention period will be assessed via questions included within  
14 the EPAO document and within the parent survey at follow up.  
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#### 22 **Statistical Analysis** 23

24 All statistical analysis will be performed with SAS (V.9.4) statistical software by an experienced  
25 statistician independent to the study. Differences in outcomes between groups will be  
26 assessed using hierarchical linear regression models, adjusting for pre-specified prognostic  
27 variables associated with the outcome, (service level EPAO scores) as well as clustering,  
28 controlling for baseline outcome. A subgroup analyses by child gender and socio economic  
29 status will also be undertaken to assess whether there was a differential impact according to  
30 such variables. Using intention to treat principles,[58] missing data from primary and  
31 secondary outcomes at follow-up due to attrition, will be imputed using multiple imputation[58]  
32 through the SAS MI and MIANALYZE Procedure and will be the main analyses. Findings from  
33 the complete case analyses will also be reported. An additional outcome analysis will be  
34 conducted whereby only parents who have downloaded the app will be included.  
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#### 45 **DISCUSSION** 46

47 This randomised controlled trial is the first to assess the impact of a m-health intervention  
48 targeting the packing of discretionary foods in lunchboxes in the childcare setting. It  
49 significantly adds to the limited evidence available for interventions that aim to successfully  
50 engage parents and improve centre-based childcare lunchboxes with high potential for  
51 delivery at scale. The use of technology to directly support parents packing behaviours  
52 represents a highly innovative approach to improve the diets of young children attending  
53 centre-based childcare services.  
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3 The research also has the potential to significantly improve the health outcomes of young  
4 children. The benefits of reducing discretionary foods includes a likely improvement in diet  
5 quality, potentially facilitating risk factor reduction for conditions such as Type II diabetes,  
6 cardiovascular disease and certain cancers later in life.[8] If shown to be effective, this  
7 intervention has the potential to be embedded into other m-health or childcare online  
8 technology-based communication platforms providing an opportunity to reach parents  
9 nationally to improve the health of young children.  
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22 of participating centre-based childcare services.  
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## 29 **DATA STATEMENT**

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31 Technical appendix, statistical code and dataset will be made available. Please contact the  
32 corresponding author.  
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## 37 **COMPETING INTERESTS**

38  
39 The authors declare that they have no competing interests.  
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7 NHMRC.  
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## 11 **ETHICS AND DISSEMINATION**

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14 Ethics approval has been provided by the Hunter New England Local Health District Human  
15 Ethics Committee (06/07/26/4.04) and ratified by the University of Newcastle, Human  
16 Research Ethics Committee (H-2008-0343). The trial is prospectively registered with the  
17 Australian New Zealand clinical trials registry (ACTRN12618000133235p). Evaluation and  
18 process data collected as part of the study will be disseminated peer-reviewed publications  
19 and local, national and international presentations, and will form part of a PhD student thesis.  
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## 24 **AUTHOR CONTRIBUTIONS**

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26  
27 First author Nicole Pond led the development of this manuscript. Meghan Finch, Nicole Pond,  
28 Sze Lin Yoong, Rachel Sutherland, Nicole Nathan, Luke Wolfenden and Vanessa Herrmann  
29 led the development of the intervention, Meghan Finch, Nicole Pond, Sze Lin Yoong, Rachel  
30 Sutherland, Nicole Nathan, Alice Grady, Melanie Kingsland, Karen Gillham contributed to the  
31 evaluation protocol and research design. Meghan Finch, Nicole Pond, Sze Lin Yoong, Rachel  
32 Sutherland, Nicole Nathan, Luke Wolfenden, Alice Grady, Melanie Kingsland, Karen Gillham  
33 and Vanessa Herrmann contributed to drafting and final approval of the manuscript.  
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## REFERENCES

1. Joint WHO/FAO Expert Consultation on Diet, Nutrition and the prevention of Chronic Disease. Diet, Nutrition and the Prevention of Chronic Disease: report of a joint WHO/FAO expert consultation, in WHO technical report series; 916. Geneva: 2003.
2. Australian Institute of Health and Welfare. Australia's health 2016. Australia's health series no. 15. Cat. no. AUS 199. 2016. Canberra: AIHW.
3. World Health Organisation. Guideline: Sugars intake for adults and children. Geneva:2015.
4. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. *Pediatrics* 2011;128 (December).
5. Kumar S and Kelly AS. Review of Childhood Obesity: From Epidemiology, Etiology, and Comorbidities to Clinical Assessment and Treatment. *Mayo Clin Proc* 2017;92:251-265.
6. Mura PM, Caton SJ, Vereijken C, et al. How infants and young children learn about food: a systematic review. *Frontiers in Psychology*2017;8:1046.
7. National Health and Medical Research Council. Educator Guide, p22. 2013. National Health and Medical Research Council: Canberra.
8. Johnson BJ, Bell LK, Zarnowiecki D, et al. Contribution of Discretionary Foods and Drinks to Australian Children's Intake of Energy, Saturated Fat, Added Sugars and Salt. *Children (Basel)* 2017;4(12).
9. Public Health England, National Diet and Nutrition Survey. Results from Years 5-6 (combined) of the Rolling Programme (2012/13 – 2013/14). 2016: London.
10. Drewnowski A and Rehm CD. Consumption of added sugars among US children and adults by food purchase location and food source. *Am J Clin Nutr*2014;100(3):901-7.
11. Buscemi J, Odoms-Young A, Stolley ML, et al. Adaptation and dissemination of an evidence-based obesity prevention intervention: design of a comparative effectiveness trial. *Contemp Clin Trials*2014;38(2):355-60.
12. Larson N, Ward DS, Neelon S B et al. What role can child-care settings play in obesity prevention? A review of the evidence and call for research efforts. *J Am Diet Assoc*2011; 111(9):1343-62.
13. Mikkelsen MV, Husby S, Skov LR et al. A systematic review of types of healthy eating interventions in preschools. *Nutr J*2014;13:56.
14. Lucas PJ, Patterson E, Sacks G, et al. Preschool and School Meal Policies: An Overview of What We Know about Regulation, Implementation, and Impact on Diet in the UK, Sweden, and Australia. *Nutrients*2017;9(7).
15. Sweitzer, SJ, Briley ME, and Robert-Gray C R. Do sack lunches provided by parents meet the nutritional needs of young children who attend child care? *J Am Diet Assoc*2009;109(1):141-4.
16. Australian Government Australian Institute of Family Studies. Child care and early childhood education in Australia. 2015 Accessed: 20th September 2018. URL: <https://aifs.gov.au/publications/child-care-and-early-childhood-education-australia>.
17. Soanes, R, Miller M, and A Begley, Nutrient intakes of two- and three-year-old children: a comparison between those attending and not attending long day care centres. *Nutr Diet*2001;58(2):114-120.
18. NSW Ministry of Health, Population Health Information Management System (PHIMS), Healthy Children Initiative. 2018.
19. Kelly B, Hardy L, Howlett S, et al. Opening up Australian preschoolers' lunchboxes. *Aust N Z J Public Health*2010;34(3):288-92.

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20. Romo-Palafox MJ, Ranjit N, Sweitzer SJ, et al. Adequacy of Parent-Packed Lunches and Preschooler's Consumption Compared to Dietary Reference Intake Recommendations. *J Am Coll Nutr*2017;36(3)169-176.
21. Roberts-Gray C, Briley ME, Ranjit N, et al. Efficacy of the Lunch is in the Bag intervention to increase parents' packing of healthy bag lunches for young children: a cluster-randomized trial in early care and education centers. *Int J Behav Nutr Phys Act*2016;13:3.
22. Zask A, Adams JK, Brooks LO, et al. Tooty Fruity Veggie: an obesity prevention intervention evaluation in Australian preschools. *Health Promot J Austr*2012;23(1)10-5.
23. Hardy LL, King L, Kelly B, et al. Munch and Move: evaluation of a preschool healthy eating and movement skill program. *Int J Behav Nutr Phys Act*2010;7(1):80.
24. Roberts-Gray C, Ranjit N, Sweitzer, SJ et al. Parent packs, child eats: Surprising results of Lunch is in the Bag's efficacy trial. *Appetite*2018;121:249-262.
25. Roberts-Gray C, Sweitzer SJ, Ranjit N, et al. Structuring Process Evaluation to Forecast Use and Sustainability of an Intervention: Theory and Data From the Efficacy Trial for Lunch Is in the Bag. *Health Educ Behav* 2017;44(4):559-569.
26. Mitchell GL, Farrow C, Haycraft E, et al. Parental influences on children's eating behaviour and characteristics of successful parent-focussed interventions. *Appetite*2013;60(1)85-94.
27. Curtis KE, Lahiri S, and Brown KE. Targeting Parents for Childhood Weight Management: Development of a Theory-Driven and User-Centered Healthy Eating App. *JMIR Mhealth Uhealth*2015;3(2):e69.
28. Schoeppe S, Alley S, Lippevelde W, et al. Efficacy of interventions that use apps to improve diet, physical activity and sedentary behaviour: a systematic review. *Int J Behav Nutr Phys Act*2016;13(1):127.
29. Rose T, Barker M, Jacob M, et al. A Systematic Review of Digital Interventions for Improving the Diet and Physical Activity Behaviors of Adolescents. *J Adolesc Health* 2017;61(6)669-677.
30. Fjeldsoe BS, Miller YD, O'Brien JL, et al. Iterative development of MobileMums: a physical activity intervention for women with young children. *Int J Behav Nutr Phys Act*2012;9:151.
31. Yellow Social Media Report 2018 Consumers. Yellow Social Media Report 2018- Consumers. June 2018: Melbourne, Australia.
32. Reynolds R, Sutherland R, Nathan, N, et al. Feasibility and principal acceptability of school-based mobile communication applications to disseminate healthy lunchbox messages to parents. *Health Promot J Austr*Published Online First: 12 March 2018. doi:10.1002/hpja.57
33. Australian Bureau of Statistics. Census of Population Health and Housing-Community Profiles. 2016. Accessed Sept 2018. URL: <http://www.abs.gov.au/websitedbs/D3310114.nsf/Home/2016%20Census%20Community%20Profiles>.
34. NSW Health website. Accessed August 2018. URL: <https://www.health.nsw.gov.au/lhd/pages/hnelhd.aspx>.
35. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol*2010;63(8)834-40.
36. Australian Bureau of Statistics. *4240.0 Preschool Education, Australia*. 2006: Canberra.
37. Skoolbag PTY LTD, MOQ group of companies. *Skoolbag*. 2018.
38. Burns CM, Gibbon P, Boak RL, et al. Food cost and availability in a rural setting in Australia. *Rural Remote Health*2004;4(4)311.
39. Ward PR, Coveney J, Verity F, et al. Cost and affordability of healthy food in rural South Australia. *Rural Remote Health*2012;12:1938.
40. Kang M, Ragan BG, and Park JH. Issues in outcomes research: an overview of randomization techniques for clinical trials. *J Athl Train*2008;43(2)215-21.
41. Delaney T, Wyse R, Yoong SL, et al. Cluster randomized controlled trial of a consumer behavior intervention to improve healthy food purchases from online canteens. *Am J Clin Nutr*2017;106(5):1311-1320.

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42. Yoong SL, Grady A, Wiggers J et al. A randomised controlled trial of an online menu planning intervention to improve childcare service adherence to dietary guidelines: a study protocol. *BMJ Open*2017;7:e017498. doi:10.1136/bmjopen-2017-017498
43. Cochrane T, Davey R, and de Castella FR. Estimates of the energy deficit required to reverse the trend in childhood obesity in Australian schoolchildren. *Aust N Z J Public Health*2016; 40(1):62-7.
44. Michie S, van Stralen MM, and West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
45. NSW Ministry of Health. Caring for Children birth to 5 years. 2014: Sydney:NSW Government.
46. Australian Children's Education and Care Quality Authority. What is the NQF? Accessed August 2018. URL: <https://www.acecqa.gov.au/nqf/about>.
47. Ward S, Blanger M, Donovan D, et al. Association between childcare educators' practices and preschoolers' physical activity and dietary intake: a cross-sectional analysis. *BMJ Open* 2017;7(5):e013657.
48. Xyris software. *Foodworks*. 2017: High Gate Hill, QLD.
49. Seward K, Wolfenden L, Finch M. et al, Multistrategy childcare-based intervention to improve compliance with nutrition guidelines versus usual care in long day care services: a study protocol for a randomised controlled trial. *BMJ Open*2016;6(6):e010786.
50. Hendrie GA, Viner Smith E, and Golley RK. The reliability and relative validity of a diet index score for 4-11-year-old children derived from a parent-reported short food survey. *Public Health Nutr*2014;17(7)1486-97.
51. Ward D, Hales D, Haverly K. An instrument to assess the obesogenic environment of child care centers. *Am J Health Beha*2008;32(4)380-6.
52. Finch M, Wolfenden L, Falkiner M, et al. Impact of a population based intervention to increase the adoption of multiple physical activity practices in centre based childcare services: a quasi experimental, effectiveness study. *Int J Behav Nutr Phys Act*2012;9:101.
53. Razak LA, Yoong SL, Wiggers J, et al. Impact of scheduling multiple outdoor free-play periods in childcare on child moderate-to-vigorous physical activity: a cluster randomised trial. *Int J Behav Nutr Phys Act*2018;15(1):34.
54. Bell AC, Davies L, Finch M, et al., An implementation intervention to encourage healthy eating in centre-based child-care services: impact of the Good for Kids Good for Life programme. *Public Health Nutrition*2014;18(9)1610-1619.
55. Weiner BJ, Lewis CC, Stanick C, et al., Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci*2017;12(1):108.
56. Taki S, Lymer S, Russell, CG, et al. Assessing User Engagement of an mHealth Intervention: Development and Implementation of the Growing Healthy App Engagement Index. *JMIR Mhealth Uhealth*2017;5(6):e89.
57. Breitenstein SM, Fogg L, Garvey C, et al. Measuring implementation fidelity in a community-based parenting intervention. *Nurs Res*2010;59(3)158-65.
58. White IR, Horton NJ, Carpenter J, et al. Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ*2011;342:d40.

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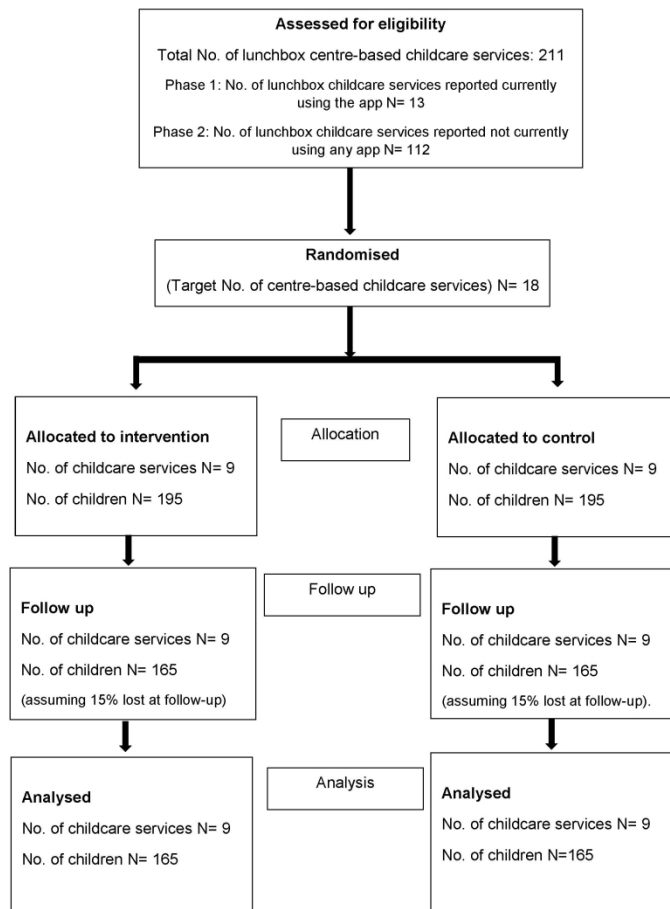


Figure 1 CONSORT flow diagram estimating the progress of preschools and parents through the trial

210x297mm (300 x 300 DPI)

### **Supplementary file 1: Application of a theoretical framework: Behaviour Change Wheel**

The “SWAP It Childcare” intervention content was developed using the Behaviour Change Wheel (BCW).<sup>1</sup> Based on a similar process described by behavioural researchers for designing an intervention to change diet behaviours using the BCW,<sup>2</sup> a three-step approach was used to apply the framework.

Step one included the identification of the target behaviour (ie to pack less discretionary foods in lunchboxes) and formative work to assess barriers and facilitators to packing healthy foods in children’s lunchboxes through literature reviews and semi-structured interviews with a convenience sample of parents (n= 28). A behavioural analysis, involving mapping of barriers to the COM B components of the BCW was undertaken with the purpose of ensuring the behavioural diagnosis was comprehensive.

Step two involved identifying intervention options using the BCW. The intervention functions (the means by which an intervention may change behaviour) of education, persuasion, and modelling were identified using the COM B/ intervention function matrix and the APEASE (Acceptability, Practicability, Effectiveness/ cost-effectiveness, Affordability, Safety/ side effects, Equity) criteria.<sup>2</sup> Policy categories were then considered to determine the delivery method of the intervention functions. The pre-determined mode of delivery (use of an app to deliver the intervention), fitted the category of “service provision” and was our only identified policy category.

Step three involved identifying the content and delivery options for the intervention. Behaviour change techniques most likely to bring about the desired change were mapped to the identified barriers (with reference to their COM B classifications) using the Behaviour Change Technique taxonomy.<sup>3</sup> A summary of the identified barriers, their COM B classification and the selected behaviour change techniques can be found in table 1. The resulting intervention consists of three key components which address nine identified barriers incorporating eight behaviour change techniques (See table 1 in main text).

<sup>1</sup>. Michie S, van Stralen MM, and West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.

<sup>2</sup>. Atkins L and Michie S. Conference on ‘Changing dietary behaviour: physiology through to practice’. Symposium 4: Changing diet and behaviour – putting theory into practice. *Proceedings of the Nutrition Society*2015;74:164-170.

<sup>3</sup>. Michie S, Wood CE, Johnston M, et al. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). *Health Technol Assess*2015;19(99):1-188.



# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	<a href="#">#2b</a>	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	<a href="#">#3</a>	Date and version identifier	1
Funding	<a href="#">#4</a>	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	<a href="#">#5a</a>	Names, affiliations, and roles of protocol contributors	20
Roles and responsibilities:	<a href="#">#5b</a>	Name and contact information for the trial sponsor	NA

1	sponsor contact			
2	information			
3				
4	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study design;	NA
5	responsibilities:		collection, management, analysis, and interpretation of	
6	sponsor and funder		data; writing of the report; and the decision to submit the	
7			report for publication, including whether they will have	
8			ultimate authority over any of these activities	
9				
10				
11				
12	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the coordinating	NA
13	responsibilities:		centre, steering committee, endpoint adjudication	
14	committees		committee, data management team, and other individuals or	
15			groups overseeing the trial, if applicable (see Item 21a for	
16			data monitoring committee)	
17				
18				
19				
20	Background and	<a href="#">#6a</a>	Description of research question and justification for	3
21	rationale		undertaking the trial, including summary of relevant studies	
22			(published and unpublished) examining benefits and harms	
23			for each intervention	
24				
25				
26				
27	Background and	<a href="#">#6b</a>	Explanation for choice of comparators	6
28	rationale: choice of			
29	comparators			
30				
31				
32	Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	5
33				
34				
35	Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel	5
36			group, crossover, factorial, single group), allocation ratio,	
37			and framework (eg, superiority, equivalence, non-inferiority,	
38			exploratory)	
39				
40				
41				
42	Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	5
43			academic hospital) and list of countries where data will be	
44			collected. Reference to where list of study sites can be	
45			obtained	
46				
47				
48	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable,	6
49			eligibility criteria for study centres and individuals who will	
50			perform the interventions (eg, surgeons, psychotherapists)	
51				
52				
53				
54	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow	8
55	description		replication, including how and when they will be	
56			administered	
57				
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1	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated	NA
2	modifications		interventions for a given trial participant (eg, drug dose	
3			change in response to harms, participant request, or	
4			improving / worsening disease)	
5				
6				
7	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols,	17
8	adherence		and any procedures for monitoring adherence (eg, drug	
9			tablet return; laboratory tests)	
10				
11				
12				
13	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that are	NA
14	concomitant care		permitted or prohibited during the trial	
15				
16				
17	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including the	14
18			specific measurement variable (eg, systolic blood pressure),	
19			analysis metric (eg, change from baseline, final value, time	
20			to event), method of aggregation (eg, median, proportion),	
21			and time point for each outcome. Explanation of the clinical	
22			relevance of chosen efficacy and harm outcomes is strongly	
23			recommended	
24				
25				
26				
27				
28	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any	6
29			run-ins and washouts), assessments, and visits for	
30			participants. A schematic diagram is highly recommended	
31			(see Figure)	
32				
33				
34				
35	Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study	7
36			objectives and how it was determined, including clinical and	
37			statistical assumptions supporting any sample size	
38			calculations	
39				
40				
41				
42	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to	7
43			reach target sample size	
44				
45				
46	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,	7
47	generation		computer-generated random numbers), and list of any	
48			factors for stratification. To reduce predictability of a random	
49			sequence, details of any planned restriction (eg, blocking)	
50			should be provided in a separate document that is	
51			unavailable to those who enrol participants or assign	
52			interventions	
53				
54				
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56				
57	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation sequence (eg,	7
58	concealment		central telephone; sequentially numbered, opaque, sealed	
59				
60				

1	mechanism		envelopes), describing any steps to conceal the sequence	
2			until interventions are assigned	
3				
4	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who will enrol	7
5	implementation		participants, and who will assign participants to	
6			interventions	
7				
8				
9	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to interventions (eg,	7
10			trial participants, care providers, outcome assessors, data	
11			analysts), and how	
12				
13				
14	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is	NA
15	emergency		permissible, and procedure for revealing a participant's	
16	unblinding		allocated intervention during the trial	
17				
18				
19				
20	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome, baseline,	14
21			and other trial data, including any related processes to	
22			promote data quality (eg, duplicate measurements, training	
23			of assessors) and a description of study instruments (eg,	
24			questionnaires, laboratory tests) along with their reliability	
25			and validity, if known. Reference to where data collection	
26			forms can be found, if not in the protocol	
27				
28				
29				
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31	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and complete follow-	13
32	retention		up, including list of any outcome data to be collected for	
33			participants who discontinue or deviate from intervention	
34			protocols	
35				
36				
37				
38	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, including	19
39			any related processes to promote data quality (eg, double	
40			data entry; range checks for data values). Reference to	
41			where details of data management procedures can be	
42			found, if not in the protocol	
43				
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46	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and secondary	18
47			outcomes. Reference to where other details of the statistical	
48			analysis plan can be found, if not in the protocol	
49				
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52	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup and	18
53	analyses		adjusted analyses)	
54				
55				
56	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to protocol non-	18
57	population and		adherence (eg, as randomised analysis), and any statistical	
58	missing data		methods to handle missing data (eg, multiple imputation)	
59				
60				

1	Data monitoring:	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); summary	NA
2	formal committee		of its role and reporting structure; statement of whether it is	
3			independent from the sponsor and competing interests; and	
4			reference to where further details about its charter can be	
5			found, if not in the protocol. Alternatively, an explanation of	
6			why a DMC is not needed	
7				
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11	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines,	NA
12	interim analysis		including who will have access to these interim results and	
13			make the final decision to terminate the trial	
14				
15				
16	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing	17
17			solicited and spontaneously reported adverse events and	
18			other unintended effects of trial interventions or trial conduct	
19				
20				
21	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any,	NA
22			and whether the process will be independent from	
23			investigators and the sponsor	
24				
25				
26				
27	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional	20
28	approval		review board (REC / IRB) approval	
29				
30				
31	Protocol	<a href="#">#25</a>	Plans for communicating important protocol modifications	NA
32	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
33			relevant parties (eg, investigators, REC / IRBs, trial	
34			participants, trial registries, journals, regulators)	
35				
36				
37	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential	6
38			trial participants or authorised surrogates, and how (see	
39			Item 32)	
40				
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42				
43	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and use of	NA
44	ancillary studies		participant data and biological specimens in ancillary	
45			studies, if applicable	
46				
47				
48	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled	14
49			participants will be collected, shared, and maintained in	
50			order to protect confidentiality before, during, and after the	
51			trial	
52				
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55	Declaration of	<a href="#">#28</a>	Financial and other competing interests for principal	19
56	interests		investigators for the overall trial and each study site	
57				
58				
59	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset,	NA
60				

1		and disclosure of contractual agreements that limit such	
2		access for investigators	
3			
4	Ancillary and post	<a href="#">#30</a> Provisions, if any, for ancillary and post-trial care, and for	NA
5	trial care	compensation to those who suffer harm from trial	
6		participation	
7			
8			
9	Dissemination policy:	<a href="#">#31a</a> Plans for investigators and sponsor to communicate trial	20
10	trial results	results to participants, healthcare professionals, the public,	
11		and other relevant groups (eg, via publication, reporting in	
12		results databases, or other data sharing arrangements),	
13		including any publication restrictions	
14			
15			
16			
17	Dissemination policy:	<a href="#">#31b</a> Authorship eligibility guidelines and any intended use of	NA
18	authorship	professional writers	
19			
20			
21	Dissemination policy:	<a href="#">#31c</a> Plans, if any, for granting public access to the full protocol,	19
22	reproducible	participant-level dataset, and statistical code	
23	research		
24			
25			
26			
27	Informed consent	<a href="#">#32</a> Model consent form and other related documentation given	7
28	materials	to participants and authorised surrogates	
29			
30			
31	Biological specimens	<a href="#">#33</a> Plans for collection, laboratory evaluation, and storage of	NA
32		biological specimens for genetic or molecular analysis in the	
33		current trial and for future use in ancillary studies, if	
34		applicable	
35			
36			

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 39 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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