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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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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 heathy 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-

based childcare,[17] achieving even modest dietary improvements in this setting is likely to have considerable potential to improve child health.

In Australia, the U.K. and the U.S. it is estimated that between 30% -50% of centre-based childcare services require parents to pack food in a lunchbox for their children to consume in care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain excessive amounts of discretionary foods. For example, a study of Australian children from 29 centre-based childcare services found that 38% of lunchboxes contained more than one serve of discretionary food and lacked vegetables, fruit or a healthy main meal.[19] A study in 30 centre-based care services in Texas US (607 children) similarly found a disproportionate amount of discretionary foods packed in lunchboxes with contents exceeding recommendations for saturated fat, sugar and sodium.[20]

Despite the potential to improve child diet via interventions to reduce packing of discretionary foods in lunchboxes of children attending centre-based childcare, to our knowledge just three randomised trials have been conducted,[21-23] with only one reporting impact on child dietary intake.[24] Two of these trials utilised multi-component service based strategies including staff nutrition training and child education, alongside parent targeted strategies (including workshops, and parent activity stations).[21, 22] Both trials reported significant improvements in packing of discretionary foods. The remaining trial involved training of childcare staff without any direct parent strategies. This trial was ineffective in reducing packing of discretionary foods.[23] While these findings suggest that interventions targeting parents are more likely to have an impact, previous approaches have been time and resource intensive, requiring parents to attend face to face sessions. These strategies have been reported to have limited reach [25] and reduce potential for intervention delivery at a population level.

Utilising mobile technology to directly reach parents has been suggested as a potentially effective strategy to overcome the limited reach of previous parent targeted interventions.[26, 27] Evidence demonstrates mobile health (m-health) interventions can be effective in changing dietary behaviours in both adults [28] and children.[28, 29] The use of mobile phone apps has been identified as highly acceptable to parents as a preferred health engagement tool,[30] and has potential to successfully reach the large majority (over 86%) of parents who are estimated to now own a smart phone.[31] Embedding interventions within existing childcare service mobile phone apps may also overcome previously reported barriers related to reach and engagement via their ability to reach parents at any place or time, deliver education materials and provide reminders or prompts targeting specific

behaviours.[27] Using an existing school communication app for the purpose of delivering healthy lunchbox information to parents was found to be highly feasible and acceptable by principals in primary school setting in the HNE area,[32] and the results of a healthy lunchbox pilot study utilising this model showed promising effects on the nutritional quality of children's lunchbox contents [unpublished data from a randomized controlled trial to assess the effectiveness, feasibility and acceptability of an m-health intervention 'SWAP IT', provided by RS, 2018]. Utilising a similar approach in the centre-based care setting to reduce packing of discretionary foods in lunchboxes therefore appears highly feasible. Despite this, to the author's knowledge no such m-health intervention has yet been conducted in this setting.

STUDY AIMS

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

METHODS AND ANALYSIS

Setting and Design

The study will utilise a cluster randomised controlled trial design, and will be conducted with parents and children attending centre-based childcare services in the Hunter New England (HNE) Local Health District of New South Wales (NSW), Australia (see Fig 1). Allocation will be at the unit of the childcare service. Approximately 819 814 people reside in the HNE area, of which 51 900 are children aged 0 to 4 years.[33] The area encompasses major metropolitan centres and inner regional communities, with a small percentage (14%) of people located in remote communities.[34]

Following baseline data collection, services will be randomly allocated to receive the 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 at approximately four months (post intervention) following baseline. The study will follow the CONSORT reporting guidelines.[35]

Figure 1: CONSORT diagram estimating the progress of centre based childcare services and children through the trial

Insert Figure 1

Participants and eligibility

Sample

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

Eligibility

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

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

supporting behaviour change.[43] For a description of the application of the framework please refer to supplementary file 1.

Intervention strategies

A four month intervention (Table 2) consisting of the following components will be delivered as part of "SWAP IT Childcare":

1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes
2. Provision of "SWAP IT Options" which are centre-based childcare lunchbox guidelines designed to provide specific information to parents on suitable foods for the lunchbox.
3. Centre-based childcare service endorsement of the program in order to support adoption of the "SWAP IT Options" lunchbox guidelines.

Further details regarding each strategy and delivery mode are provided in table 2.

Control Group

Services allocated to the control group will participate in data collection only. Parents from these services will receive routine centre-based childcare communication via the app (usual care) with no access to the lunchbox content.

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				
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)
	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) 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
1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes	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.	**a) "SWAP IT Childcare" push notification topics delivered via the app** Week 1 (2 messages): Welcome to "SWAP IT" The ultimate list of healthy lunchbox foods Week 2: "Sweet" food ideas for the lunchbox Week 3: Cost saving ideas for the lunchbox Week 4: Common fussy eating concerns Week 5: Healthy savoury snacks that are a hit! Week 6: Why are some lunchbox snacks better than others? Week 7: Is your child drinking enough? Week 8: Top 5 time saving ideas when packing a healthy lunchbox Week 9: Supporting children to try new foods Week 10: Thanks for being part of SWAP IT **b) Links to fact sheets and videos within messages** Top time saving tips (fact sheet and video) 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)
2. Provision of "SWAP IT Options" Lunchbox Guidelines	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]	**a) "SWAP IT Options" Lunchbox Guidelines, provided via links in push notification messages delivered via the app** SWAP IT Options Savoury SWAP IT Options Sweet SWAP IT Options Lunch foods SWAP IT Options Drinks
3. Centre-based childcare service endorsement of the program	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. 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	**a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.** **b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.**

	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. 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.	**c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).** **d) Provision of a service-completed record of implementation form.**

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^{TM})[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^{TM} 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

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 in 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 previous trials conducted with 26 childcare services.[48]

Serves of lunchbox discretionary foods packed and consumed

The number (count of individual items) and serves (600kJs 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 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 4-11 years with a significant correlation reported for serves of discretionary foods against 24 hour recalls.[49] Minor adaptations to the survey were made to capture foods frequently served in the centre-based care setting.

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

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 to3pm. 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.

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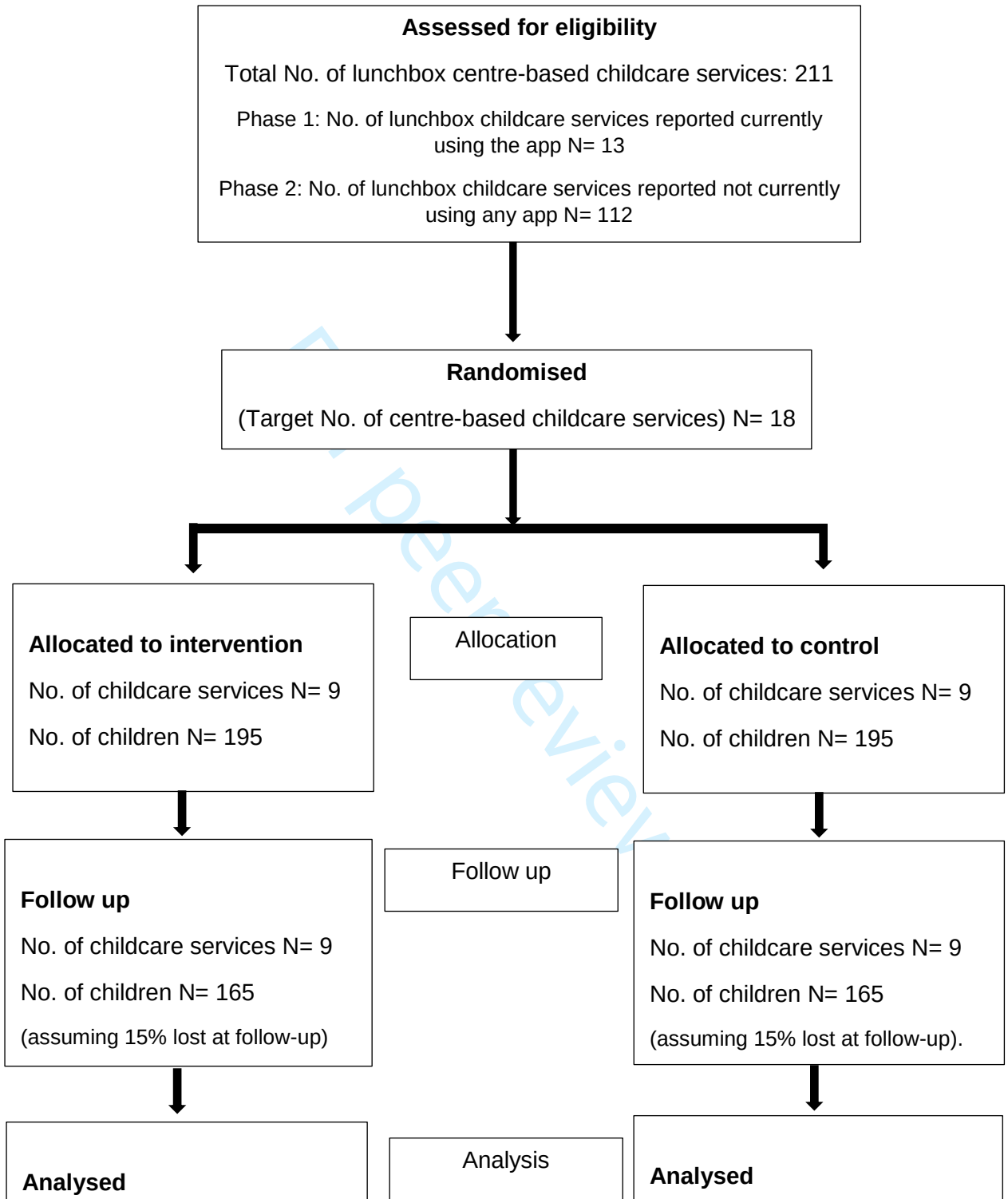

Figure 1CONSORT flow diagram estimating the progress of preschools and parents through the trial

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.

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

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	NA
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	17
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	7

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18

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

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	NA
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	7
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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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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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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 heathy 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

some form of centre-based care in the year prior to compulsory schooling in Australia, the United Kingdom (U.K.) and United States (U.S.). [14-16] As children can consume between one third to two thirds of their daily food intake whilst in centre- based childcare,[17] achieving even modest dietary improvements in this setting is likely to have considerable potential to improve child health.

In Australia, the U.K. and the U.S. it is estimated that between 30% and 50% of centre-based childcare services require parents to pack food in a lunchbox for their children to consume while in care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain excessive amounts of discretionary foods. For example, a study of Australian children attending 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 containing more than one serve of discretionary food and lacked vegetables, fruit or a healthy main meal. [19] An additional study conducted in 30 centre-based childcare services in Texas U.S., (607 children) similarly found a disproportionate amount of discretionary foods packed in lunchboxes with contents exceeding recommendations for saturated fat, sugar and sodium.[20]

Despite the potential to improve child diet via interventions to reduce packing of discretionary foods in lunchboxes of children attending centre-based childcare, to our knowledge just three randomised trials have been conducted,[21-23] with only one reporting on impact on child dietary intake.[24] Two of these trials utilised multi-component service based strategies including staff nutrition training and child education, alongside parent targeted strategies (including workshops, and parent activity stations).[21,22] Both trials reported significant improvements in the packing of discretionary foods. The remaining trial involved training of childcare staff without any direct parent strategies. This trial was ineffective in reducing packing of discretionary foods.[23] While these findings suggest that interventions targeting parents are more likely to have an impact, previous approaches have been time and resource intensive, requiring parents to attend face to face educational sessions. Such strategies have been reported to have limited reach,[25] and reduce the potential for intervention delivery at a population level.

Utilising mobile technology to directly reach parents has been suggested as a potentially effective strategy to overcome the limited reach of previous parent targeted interventions.[26,27] Evidence demonstrates that mobile health (m-health) interventions can be effective in changing dietary behaviours in both adults [28] and children.[28,29] The use of

mobile phone applications (apps) has been identified as highly acceptable to parents as a preferred health engagement tool,[30] and has the potential to successfully reach the large majority (over 86%) of parents who are estimated to now own a smart phone.[31] Embedding interventions within existing childcare service mobile phone apps may also overcome previously reported barriers related to reach and engagement via their ability to reach parents at any place or time, deliver education materials and provide reminders or prompts targeting specific behaviours.[27] Using an existing school communication app for the purpose of delivering healthy lunchbox information to parents was found to be highly feasible and acceptable by principals in the primary school setting within the Hunter New England region of NSW,[32] and the results of a healthy lunchbox pilot study utilising this model showed promising effects on the nutritional quality of children's lunchbox contents [unpublished data from a randomised controlled trial to assess the effectiveness, feasibility and acceptability of an m-health intervention 'SWAP IT', provided by author RS, 2018]. Utilising a similar approach in the centre-based childcare setting to reduce the packing of discretionary foods in lunchboxes therefore appears highly feasible. Despite this, to the author's knowledge no such m-health intervention has been conducted in this setting.

STUDY AIMS

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

METHODS AND ANALYSIS

Settings and Design

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

Allocation will be at the unit of the childcare service. 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] The area encompasses major metropolitan centres and inner regional communities, with a small percentage (14%) of people located in remote communities.[34]

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. The study will follow the CONSORT reporting guidelines.[35]

Figure 1: CONSORT diagram estimating the progress of centre based childcare services and children through the trial

Insert Figure 1

Participants and eligibility

Sample

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

Eligibility

To be eligible to participate, lunchbox services must cater for children three to six years of age, and be either existing users of the designated parent communication app (Skoolbag),[37] or have a willingness to commence using the app. Services will be excluded if they are; participating in any other trial related to improving child nutrition, cater exclusively for children with special needs or are a Department of Education community run service (as they are not covered within the existing ethics arrangement). Parents or carers (hereafter referred to as "parents") of children aged 3-6 years will be eligible to participate if their child attends during the days of data collection period and if they indicated willingness to download or use the app.

Children will be excluded if they have special dietary requirements or allergies that would necessitate specialised tailoring of their diet.

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 in the trial. 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 to participate in the trial will be provided by the manager on behalf of the services.

Children

Centre-based childcare staff will distribute hard copies of information statements and consent forms to parents approximately two weeks prior to baseline data collection. To maximise consent rates, 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 following baseline data collection 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 123 kJ in the primary outcome, with an alpha of 0.01 (adjusting for multiple outcomes), and an estimated ICC of 0.1, with 80% power [41,42] and a standard deviation of 200 kJ. 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. 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)[43] and proportionally adjusted to the amount of time children spend in care (approximately one third 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 store information available for permanent access.

The program was co-produced by a team of behavioural researchers, public health nutritionist, centre-based childcare staff and the technology provider “Skoolbag” and was based on formative evaluations with parents. Key differences between the primary 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 three to six 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 childcare 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).[44] This theoretically driven framework is based on 19 theories of health behaviour and is designed to enable the systematic development of interventions for supporting behaviour change.[44] For a description of the application of the framework please refer to supplementary file 1. An overview of the intervention mapping process is provided in Table 1.

Intervention strategies

A four month intervention (Table 2) consisting of the following components will be delivered as part of "SWAP IT Childcare":

1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes
2. Provision of "SWAP IT Options" which are centre-based childcare lunchbox guidelines designed to provide specific information to parents on suitable foods for the lunchbox.
3. Centre-based childcare service endorsement of the program in order to support adoption of the "SWAP IT Options" lunchbox guidelines.

Further details regarding each strategy and delivery mode are provided in table 2.

Control Group

Services allocated to the control group will participate in data collection only. Parents from these services will receive routine centre-based childcare communication via the app (usual care) with no access to the lunchbox content.

Patient and Public Involvement

The research question and intervention was co-designed together with the local health promotion unit (Hunter New England Population Health) responsible for supporting childcare services to support parents with packing healthier lunchboxes. As described in the methods, intervention design and content was informed in part, by the results of a survey of parents

(n= 29) from a convenience sample of local childcare services and consultation with two local Aboriginal centre based childcare service managers. Service managers were also consulted about the acceptability of app technology for delivering the intervention to parents. The participating parents were not involved in the design, recruitment or conduct of the study however childcare staff will support recruitment via assistance with distribution and collection of consent forms and assistance with the data collection process by identifying lunchboxes for weighing. Participant burden to engaging with the intervention will be assessed as part of a follow up survey with parents assessing acceptability and time and cost of changing behaviours. A summary of the results will be provided to participating services to distribute to parents and a copy of the summary will be available on the research unit's website or upon individual request from parents.

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				
Opportunity	3. Perception that it takes longer to prepare and/ or shop for healthy foods for the lunchbox.				4.3 Information about health consequences (8)
	4. Perception that it costs more to pack a healthy lunchbox				6.1 Demonstration of the behaviour (3, 4, 5; 7)
	5. Child is a fussy eater (i.e. will not accept new foods packed in the lunchbox)				7.1 Prompts/cues (8)
	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)
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.				11.1 Conserving mental resources (1, 2)
	8. Lack of motivators or prompts to change lunchbox packing behaviours				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
1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes	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	**a) "SWAP IT Childcare" push notification topics delivered via the app** Week 1 (2 messages): Welcome to "SWAP IT" The ultimate list of healthy lunchbox foods Week 2: "Swap" food ideas for the lunchbox Week 3: Cost saving ideas for the lunchbox Week 4: Common fussy eating concerns Week 5: Healthy savoury snacks that are a hit! Week 6: Why are some lunchbox snacks better than others? Week 7: Is your child drinking enough? Week 8: Top 5 time saving ideas when packing a healthy lunchbox Week 9: Supporting children to try new foods Week 10: Thanks for being part of SWAP IT **b) Links to fact sheets and videos within messages** Top time saving tips (fact sheet and video)

	further information on behaviour change techniques used to address each barrier please refer to Table 1.	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)
2. Provision of "SWAP IT Options" Lunchbox Guidelines	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]	**a) "SWAP IT Options" Lunchbox Guidelines, provided via links in push notification messages delivered via the app** SWAP IT Options Savoury SWAP IT Options Sweet SWAP IT Options Lunch foods SWAP IT Options Drinks
3. Centre-based childcare service endorsement of the program	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.	**a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.**

	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. 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.	**b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.** **c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).** **d) Provision of a service-completed record of implementation form.**

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

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

Other Measures

Parent and child demographics

Parent and child demographic information 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, as part of the consent form, and additional questions on income level, living arrangements and language spoken at home will be collected via the online survey.

Service operational characteristics

Service operational characteristics will be assessed via a pen and paper survey completed by the service manager at 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.[51] Modified versions of the EPAO have been used previously by the research team in other intervention trials.[52-54] Completion of the EPAO will be undertaken by a third trained research assistant on one of the two days allocated for service-level 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 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

records. Measuring fidelity across various domains such as these has been recommended as key to informing “real world uptake” of interventions.[57]

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 questions included within the EPAO document and within the parent survey at follow up.

Statistical Analysis

All statistical analysis will be performed with SAS (V.9.4) statistical software by an experienced statistician independent to the study. Differences in outcomes between groups 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 a differential impact according to such variables. Using intention to treat principles,[58] missing data from primary and secondary outcomes at follow-up due to attrition, will be imputed using multiple imputation[58] through the SAS MI and MIANALYZE Procedure 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 the 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 DISSEMINATION

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 will form part of a PhD student thesis.

AUTHOR CONTRIBUTIONS

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

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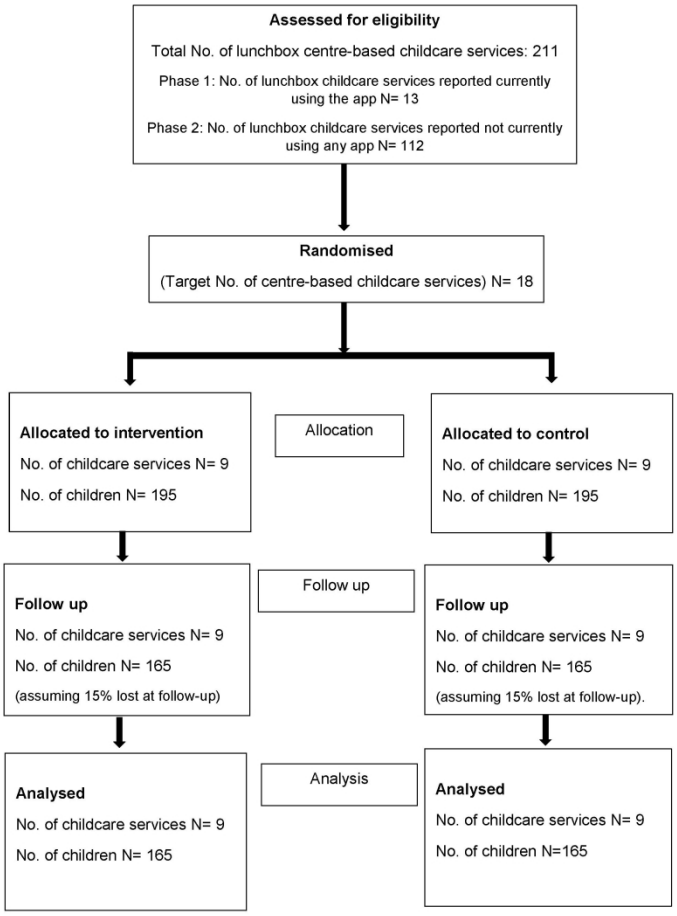

Figure 1 CONSORT flow diagram estimating the progress of preschools and parents through the trial

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).[1] Based on a similar process described by behavioural researchers for designing an intervention to change diet behaviours using the BCW,[2] 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.[2] 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.[3] 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).

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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.

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

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	NA
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	17
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	7

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18

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

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	NA
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	7
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

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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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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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 heathy 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

some form of centre-based care in the year prior to compulsory schooling in Australia, the United Kingdom (U.K.) and United States (U.S.). [14-16] As children can consume between one third to two thirds of their daily food intake whilst in centre- based childcare,[17] achieving even modest dietary improvements in this setting is likely to have considerable potential to improve child health.

In Australia, the U.K. and the U.S. it is estimated that between 30% and 50% of centre-based childcare services require parents to pack food in a lunchbox for their children to consume while in care.[14, 15, 18] Evidence suggests, however, that children's lunchboxes contain excessive amounts of discretionary foods. For example, a study of Australian children attending 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 containing more than one serve of discretionary food and lacked vegetables, fruit or a healthy main meal. [19] An additional study conducted in 30 centre-based childcare services in Texas U.S., (607 children) similarly found a disproportionate amount of discretionary foods packed in lunchboxes with contents exceeding recommendations for saturated fat, sugar and sodium.[20]

Despite the potential to improve child diet via interventions to reduce packing of discretionary foods in lunchboxes of children attending centre-based childcare, to our knowledge just three randomised trials have been conducted,[21-23] with only one reporting on impact on child dietary intake.[24] Two of these trials utilised multi-component service based strategies including staff nutrition training and child education, alongside parent targeted strategies (including workshops, and parent activity stations).[21,22] Both trials reported significant improvements in the packing of discretionary foods. The remaining trial involved training of childcare staff without any direct parent strategies. This trial was ineffective in reducing packing of discretionary foods.[23] While these findings suggest that interventions targeting parents are more likely to have an impact, previous approaches have been time and resource intensive, requiring parents to attend face to face educational sessions. Such strategies have been reported to have limited reach,[25] and reduce the potential for intervention delivery at a population level.

Utilising mobile technology to directly reach parents has been suggested as a potentially effective strategy to overcome the limited reach of previous parent targeted interventions.[26,27] Evidence demonstrates that mobile health (m-health) interventions can be effective in changing dietary behaviours in both adults [28] and children.[28,29] The use of

mobile phone applications (apps) has been identified as highly acceptable to parents as a preferred health engagement tool,[30] and has the potential to successfully reach the large majority (over 86%) of parents who are estimated to now own a smart phone.[31] Embedding interventions within existing childcare service mobile phone apps may also overcome previously reported barriers related to reach and engagement via their ability to reach parents at any place or time, deliver education materials and provide reminders or prompts targeting specific behaviours.[27] Using an existing school communication app for the purpose of delivering healthy lunchbox information to parents was found to be highly feasible and acceptable by principals in the primary school setting within the Hunter New England region of NSW,[32] and the results of a healthy lunchbox pilot study utilising this model showed promising effects on the nutritional quality of children's lunchbox contents [unpublished data from a randomised controlled trial to assess the effectiveness, feasibility and acceptability of an m-health intervention 'SWAP IT', provided by author RS, 2018]. Utilising a similar approach in the centre-based childcare setting to reduce the packing of discretionary foods in lunchboxes therefore appears highly feasible. Despite this, to the author's knowledge no such m-health intervention has been conducted in this setting.

STUDY AIMS

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

METHODS AND ANALYSIS

Settings and Design

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

Allocation will be at the unit of the childcare service. 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] The area encompasses major metropolitan centres and inner regional communities, with a small percentage (14%) of people located in remote communities.[34]

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. The study will follow the CONSORT reporting guidelines.[35]

Figure 1: CONSORT diagram estimating the progress of centre-based childcare services and children through the trial

Insert Figure 1

Participants and eligibility

Sample

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

Eligibility

To be eligible to participate, lunchbox services must cater for children three to six years of age, and be either existing users of the designated parent communication app (Skoolbag),[37] or have a willingness to commence using the app. Services will be excluded if they are; participating in any other trial related to improving child nutrition, cater exclusively for children with special needs or are a Department of Education community run service (as they are not covered within the existing ethics arrangement). Parents or carers (hereafter referred to as "parents") of children aged 3-6 years will be eligible to participate if their child attends during the days of data collection period and if they indicated willingness to download or use the app.

Children will be excluded if they have special dietary requirements or allergies that would necessitate specialised tailoring of their diet.

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 in the trial. 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 to participate in the trial will be provided by the manager on behalf of the services.

Children

Centre-based childcare staff will distribute hard copies of information statements and consent forms to parents approximately two weeks prior to baseline data collection. To maximise consent rates, 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 following baseline data collection 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 123 kJ in the primary outcome, with an alpha of 0.01 (adjusting for multiple outcomes), and an estimated ICC of 0.1, with 80% power [41,42] and a standard deviation of 200 kJ. 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. 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)[43] and proportionally adjusted to the amount of time children spend in care (approximately one third 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 store information available for permanent access.

The program was co-produced by a team of behavioural researchers, public health nutritionist, centre-based childcare staff and the technology provider “Skoolbag” and was based on formative evaluations with parents. Key differences between the primary 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 three to six 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 childcare 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).[44] This theoretically driven framework is based on 19 theories of health behaviour and is designed to enable the systematic development of interventions for supporting behaviour change.[44] For a description of the application of the framework please refer to supplementary file 1. An overview of the intervention mapping process is provided in Table 1.

Intervention strategies

A four month intervention (Table 2) consisting of the following components will be delivered as part of "SWAP IT Childcare":

1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes
2. Provision of "SWAP IT Options" which are centre-based childcare lunchbox guidelines designed to provide specific information to parents on suitable foods for the lunchbox.
3. Centre-based childcare service endorsement of the program in order to support adoption of the "SWAP IT Options" lunchbox guidelines.

Further details regarding each strategy and delivery mode are provided in table 2.

Control Group

Services allocated to the control group will participate in data collection only. Parents from these services will receive routine centre-based childcare communication via the app (usual care) with no access to the lunchbox content.

Patient and Public Involvement

The research question and intervention was co-designed together with the local health promotion unit (Hunter New England Population Health) responsible for supporting childcare services to support parents with packing healthier lunchboxes. As described in the methods, intervention design and content was informed in part, by the results of a survey of parents

(n= 29) from a convenience sample of local childcare services and consultation with two local Aboriginal centre-based childcare service managers. Service managers were also consulted about the acceptability of app technology for delivering the intervention to parents. The participating parents were not involved in the design, recruitment or conduct of the study however childcare staff will support recruitment via assistance with distribution and collection of consent forms and assistance with the data collection process by identifying lunchboxes for weighing. Participant burden to engaging with the intervention will be assessed as part of a follow up survey with parents assessing acceptability and time and cost of changing behaviours. A summary of the results will be provided to participating services to distribute to parents and a copy of the summary will be available on the research unit's website or upon individual request from parents.

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				
Opportunity	3. Perception that it takes longer to prepare and/ or shop for healthy foods for the lunchbox.				4.3 Information about health consequences (8)
	4. Perception that it costs more to pack a healthy lunchbox				6.1 Demonstration of the behaviour (3, 4, 5; 7)
	5. Child is a fussy eater (i.e. will not accept new foods packed in the lunchbox)				7.1 Prompts/cues (8)
	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)
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.				11.1 Conserving mental resources (1, 2)
	8. Lack of motivators or prompts to change lunchbox packing behaviours				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
1. Provision of weekly push notifications targeting identified barriers to the packing of healthier lunchboxes	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	**a) "SWAP IT Childcare" push notification topics delivered via the app** Week 1 (2 messages): Welcome to "SWAP IT" The ultimate list of healthy lunchbox foods Week 2: "Swap" food ideas for the lunchbox Week 3: Cost saving ideas for the lunchbox Week 4: Common fussy eating concerns Week 5: Healthy savoury snacks that are a hit! Week 6: Why are some lunchbox snacks better than others? Week 7: Is your child drinking enough? Week 8: Top 5 time saving ideas when packing a healthy lunchbox Week 9: Supporting children to try new foods Week 10: Thanks for being part of SWAP IT **b) Links to fact sheets and videos within messages** Top time saving tips (fact sheet and video)

	further information on behaviour change techniques used to address each barrier please refer to Table 1.	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)
2. Provision of "SWAP IT Options" Lunchbox Guidelines	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]	**a) "SWAP IT Options" Lunchbox Guidelines, provided via links in push notification messages delivered via the app** SWAP IT Options Savoury SWAP IT Options Sweet SWAP IT Options Lunch foods SWAP IT Options Drinks
3. Centre-based childcare service endorsement of the program	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.	**a) Health Promotion Officer Service visit and provision of hard copies of resources prior to commencement of push notification messages.**

	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. 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.	**b) Service-delivered communication to parents prior to commencement of push notifications and provision of sample message template to the service.** **c) Service-delivered communication to parents mid-way through push notification delivery period and provision of sample message template and (week 5).** **d) Provision of a service-completed record of implementation form.**

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

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

Other Measures

Parent and child demographics

Parent and child demographic information 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, as part of the consent form, and additional questions on income level, living arrangements and language spoken at home will be collected via the online survey.

Service operational characteristics

Service operational characteristics will be assessed via a pen and paper survey completed by the service manager at 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.[51] Modified versions of the EPAO have been used previously by the research team in other intervention trials.[52-54] Completion of the EPAO will be undertaken by a third trained research assistant on one of the two days allocated for service-level 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 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

records. Measuring fidelity across various domains such as these has been recommended as key to informing “real world uptake” of interventions.[57]

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 questions included within the EPAO document and within the parent survey at follow up.

Statistical Analysis

All statistical analysis will be performed with SAS (V.9.4) statistical software by an experienced statistician independent to the study. Differences in outcomes between groups 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 a differential impact according to such variables. Using intention to treat principles,[58] missing data from primary and secondary outcomes at follow-up due to attrition, will be imputed using multiple imputation[58] through the SAS MI and MIANALYZE Procedure 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 a 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 the 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 DISSEMINATION

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 will form part of a PhD student thesis.

AUTHOR CONTRIBUTIONS

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

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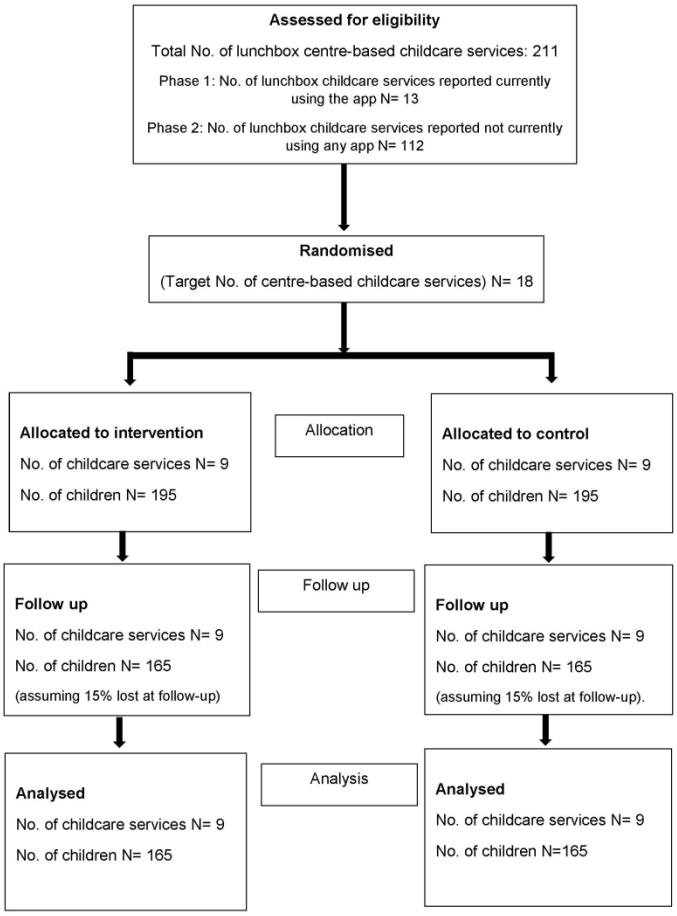

Figure 1 CONSORT flow diagram estimating the progress of preschools and parents through the trial

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).[1] Based on a similar process described by behavioural researchers for designing an intervention to change diet behaviours using the BCW,[2] 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.[2] 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.[3] 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).

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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.

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

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	NA
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	17
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	7

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18

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

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	NA
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	7
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA