PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Pond, Nicole; Finch, Meghan; Sutherland, Rachel; Wolfenden, Luke; Nathan, Nicole; Kingsland, Melanie; Grady, Alice; Gillham, Karen; Herrmann, Vanessa; Yoong, Sze Lin

VERSION 1 – REVIEW

REVIEWER	Jessica Grieger University of Adelaide, Australia
REVIEW RETURNED	14-Oct-2018

GENERAL COMMENTS	This is an excellent protocol for a randomised controlled trial to improve lunchbox food choices in childcare. It has been very well thought out with signifiant attention to detail regarding how the trial will run and outcome measurements. It is very timely given the prevalence of overweight and obesity in young children and the general poor diets of children that could be significantly modified. I am intrigued that so many centres have not already had nutrition counselling and education on the types of foods children should be provided. Introduction; This has been very well written with appropriate rationale and study aims. Methods: Please include the dates the trial will potentially run. Are there any specified days where data will be collected? If a child attends a centre more frequently or on certain days of the week, would it be likely that the food provided is different (e.g. potentially more packaged/less time to cut up fruit etc) than children who attend less frequently? Intervention strategies, page 9: To be eligible, do you need to have the notifications 'turned on' for weekly notifications? It would be useful to list some 'swap it' options that you will be providing parents. Overall daily usual intake of discretionary foods, page 15: How will you handle homemade recipes and whether items are low fat/no sugar etc if they are not in packages? Other considerations:

	- What is the difficulty for 3 year olds opening packed lunchboxes/packets etc? I assume this age group would require a large number of staff to assist. - Will any of the centres have a focus on 'nude food' where the aim is to minimise packaging; this will likely impact discretionary choices as many of those come in packages compared to fruits and vegetables. Suggestions for minor grammatical changes: Introduction: in paragraph 1, include 'future' before "chronic disease" Full stop required before references 14-16. Page 4 first paragraph: Comma after US Page 15, line 17: Remove the word 'in' after the word 'undertaken'

REVIEWER	Charlotte Evans University of Leeds, UK
REVIEW RETURNED	26-Oct-2018

GENERAL COMMENTS	This is a protocol of a proposed trial that is funded by a local Health District in Australia. It is clearly described and registered on a clinical trials register. I have some minor comments. General comments Sugar is an ambiguous term and needs to be defined more clearly throughout. Do you mean total sugar, free sugars, added sugars? Could you also include % of total energy of saturated fats and free sugars as additional outcomes as the recommendations for some countries are in percentage terms rather than actual values and it would enable comparison. Introduction: I am struggling to find the recommendation for total of 0.5 servings of discretionary food for under 8s in the Australian dietary Guidelines 2013. Can you give a clear reference with page number. It seems a very low recommendation (compared with actual 4.5 servings). What does this recommendation equate to in terms of percent of total energy so it can be compared with recommendations elsewhere. Page 5 38% of lunchboxes were poor but could you provide percent for individual results. P6 line 49. Very precise figure for number of residents. This figure needs a date. Sample size and power: in trials the power is usually set at 90% power not 80% for best practice. Some funders would insist on this. Can you provide a reference for similar trials that have used 80%. An ICC of 0.1 is high. I would have expected it to be lower for this age group that are not as likely to ask for the same thing as their friend (compared to older children). Is this ICC for energy in this age group? If not then it is worth stating this. I wonder whether the primary outcome should be based on diet quality (percent of free sugars, saturated fat or discretionary food) rather than energy. Discretionary foods could be replaced with a cheese sandwich but energy would not decrease even though this would be likely to increase satiety. I think this is particularly important when only looking at part of the day as it would be likely that children who had lower energy at lunchtime would make it up later. Maybe it is not possible to calculate power for these alternative outcomes if no ICC available. Page 9 line 31 what is house static information? P16 is it a validated FFQ? More information is needed on where it came from.

	Statistical analysis: what software will be used? STATA, SAS? Who will analyse? Will it be an experienced statistician? No trials unit involved so some indication that this is a centre of expertise when it comes to running and analysing trials needed. Multiple implication mentioned but needs a bit more detail including a reference for the method and software to be used. Minor comments P6 line 6 s needed on end of setting. P7 line 27 'to' pack foods Line 41 semi colon needed after are P16 line 16 remove in Line 34 remove a before food P17 line 8 remove and Line 41 insert space before 3pm P19 statistical analysis: Differences in outcomes between groups reads better

REVIEWER	Aulo Gelli IFPRI, USA.
REVIEW RETURNED	29-Oct-2018

GENERAL COMMENTS	Carefully designed trial on very relevant topic in child health and nutrition that will provide rigorous evidence for policymakers. One minor suggestion would be for the authors to discuss the possibility that parents may not have enough credit on their phones to access the mobile application regularly, particularly those parents in low-income settings. Some discussion around this, or some description of this issue in the context of the study population would help.

VERSION 1 – AUTHOR RESPONSE

Reviewer #1

Introduction
1. This has been very well written with appropriate rationale and study aims.

Response: None required.

Methods:
2. Please include the dates the trial will potentially run.

Response: The dates the trial will be run have been included under Methods and Analysis, Setting and Design, page 6. The paragraph now reads as follows:

The trial will run between March 2018 and January 2019. Following baseline data collection, services will be randomly allocated to receive the approximately four month intervention or to a usual care control group. The trial outcome measures will be assessed in the same child cohort within both groups at baseline and post intervention at approximately four months (post intervention) following baseline. The study will follow the CONSORT reporting guidelines.[35]

3. Are there any specified days where data will be collected? If a child attends a centre more frequently or on certain days of the week, would it be likely that the food provided is different (e.g. potentially more packaged/less time to cut up fruit etc) than children who attend less frequently?

Response: The day which the data will be collected will be based on service availability for pragmatic reasons. As such it is likely that this will differ for each participating service. Parents will not be aware of the specific day in which data collection will occur to minimise reactivity bias. To clarify the method of data collection however we have amended the text to specify that days of the week that data was collected differed by service. It now reads as follows (see page 15)

"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."**

Intervention strategies, page 9
4. To be eligible, do you need to have the notifications 'turned on' for weekly notifications?

Response: Having the notifications turned on is not an eligibility criteria as this is likely to result in a selected group of participants with high intentions to change their behaviour. Instead, to be eligible to participate, parents must have indicated a willingness to download or use the app at baseline.

5. It would be useful to list some 'swap it' options that you will be providing parents

Response: Thankyou for this suggestion. We have added an example of specific "swaps" to Table 2: Intervention Components, strategies and resources under point 1, page 12. The text now reads:

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.

Overall daily usual intake of discretionary foods, page 15
6. How will you handle homemade recipes and whether items are low fat/no sugar etc if they are not in packages?

Response: The section of the manuscript (page 15) referred to in this comment describe the overall daily usual intake of discretionary foods as measured by a validated parent completed food frequency questionnaire (Short Food Survey), with standard items that do not require the need for classification of foods (ie the presumption is made that all foods in this category are discretionary). For example:
- How often does your child usually eat SWEET BISCUITS/CAKES/ /MUFFINS/SLICES/DOUGHNUTS?
- How often does your child usually eat SAVOURY PASTRIES? This includes meat pies, sausage rolls and pasties.

We believe that this comment may however relate to how we will classify these foods when entering data from the lunchbox photography and weighing measures. The following paragraph has been amended to explain the procedure for home-made recipes and foods not in their packaging and can be found on page 15.

Where foods are home-made, an appropriate standard recipe will be used 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 documented.

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. **Where foods are home-made, an appropriate standard recipe will be used 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 documented.**

Other considerations:
7. What is the difficulty for 3 year olds opening packed lunchboxes/packets etc? I assume this age group would require a large number of staff to assist.

Response: Thankyou for your comment. Based on the types of food swaps recommended, it is not anticipated that the intervention will result in any substantial increase in the packing of packaged foods in children's lunchboxes. Further from the team's 12 years of experience working with local centre based childcare services, we believe that childcare staff are able to adequately provide assistance and support children if they may require it when having to open packages and containers.

8. Will any of the centres have a focus on 'nude food' where the aim is to minimise packaging; this will likely impact discretionary choices as many of those come in packages compared to fruits and vegetables.

Response: Thankyou for this comment. It is possible some of our participating services will have a Nude Food policy in order to minimise packaging, which in turn could affect the type of foods packed. Data will be collected on such policies as part of the EPAO observation and interview tool and the potential impact on type of foods packed will be considered when interpreting our results.

Suggestions for minor grammatical changes:
9. a) Introduction: in paragraph 1, include 'future' before "chronic disease"
b) Full stop required before references 14-16.
c) Page 4 first paragraph: Comma after US
d) Page 15, line 17: Remove the word 'in' after the word 'undertaken'

Response: All changes indicated above have been made.

Reviewer #2

General comments
1. Sugar is an ambiguous term and needs to be defined more clearly throughout. Do you mean total sugar, free sugars, added sugars?

Response: Thankyou for your comment. We agree that the term sugar should be further defined and have updated all references to this outcome measure throughout the document to include both total and added sugars. Please see example below and see all amendments on page 2, 5, 15 and 16.

"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)……"

2. Could you also include % of total energy of saturated fats and free sugars as additional outcomes as the recommendations for some countries are in percentage terms rather than actual values and it would enable comparison.

Response: We agree this is an important consideration. Given the number of outcomes already reported, we are unable to add further outcomes as this is likely to impact on our sample size calculation and the need to further account for multiple outcomes. Our current outcome measures were chosen on the basis that they were the primary targets of our intervention. We will however,

endeavour to include sufficient data in our reporting tables for these nutrients in order for external researchers and clinicians to extrapolate such data.

Introduction:

3. I am struggling to find the recommendation for total of 0.5 servings of discretionary food for under 8s in the Australian dietary Guidelines 2013. Can you give a clear reference with page number.

Response: The source of this recommendation is the reference "National Health and Medical Research Council. Educator Guide. 2013. National Health and Medical Research Council: Canberra", on page 22. The page number has been added to this reference (see page 22), and additional information for children who are taller or more active has been added, as this higher number of serves for more active children may provide more context for the lower number of serves quoted for the average child. The text now reads as below (see page 3)

"For younger children, up to about eight years of age, discretionary choices are best avoided or limited to no more than half a serve a day **unless the child is taller or more active, in which case they consume up to two serves a day".**

The reference reads:

National Health and Medical Research Council. Educator Guide, **pp 22.** 2013. National Health and Medical Research Council: Canberra.

4. It seems a very low recommendation (compared with actual 4.5 servings). What does this recommendation equate to in terms of percent of total energy so it can be compared with recommendations elsewhere.

Response: The Australian dietary guidelines do not provide recommendations regarding maximum percentage of total energy to come from discretionary foods. A serve of discretionary food is estimated to be approximately 600 kJ. As such, we have added the equivalent number of kilojoules that this number of serves provides to aid further in translation. This section now reads as follows (see page 3).

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. nor more than 300- 1200 kJ per day from discretionary foods**).[7]

5. Page 5 38% of lunchboxes were poor but could you provide percent for individual results.

Response: The cited study did not report on individual child results, however it did provide further information including:

- % of lunchboxes that contained "more than one serve" of discretionary foods and the average number of discretionary foods packed
- the average number of serves provided in "all lunchboxes containing any discretionary foods" (however the total number of lunchboxes containing any discretionary foods was not reported)

We have included the additional information related to discretionary food in the following text (see page 4):

"For example, a study of Australian children from 29 centre-based childcare services **found that 60% of lunchboxes contained more than one serve of discretionary food, with an average of two serves of discretionary foods provided per lunchbox. In addition,** 38% of lunchboxes were considered poorly balanced contained more than one serve of discretionary food and lacked vegetables, fruit or a healthy main meal." [19]

6. P6 line 49. Very precise figure for number of residents. This figure needs a date.

Response: Thanks for your comment. We have added a year to the statistic on the number of residents in our study area. Please see the amended sentence below (page 6).

In 2016, approximately 819 814 people were reported to reside in the HNE area, of which 51 900 were children aged 0 to 4 years.[33]

7. Sample size and power: in trials the power is usually set at 90% power not 80% for best practice. Some funders would insist on this. Can you provide a reference for similar trials that have used 80%.

Response: We have added references to two previous trials that aimed to improve the diets of young children in schools and childcare services (Delaney 2017 and Yoong 2017) that have used 80% power and the section now reads as follows (see page 8).

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, with 80%**[41,42]** power and a standard deviation of 200 kJ.

The following references have also been added to the reference list (see page 23):

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* Nutr2017;106(5):1311-1320.

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

8. An ICC of 0.1 is high. I would have expected it to be lower for this age group that are not as likely to ask for the same thing as their friend (compared to older children). Is this ICC for energy in this age group? If not then it is worth stating this.

Response: The following statement has been added to the text and can be found on page 8.

The ICC applied is based on internal and unpublished pilot data undertaken with a smaller number of lunchboxes. As children are recruited from childcare centres which may have existing lunchbox policies that may impact on provision of food, we anticipate that an ICC of 0.1 may be a conservative estimate of clustering.

9. I wonder whether the primary outcome should be based on diet quality (percent of free sugars, saturated fat or discretionary food) rather than energy. Discretionary foods could be replaced with a cheese sandwich but energy would not decrease even though this would be likely to increase satiety. I think this is particularly important when only looking at part of the day as it would be likely that children who had lower energy at lunchtime would make it up later. Maybe it is not possible to calculate power for these alternative outcomes if no ICC available.

Response: Thanks for this comment. We believe that the current primary outcome of **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 would adequately address this.

In the example where a cheese sandwich has replaced a discretionary item, this would reduce the overall mean energy of discretionary foods even where total energy from all foods may have remained constant.

10. Page 9 line 31 what is house static information?
Response: Thanks for your comment. We have changed our terminology to describe the app feature "house static information" to instead say "store information available for permanent access".

The sentence now reads as follows (see page 8):
"The app has the capacity to deliver content in the form of text, images and media (videos) and store information available for permanent access.

11. P16 is it a validated FFQ? More information is needed on where it came from.

Response: The description of the FFQ (the SFS), and a statement of its validity is included in the paragraph below (see page 16). The correlation statistics have been added and the text now reads (see page 16).

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 a 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 four to eleven years with a significant correlation **(r=0.43-0.44, P<0.01)** reported for serves of discretionary foods against 24 hour recalls. [49]

12. Statistical analysis: what software will be used? STATA, SAS? Who will analyse? Will it be an experienced statistician? No trials unit involved so some indication that this is a centre of expertise when it comes to running and analysing trials needed.

Response: Thankyou for drawing our attention to this omission. The following information on the statistical program and statistician responsible for analysing the data has been added and the paragraph now reads as follows (see page 19).

All statistical analysis will be performed with SAS (V.9.3 or later) statistical software by an experienced statistician independent to the study. 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.

13. Multiple implication mentioned but needs a bit more detail including a reference for the method and software to be used.

Response: The following detail including a reference for the method, has be added to the Statistical Analysis section of the manuscript which now reads as follows (see page 19).

Using intention to treat principles,[57] missing data from primary and secondary outcomes at follow-up, due to attrition, will be imputed using multiple imputation[57] through the SAS MI and MIANALYZE Procedure and will be the main analyses.

14. Minor comments
a) P6 line 6 s needed on end of setting.
b) P7 line 27 'to' pack foods
c) Line 41 semi colon needed after are
d) P16 line 16 remove in
e) Line 34 remove a before food
f) P17 line 8 remove and
g) Line 41 insert space before 3pm
h) P19 statistical analysis: Differences in outcomes between groups reads better

Response: The above amendments have been addressed.

Reviewer: #3

1. One minor suggestion would be for the authors to discuss the possibility that parents may not have enough credit on their phones to access the mobile application regularly, particularly those parents in low-income settings. Some discussion around this, or some description of this issue in the context of the study population would help.

Response: Thankyou for this comment. We are unsure if this is an existing barrier for our current population however have included additional questions in the follow up survey to assess potential cost barriers to accessing the m-health intervention. Additional detail regarding these questions had been added to the paragraph below (see page 18).

"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 and **any barriers to accessing or using the technology."**

VERSION 2 – REVIEW

REVIEWER	Jessica Grieger Adelaide University, Australia
REVIEW RETURNED	23-Dec-2018

GENERAL COMMENTS	This is my second review of this paper and my initial comments were addressed adequately. This is a well written protocol and my minimal comments relate to the grammar: Please double check the units (i.e. once sodium was in grams and not mg) of the nutrients listed, as well as the consistency in saying "an m-health" vs "a m-health"; "total and added sugar" vs "total and added sugarS"; having a space after the - for "centre-based" vs "centre-based".

REVIEWER	Charlotte Evans University of Leeds, UK
REVIEW RETURNED	23-Dec-2018

GENERAL COMMENTS	I am satisfied with all the amendments the authors have made in response to the reviewers comments.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Jessica Grieger

Institution and Country: Adelaide University, Australia

Please state any competing interests or state ‘None declared’: None declared

This is my second review of this paper and my initial comments were addressed adequately. This is a well written protocol and my minimal comments relate to the grammar: Please double check the units (i.e. once sodium was in grams and not mg) of the nutrients listed, as well as the consistency in saying "an m-health" vs "a m-health"; "total and added sugar" vs "total and added sugarS"; having a space after the - for "centre-based" vs "centre- based".

All the grammatical errors have been corrected and can be found in track changes in the “marked” version of the main document.

Reviewer: 2

Reviewer Name: Charlotte Evans

Institution and Country: University of Leeds, UK

Please state any competing interests or state ‘None declared’: none declared

I am satisfied with all the amendments the authors have made in response to the reviewers comments.

No action required.