Effectiveness of a multi-component m-health-based intervention to decrease the consumption of discretionary foods packed in school lunchboxes: the 'SWAP IT' effectiveness-implementation hybrid type 1 trial.

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Submitted to: Journal of Medical Internet Research
on: October 25, 2020

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Abstract

Background: There is significant opportunity to improve the nutritional quality of foods packed in children's school lunchboxes. Interventions that are effective and scalable targeting the school and home environment are therefore warranted.

Objective: This study aimed to assess the effectiveness of a multi-component m-health-based intervention, SWAP IT, in reducing the energy contribution of discretionary (i.e. less healthy) foods and drinks packed for children to consume at school.

Methods: A Type I hybrid effectiveness-implementation cluster randomised controlled trial was conducted in 32 primary schools located across three Local Health Districts in New South Wales (NSW), Australia, comparing the effects of a six-month intervention targeting foods packed in children's lunchboxes or usual care control. Primary schools were eligible if they were not participating in other nutrition studies and used the required school communication app. The Behaviour Change Wheel was used to co-design the multi-component SWAP IT intervention which consisted of: 1) school lunchbox nutrition guidelines; 2) curriculum lessons; 3) information pushed to parents digitally via an existing school communication app and 4) additional parent resources to address common barriers to packing healthy lunchboxes. The primary outcome, mean energy (kJ) content of discretionary lunchbox foods and drinks packed in lunchboxes, was measured via observation using a validated school food checklist (SFC) at baseline (May 2019) and six-month follow-up (October 2019). Additional secondary outcomes included mean lunchbox energy from discretionary foods consumed, mean total lunchbox energy packed and consumed, mean energy content of core lunchbox foods packed and consumed and percentage of lunchbox energy from discretionary and core foods. Measures of school engagement, consumption of discretionary foods outside of school hours and lunchbox cost were also collected at baseline and six-month follow-up. Data were analysed via hierarchical linear regression models controlling for clustering, socioeconomic status and remoteness.

Results: 3022 (41.2%) of students consented to participate in the evaluation (mean age 7.8yrs, 49.2% girls). There were

significant reductions between intervention and control group in the primary trial outcome, mean energy (kJ) content of discretionary foods packed in lunchboxes (-117.26kJ; CI=-195.59, -39.83; P=<0.01). The intervention also significantly reduced, relative to control, secondary outcomes regarding the mean total lunchbox energy (kJ) packed (-88.38kJ; CI=-172.84, -3.92; P=0.04) and consumed (-117.17kJ; CI= -233.72, -0.62; P=0.05). There was no significant difference between groups in measures of student engagement, consumption of discretionary foods outside of school hours or cost of foods packed in children's lunchboxes.

Conclusions: The SWAP IT intervention was effective in reducing the energy content of foods packed for and consumed by primary school-aged children at school. Application at a population level has the potential to influence a significant proportion of primary school aged children, impact on weight status and associated health care costs. Clinical Trial: Australian Clinical Trials Registry ACTRN: 12618001731280

(JMIR Preprints 25/10/2020:25256)
DOI: https://doi.org/10.2196/preprints.25256

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discretionary foods outside of school hours and lunchbox cost were also collected at baseline and six-month follow-up. Data were analysed via hierarchical linear regression models controlling for clustering, socioeconomic status and remoteness.

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Conclusions: The SWAP IT intervention was effective in reducing the energy content of foods packed for and consumed by primary school-aged children at school. Dissemination of the SWAP IT program at a population level has the potential to influence a significant proportion of primary school aged children, impact on weight status and associated health care costs.

Trial registration: Australian Clinical Trials Registry ACTRN: 12618001731280 (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=376191&isReview=true) registered on 17/10/2018.

Key words: childhood obesity, lunchboxes, children, child nutrition, m-health, schools, hybrid, randomised controlled trial, technology

Background

Preventing the onset of overweight and obesity in children is a global public health priority [1] given it impacts negatively on physical health, psychological wellbeing and long term chronic disease risk [2]. The frequent over consumption of energy dense, nutrient poor or 'discretionary' foods throughout childhood, which displace the consumption of core foods consistent with dietary guidelines, is known to be a major contributor to the development of overweight and obesity [3]. Of concern, the poor dietary patterns that are established in childhood track into adulthood and increase risk of adult overweight and obesity [4]. To address this, the World Health Organization recommends implementing population wide interventions to support the establishment of eating habits in children that are consistent with dietary guidelines [5].

Children consume up to two-thirds of their daily energy intake at school [6]. As such, schools have been identified as an optimal setting to implement public health nutrition interventions [5]. Internationally, school-based nutrition research has focussed on improving the provision or sale of foods at school canteens [7] or cafeterias [8]. However, in many countries, such as Australia [9], the United Kingdom [10], New Zealand [11], and Denmark [12] a significant proportion of children consume food brought to school from home in a lunchbox. Further, research suggests that the nutritional quality of foods in packed in school lunchboxes may be poorer than those available at, or provided by, schools. For example in Australia, approximately 5% of items sold at school canteens are discretionary items [13] compared to items in almost 40% in children lunchboxes [14]. A cross-sectional study undertaken in Australia of 1681 students found that lunchboxes contain an average of 3.1 serves of discretionary foods (1200kJ), and contributed to over 3000 kilojoules (kJ), significantly higher

than that recommended in dietary guidelines [15]. A further Australian study involving 2143 primary school aged children (mean age 7.96 years) found that just 12% of students lunchboxes contain only core foods (i.e. minimally processed foods recommended in Australian Dietary Guidelines), with a quarter containing four or more discretionary serves [16] exceeding the maximum daily amount for children of this age. Similar nutrient compositions have been reflected in lunchboxes across the globe including New Zealand [11], UK [10,17], Canada [18], and the USA [19].

Current evidence regarding the effectiveness of school lunchbox interventions is equivocal. A recent systematic review of such interventions in the school and childcare setting identified just ten trials, and suggested they had little to no effect on the nutritional quality of foods packed or consumed by students [20]. Existing interventions have employed either passive information dissemination strategies to parents, which have limited reach and engagement, or utilised intensive face-to-face group-based strategies attracting a biased population group and presenting considerable challenges to implement at scale.

Mobile text messaging and mobile application (referred to herein as apps) based interventions have been proven to be a scalable and effective approach for improving a variety of health behaviours including modifying parent behavior to improve child diet [21,22]. Our previous pilot study in 12 schools, assessing the feasibility, acceptability and potential efficacy of the multi-component 'SWAP IT' intervention [16], used an existing school mobile communication app in addition to the development of school nutrition guidelines, school curriculum and resources to parents to encourage parents to 'swap' discretionary foods from their child's lunchboxes to healthier alternatives consistent with the

Australian Dietary Guidelines ('everyday' foods) [23]. The intervention approach was found to be highly feasible to deliver and acceptable to both schools and parents and demonstrating promising short-term improvements in the nutritional quality of foods packed in lunchboxes [16]. Following the encouraging findings of the pilot, our primary aim was to conduct an adequately powered randomised trial to assess the effectiveness of the SWAP IT multi-component lunchbox intervention to reduce the kilojoule content from discretionary foods and drinks both packed and consumed by children from school lunchboxes whilst at school, relative to usual care. We also sought to evaluate the effectiveness of the intervention on a range of secondary outcomes including mean lunchbox energy from discretionary foods consumed, mean total lunchbox energy packed and consumed, mean energy content of core lunchbox foods packed and consumed and percentage of lunchbox energy from discretionary and core foods, measures of school engagement, consumption of discretionary foods outside of school hours and lunchbox cost.

Methods

Ethics and registration

The research was conducted and reported in accordance with the requirements of the Consolidated Standards of Reporting Trials (CONSORT) Statement [24]. Approval to conduct this study was obtained from Hunter New England Human Research Ethics Committee (Ref. No. 06/07/26/4.04), University of Newcastle (Ref. No. H-2008-0343), and the NSW Department of Education SERAP (2018247) and was prospectively registered with Australian New Zealand Clinical Trials Register 12618001731280. A detailed description of the methods and intervention are outlined in the study protocol [25].

Study design and setting

A cluster randomised Type I Hybrid effectiveness implementation trial was conducted with 32 primary (aged approximately 5-12 years) schools across three local health districts in New South Wales (NSW), Australia (Figure 1). Schools were randomised to receive a six month (two school terms), multi-component lunchbox intervention or to a usual care control arm (16 schools per arm). Outcome assessments were conducted in a cohort of students at baseline and six months post randomization. The primary outcome was mean energy (kJ) content of discretionary lunchbox foods and drinks packed in lunchboxes, assessed via lunchbox observation. Other registered outcome related to implementation processes including intervention acceptability, appropriateness and feasibility [26,27], cost effectiveness of the intervention and impact on mean daily nutrient consumption will be reported separately.

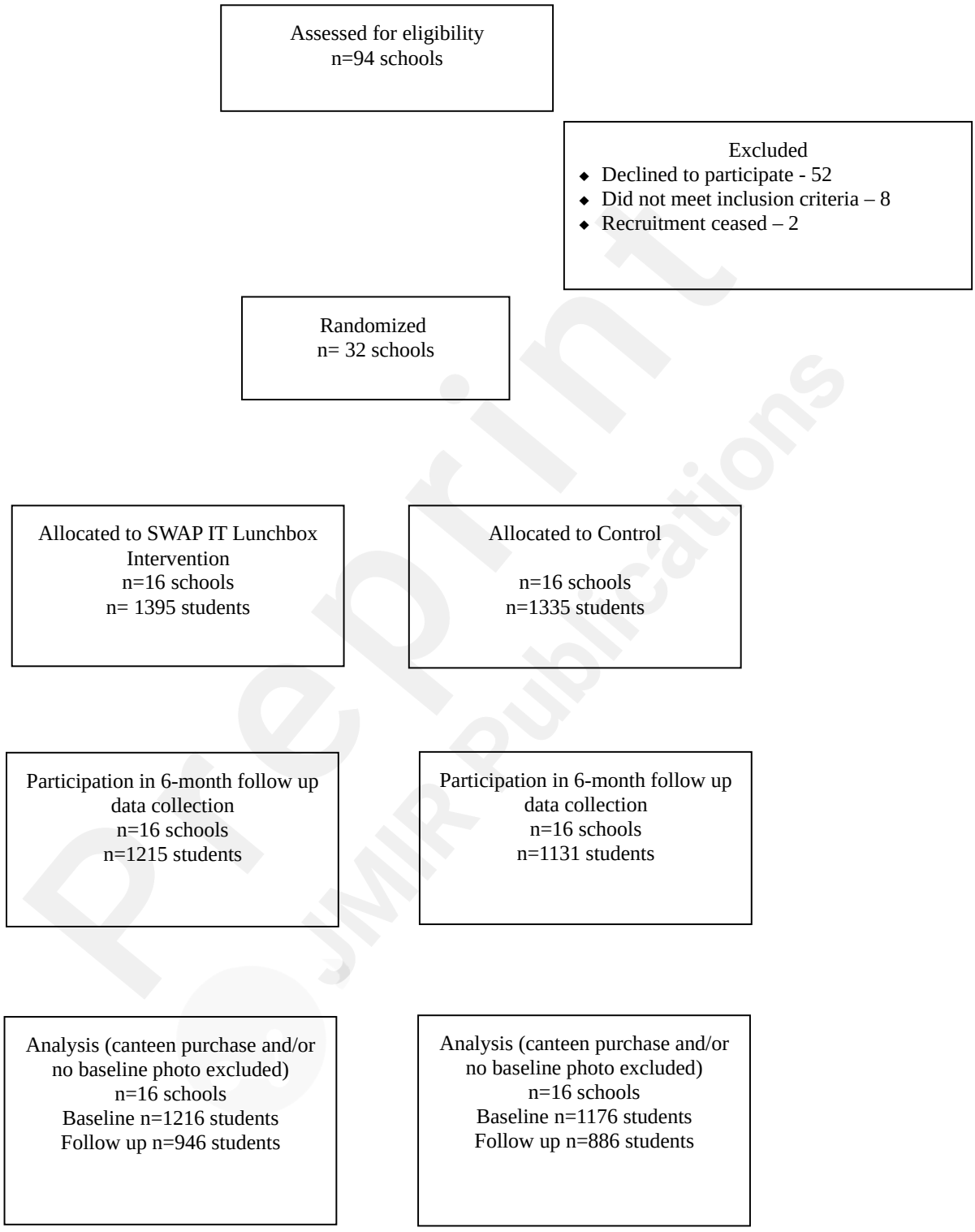

Figure 1. Consort Flow Diagram

Sample and participants

Schools: Schools were considered eligible if they met the following criteria: Government primary schools catering for students from Kindergarten to Year 6, located in one of the participating Local Health Districts; greater than 120 student enrolments; current users of the preferred school mobile communication app (SkoolBag); and not participating in other nutrition based research studies. Schools purchase the communication app for a nominal fee annually, which is then free for parents to download, to enable direct school-parent communication. The app is used by approximately 60% of schools in the region. Central schools (catering for students aged 5-18 years) and schools primarily catering for children with additional needs (such as intellectual disabilities) were excluded. Using a random number generator in Excel, eligible schools meeting the above criteria were sent a letter of invitation in random order. One week following the invitation, a member of the research team contacted the school principal via telephone to seek consent. A face-to-face meeting was offered to all schools to outline the requirements of the study. Recruitment and consent of schools occurred between February to May, 2019. Recruitment continued until 32 schools provided active signed principal consent to participate.

Parent and students: Opt-in parental consent was required for children and parents to participate in the evaluation of the behavioural outcomes. Parents were also required to be active users of the school communication app, defined as downloading the school communication app on the parent consent form. A strategy to recruit parents/students was developed based on the pilot study and reviews of evidence for facilitating participation in school-based research [16,28]. Following principal consent, all parents with a child enrolled in Kindergarten to Year 6 (5-12 years) were invited to participate in the study evaluation measures, which included a lunchbox observational assessment,

parent survey and student survey (Year 5 and 6 students). Students were provided with an information package outlining the study and a consent form. Parents were asked, via the consent form, if they were an active user (i.e. downloaded the app) of the school communication app. One week after the information package was distributed, parents who had not returned a consent form were telephoned by school-employed staff. A replacement consent form was distributed via mail to parents who provided verbal consent over the phone.

Randomization and blinding

Following baseline data collection, schools (cluster) were randomly allocated in a 1:1 ratio to the intervention or control group based on a random number function in Microsoft Excel. Randomisation was undertaken by a statistician not involved in contacting schools in the study intervention or assessment and stratified by the socioeconomic status of school locality using the Socio-Economic Index for Areas (SEIFA 2016), as socioeconomic status is associated with lunchbox contents and child diet [29,30]. Research personnel involved in data collection and lunchbox content analysis were blind to group allocation by removing all identifiable school information prior to data analysis. Data collection staff were not informed of group allocation however, this may have been disclosed to them by school staff during field activity. School personnel were notified of their group allocation via a phone call, due to the inability to conceal intervention delivery.

Multi-component Intervention

The multi-component intervention, based on the previous pilot, was co-developed by a multidisciplinary team comprising of academic and end-user stakeholders from government health agencies, educational systems, universities and technology partners and included

parent representatives with expertise in nutrition, school-based health interventions, behaviour change, implementation science and technology based interventions.

Conceptual Framework: The Behaviour Change Wheel (BCW) [31], was used to guide the development of the intervention. Extensive formative research encompassing a review of published literature, focus groups with parents to identify local contextual barriers, telephone interviews with parents (n=228) [32] and principals (n=196) [33] to assess barriers, acceptability of intervention strategies, content and delivery mode and a literature review of existing lunchbox interventions [20], were undertaken to select behaviour change techniques and strategies to support parents to pack healthy school lunchboxes. Supplementary Table 1 outlines the BCW mapping process and outlines the chosen Behaviour change techniques incorporated into the SWAP IT intervention.

Supplementary Table 1. Using the behaviour change wheel process to map barriers to packing healthy lunchboxes with identified intervention functions and suitable behaviour change techniques (BCTs)

Barrier Identified	**Description**	**Strategies / Intervention Components**	**Intervention functions**	**How (BCTs used)**
Child Preference	Packing what children like to (and will) eat.	Push notifications including images: - Fussy eating - Increasing vegetables - Involving children in packing the lunchbox	Education Persuasion	1.1 Goal setting (behaviour)? 3.1 Social support (unspecified) 4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences 7.1 Prompt/cue 8.2 Behaviour substitution 13.1 Identification of self as role model
		Website content: - Tips for fussy	Education Persuasion	4.1 Instruction on how to perform a behaviour

		eater - Swap options		5.1 Information about health consequences
		Video: - Kid's choice - Healthy Tastes Good	Modelling	6.1 Demonstration of the behaviour
		Stickers	Environment restructuring	7.1 Prompts/cues 12.1 Adding objects to the environment
		Parent brochure: - Ideas for fussy eaters	Education Persuasion	4.1 Instruction on how to perform the behaviour
		Classroom flipcharts	Education Persuasion	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour
Knowledge and skills	The knowledge and skills to purchase and prepare healthy foods.	Push notifications: - What a healthy lunchbox consists of - Benefits of healthy lunchboxes - Swaps in the lunchbox - Supermarket list	Education Persuasion	2.3 Self-monitoring of behaviour? 4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences 8.2 Behaviour substitution
		Website content: - Definition of everyday and sometimes - Swap options	Education Persuasion	4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences
		Video: - Monday to Friday	Modelling	6.1 Demonstration of the behaviour
		Parent brochure: - Lunchbox facts - What an everyday lunchbox is made up of - Swaps	Education Persuasion	4.1 Instruction on how to perform the behaviour 5.1 Information on health consequences
Cost	The cost of purchasing healthy food.	Push notification: - Healthy doesn't = expensive	Education Persuasion	1.4 Action planning? 4.1 Instruction on how to perform a behaviour 8.2 Behaviour substitution
		Website content: - Tips to save money	Education Persuasion	4.1 Instruction on how to perform the behaviour
		Video: - The cost of healthy living	Modelling	6.1 Demonstration of the behaviour
		Parent brochure: - Tips to save money	Education Persuasion	4.1 Instruction on how to perform the behaviour
Time	The time to prepare healthy	Push notification: - Quick everyday	Education Persuasion	4.1 Instruction on how to perform a behaviour

	foods. Looking for the convenience of a packaged product.	lunchboxes		8.2 Behaviour substitution
		Website content: - Tips to save time	Education Persuasion	4.1 Instruction on how to perform a behaviour
		Video: - Everyday foods quick and easy	Modelling	6.1 Demonstration of the behaviour
		Parent brochure: - Tips to save time	Education Persuasion	4.1 Instruction on how to perform the behaviour
Food Safety	Hesitation to pack refrigerated everyday foods (e.g. dairy) due to concerns that food will not be safe when consumed.	Push notification	Education Persuasion	4.1 Instruction on how to perform the behaviour
		Website content	Education Persuasion	4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences
		Parent brochure	Education Persuasion	4.1 Instruction on how to perform the behaviour
		Ice brick provision	Environment restructuring	7.1 Prompts/Cues 12. 1 Adding objects to the environment

Figure 2 provides an overview of the SWAP IT intervention logic. The SWAP IT intervention encouraged lunchbox 'swaps' from discretionary food items to Australian Dietary Guideline-based healthier alternatives known as 'everyday' foods. The multi-component lunchbox intervention consisted of four strategies outlined below. The m-health component included weekly pushed messages to parents delivered via an existing school mobile communication app, SkoolBag in addition to embedding lunchbox content within the app for parents to access. A detailed description of the intervention has been published in a protocol [25], and the strategies summarised below:

1. *Lunchbox nutrition guidelines:* Using a template developed by the project team, school principals developed, endorsed and disseminated nutrition guidelines to parents which were consistent with WHO and the NSW Department of Education Nutrition in Schools policy [34]. Guidelines were disseminated to parents in the first five weeks of the intervention via the SkoolBag app and school newsletters to demonstrate school's endorsement of the SWAP-IT program.
2. *Weekly pushed lunchbox messages:* Through the SkoolBag app, ten weekly electronic messages (push notifications) to support the packing of healthy lunchboxes were disseminated to parents/carers. Messages were co-developed by the research team, public health nutritionists, health promotion practitioners, teachers and parents and were optimised and refined via a study involving 511 parents [35]. The distribution of the messages via the school communication app was managed centrally by the project team whereby all parents at the schools allocated to the intervention group who had downloaded the app, received the pushed messages via the research team rather than relying on each individual schools to push the weekly content to parents. This centrally co-ordinated effort therefore did not require school time or resources

and thereby maximised the fidelity of the intervention. The pushed messages aligned to parent-reported barriers to packing healthy school lunchboxes: lack of time/ convenience, knowledge of suitable swaps, child preference, cost, food safety and lack of school nutrition policy. Where possible, a swap within the same food category was suggested (e.g. for packaged foods). The pushed messages were designed to act as prompts and cues to reinforce packing of 'everyday' foods. The messages were connected to embedded videos developed by the research team to align to parent reported barriers which provided tips and suggestions to assist parents to pack 'everyday' foods that were quick, convenient and low cost, and connect parents with tools and resources to improve their knowledge and skills to swap out discretionary foods and pack 'everyday' foods.

3. *Resources for parents:* Links embedded in the app messages connected parents with electronic resources housed on the program website. These resources provided information regarding health consequences, simple healthy lunchbox swaps that addressed child preference, cost, convenience and food safety. Physical resources including a SWAP IT ideas booklet (lunchbox ideas), clear drink bottle for water and an ice-brick to support food safety were also provided to parents and were distributed to students and parents via the school using their usual methods of dissemination.
4. *Curriculum resources for schools:* Schools were provided with a short online teacher professional learning module (10 minutes) developed by the research team which included public health nutritionists, health promotion practitioners and teachers outlining the rationale for the study and providing the skills and resources required to deliver the classroom curriculum lessons. Schools were also provided stage

appropriate curriculum resources which were co-developed by the research team with input from teachers, parents and education partners to align with syllabus outcomes that were developed by dietitians and teachers in order to reinforce healthy food preferences. This required teachers to deliver three curriculum lessons of ten minutes duration. Curriculum resources were designed to address the identified barrier to packing a healthy lunchbox of 'child preference for discretionary foods'.

Control schools

Schools allocated to the control group had access to the SkoolBag app but not the lunchbox intervention content. The SWAP IT website was freely accessible by the general public, including parents and schools, however schools and parents were not notified or directed to this site. There was no information (nutrition or otherwise) provided to the control group and they participated in data collection only and continued usual school business.

Data collection and measures

Lunchbox energy: The primary outcome was the mean energy (kJ) content of discretionary foods packed in the school lunchboxes by parents who were users of the school mobile application, assessed at baseline and six month follow-up. A detailed description of the study measures and data collection methods have been described in a published protocol [25]. Lunchbox energy content was assessed from photos of lunchboxes taken at school by trained research assistants prior to the first meal break, using a valid and reliable lunchbox observational audit, known as the School Food Checklist (SFC) [36,37]. The SFC is a previously validated tool shown to be accurate and reliable in measuring energy from food

and drinks for the Australian context. The SFC [36,37] enabled assessment of the kJ content and serving size for each lunchbox item. Two trained dietitians observed each school lunchbox photo and classified each food and drink item according to its SFC category as ‘everyday foods’ or ‘discretionary foods’ and assessed the kJ content and serving size for each lunchbox item and the serving size. It included 20 food and drink categories including main food items such as bread, fast food and leftovers/mixed dishes and snack items such as noodles, packaged snacks, biscuits and crackers, chocolate and lollies, cheese, eggs, dried fruit and nuts, muesli and fruit bars, cakes and buns, muffins and scones, pastries, desserts, yoghurt, fruit, vegetables, milk, soft drink, water and fruit juice. ‘Everyday’ items referred to food and drink items that were part of the core food groups as determined by the Australian Dietary Guidelines [23]. Food items classified as ‘discretionary’ were items considered to be energy dense with minimal nutritional value such as cakes, chocolate, lollies, crisps, muesli bars and fast food [23]. The serve size of each lunchbox item and kJ per serve information was obtained from FoodWorks Professional Edition V7 (version 7; Xyris Software, Highgate Hill, QLD, Australia). To further aid this process, decision rules developed in the previous study [16] were used to ensure standardisation of assessments.

The secondary outcomes associated with lunchbox energy were a) mean total energy (kJ) packed within the lunchbox; b) mean total energy (kJ) consumed from the lunchbox; c) mean energy (kJ) from discretionary foods and drinks consumed within the lunchbox; d) mean energy (kJ) from healthy foods packed and consumed from the lunchbox and e) percentage of lunchbox energy from discretionary and healthy foods and drinks, both packed and consumed. Data were collected at baseline and immediately post six month intervention using the SFC as outlined above. Following the analysis of the pre-meal lunchbox photo, dietitians analysed the post meal photo.

Student consumption of discretionary foods outside of school hours: Parents were asked to report via a short telephone survey, at baseline and follow-up, on their child's intake of discretionary foods outside of school hours and on weekends to identify any compensatory nutrition behaviour occurring out of school hours. Measures were taken from the NSW Schools Physical Activity and Nutrition Survey [38]. Parents reported on six categories of discretionary foods including: 1) fried potato products, 2) potato chips and other salty snacks, 3) sweet biscuits and cakes, 4) confectionary, 5) ice cream or ice blocks and 6) fruit juice and reported the frequency of consumption for consenting students at baseline and immediately post intervention at six months.

Procedures: To assess the foods as packed in the lunchbox (pre-meal assessment), on a randomly selected school day, prior to recess, lunch or in-class vegetable and fruit breaks [39,40], consenting students were asked to display the contents of their lunchbox on their desk in the classroom. Parents and students were not informed of the exact day of data collection. A pre-prepared paper grid was placed under the lunchbox contents and used to

assess scale and serving size of the items. Any foods not easily identified were discussed with the student and further details were recorded on the grid paper prior to being photographed. The photo was taken by trained research assistants prior to any foods being consumed. Students were asked if they intended to purchase food from the canteen that day, and if so removed from the analysis.

To assess consumption of foods packed in the lunchbox (post-meal assessment), on the same day students were asked to keep all unconsumed or partially consumed food items in their lunchboxes. Following all meal breaks, students were asked to place unconsumed or partially consumed items from their lunchbox onto the grid paper, and a second photograph of all remaining food was taken. Measures relating to consumption were based on the second photograph of the day being taken, after all meal breaks had occurred and all uneaten food was placed back into the lunchbox container. Consumption was calculated by subtracting the post-meal assessment from the pre-meal assessment.

Trained dietitians, blinded to group allocation, observed each school lunchbox photo in order to classify each food and drink item according to its SFC category and the serving size. All lunchbox photos were assessed by two dietitians working together to make a consensus decision on the analysis for each lunchbox. To further aid this process, decision rules were developed to ensure standardisation of assessments. Differences in opinion between dietitians were resolved following consultation with a third dietitian assessor. Following the analysis of the pre-meal lunchbox photo, dietitians then analysed the post-meal photo. Energy consumption was calculated by subtracting the energy content of foods and drinks remaining in student's lunchbox at the post-meal assessment from the energy content of

foods and drinks in the lunchbox during pre-meal assessment ("foods consumed").

Student school engagement: We also assessed impact on engagement as research suggests that improved nutrition correlates with greater school attendance, improved concentration and academic achievement [41]. At baseline and follow-up, students in Years 5 and 6 completed selected items from the validated School Engagement Measure (SEM) via a pen and paper survey . The SEM was a 19 item survey which provided a measure of students' behavioural (5 items), emotional (6 items) and cognitive engagement (8 items) at school, outcomes considered important for achieving positive academic outcomes [42].

Student consumption of discretionary foods outside of school hours: To ensure any reduction in energy intake occurring while at school did not result in compensatory intake outside of school hours (potential adverse event), parents were asked to report via a short telephone survey, at baseline and follow-up, on their eldest eligible child's intake of discretionary foods outside of school hours and on weekends. Measures were taken from the NSW Schools Physical Activity and Nutrition Survey [38]. Parents reported on six categories of discretionary foods including: 1) fried potato products, 2) potato chips and other salty snacks, 3) sweet biscuits and cakes, 4) confectionary, 5) ice cream or ice blocks and 6) fruit juice and reported the frequency of consumption including never or rarely, one to two times per week, three to four times per week, five to six times per week, once per day or two or more times per day.

Lunchbox cost: It has been hypothesized that one potential adverse effect of encouraging healthier lunchbox swaps is increased family financial burden due to the potential higher

cost of healthier products [43]. To assess this, the mean cost of lunchbox items pre and post intervention were assessed via the SFC and were compared between intervention and control groups at baseline and follow-up to determine if the intervention resulted in any adverse financial effects for families. Costing was determined using an average of prices from food within the category accessed from local retail audit of similar foods determined in October 2018.

Statistical analysis

Analyses were conducted using SAS, version 9.3, from January-June 2020. School and student characteristics were summarised for intervention and control schools. Summary statistics were used to describe all variables of interest. Students that resided in post-codes ranked in the top 50% of state post-codes based on the 2016 Socio-Economic Indexes for Australia (SEIFA) [30] were categorized as 'higher socio-economic areas', whereas those in the lower 50% were categorized as 'lower socio-economic areas'. Students' postcodes were also used to categorize their locality as either 'rural' (those schools in outer regional, remote and very remote areas) or 'urban' (those in regional or major cities) based upon the 2016 Accessibility/Remoteness Index of Australia [44].

The differences between groups in the primary and secondary outcomes were assessed using hierarchical linear (or logistic for binary outcomes) regression models. Models were adjusted for SEIFA, remoteness and baseline values and a random level intercept for school was included to adjust for the clustered design of the study. Analysis followed intention to treat principles, where schools and students were analysed according to their randomised treatment allocation. All statistical tests were two-tailed with an alpha of 0.05. As specified

in the study protocol [25], data were analysed only for students whose parents had reported downloading the required SkoolBag app to ensure exposure to the intervention and students intending to purchase food or drinks from the canteen, or did not bring lunch were removed from the primary analysis to focus on students whose lunchbox was their source of energy for the day [16].

Sample size and power

Based on our pilot results [16], a standard lunchbox contained 1089kJ (SD=900kJ) from discretionary foods. With an ICC of 0.05, 32 schools with 140 students per school enabled detection of a 200kJ difference between groups at follow-up on the primary trial outcome, with 80% power at the 0.05 significance level. As approximately 420kJ across a whole day has potential to reduce the prevalence of childhood obesity [45,46], and it is recommended a child consumes a third of their daily energy requirements whilst at school [9], this magnitude of effect was considered meaningful at a population level.

Results

Sample

A sample of 94 schools were assessed for eligibility to participate in the study, and 91 were approached in order to obtain the quota of 32 consenting schools (35.2%). Consenting and non-consenting schools were similar in geographic location, size and school socioeconomic status, with the 32 consenting schools enrolling a total of 7212 students (or 5048 families). Of these, 3022 provided parental consent to participate in the lunchbox observation to evaluate the outcomes of the study (41.2%). Of the 3022 consenting students, 2730 (1395 intervention, 1335 control) lunchboxes were observed at baseline and 2346 (1215

intervention, 1131 control) at follow-up, due to student absences and school events or excursions. Table 1 outlines the school and student characteristics of those consenting to participate. At baseline, the consenting schools and students allocated to the intervention and control groups were similar in characteristics however the intervention group had a higher proportion of schools located in disadvantaged areas.

Table 1. Sample characteristics of schools and students at baseline

School characteristics	**Intervention**	**Control**
Number of schools	16	16
Location		6 (37.5%)
• Urban	8 (50.0%)	10 (62.5%)
• Rural	8 (50.0%)	
School SES		
• Most disadvantaged	13 (81.2%)	13 (81.2%)
• Least disadvantaged	3 (18.8%)	3 (18.8%)
Number of schools greater that 10% Aboriginal or Torres Strait Islander student enrolments	10	11
Student Characteristics	**Intervention n (%)**	**Control n (%)**
Total students	**1216**	**1176**
Sex		
• Female	592 (50.04%)	550 (48.37%)
• Male	591 (49.96%)	587 (51.63%)
Sex missing = 72		
Mean age (years)	7.88	7.68
Socioeconomic status of student		
• Most disadvantaged	938 (77.14%)	789 (67.09%)
• Least disadvantaged	278 (22.86%)	387 (32.91%)

Socioeconomic status (SES) based on SEIFA Index of relative socio-economic disadvantage 2016. Most disadvantaged = lowest quartiles of SEIFA; Least disadvantaged = highest quartiles of SEIFA; SD, standard deviation;

*Primary outcome - Mean energy (kJ) content of discretionary foods **packed** from the school lunchboxes*

At six months follow-up, the difference between the intervention and control group in the

mean energy (kJ) content of discretionary foods ***packed*** in school lunchboxes was -117.71kJ (CI=-195.59, -39.83; *P*=<.01). A sensitivity analysis on the primary outcome using complete cases indicates a similar result -120.43kJ (CI=-200.82, -40.04; *P*<.01).

Secondary lunchbox energy outcomes

The mean total energy (kJ) packed in lunchboxes (-88.38kJ; CI=-172.84, -3.92; *P*=.04) and mean total energy (kJ) consumed from lunchboxes (-117.17kJ; CI= -233.72, -0.62; *P*=.05) both reduced in favour of the intervention group. There was also a significant reduction in percentage of lunchbox energy packed from discretionary foods between groups (-3.16%; CI=-5.46, -0.86; *P*=.01) whilst the percentage of lunchbox energy from everyday foods increased (3.16%; CI=0.86, 5.46; *P*=0.01). A significant reduction favouring the intervention group in the mean energy (kJ) from discretionary foods consumed from lunchboxes (-96.31kJ; CI=-194.63, 2.01; *P*=.05) was also observed. There was no statistical difference between groups in the mean lunchbox energy from everyday foods (kJ) packed in lunchboxes (32.85kJ; CI=-31.61, 97.31; *P*=.31) or consumed (-21.91kJ; CI=-112.38, 68.56; *P*=.62). Table 2 outlines the lunchbox energy packed and consumed by group. Supplementary Table 2. outlines the food and drink items packed in lunchboxes.

Supplementary Table 2. Food and drink items packed in lunchboxes.

SFC food or drink category	n (% of lunchboxes item)
Main	
- Bread*	1947 (81.40)
- Leftovers/mixed dishes*	109 (4.56)
- Fast food	66 (2.76)
Snacks	
- Fruit*	1992 (83.28)
- Muesli and/or fruit bars	1483 (62.00)
- Savoury biscuits	586 (24.50)

- Chocolate biscuits	520 (21.74)
- Vegetables*	485 (20.28)
- Crisps	463 (19.36)
- Extruded snacks	429 (17.93)
- Cheese, eggs, dried fruit, nuts*	373 (15.59)
- Yoghurt*	354 (14.80)
- Sweet biscuits	329 (13.75)
- Dips*	327 (13.67)
- Chocolates and lollies	295 (12.33)
- Rice or water crackers*	293 (12.25)
- Cakes	259 (10.83)
- Popcorn*	205 (8.57)
- Rice cakes/corn thin*	166 (6.94)
- Muffins	152 (6.35)
- Noodles	103 (4.31)
- Crispbreads*	87 (3.64)
- Pretzels	75 (3.14)
- Slices	67 (2.80)
- Processed meat	62 (2.59)
- ‘Everyday’ buns*	44 (1.84)
- Fruit jelly	31 (1.30)
- Leftovers/mixed dishes as a snack*	31 (1.30)
- Dairy dessert	30 (1.25)
- Butter popcorn	29 (1.21)
- Bread*	24 (1.00)
- Fast food snacks	23 (0.96)
- Pikelets*	22 (0.92)
- Donut	20 (0.84)
- Custards*	16 (0.67)
- Sometimes miscellaneous	16 (0.67)
- Sometimes buns	13 (0.54)
- Sauce	13 (0.54)
- Tuna*	13 (0.54)
- Refined cereals	12 (0.50)
- Baked beans or legumes*	11 (0.46)
- Pastries	11 (0.46)
- Cheese and bacon roll	10 (0.42)
- Wholegrain cereals*	6 (0.25)
- Scone*	3 (0.13)
Drinks	
- Water*	1483 (83.28)
- Juice or cordial	230 (9.62)
- Fortified milk drink (e.g. breakfast drinks)*	31 (1.30)
- Milk (full fat, reduced fat, flavoured)*	25 (1.05)
- Soft drink	2 (0.08)

* Items classified as an ‘everyday’ food or drink

Table 2. Mean energy and percentage of energy from everyday and discretionary foods packed and consumed from student lunchboxes

Outcome	Intervention		Control		Mean difference in energy (kJ) between groups at follow up Mean (CI)	*P* value
	Baseline Mean (SD) (n=1216)	Follow-up Mean (SD) (n=946)	Baseline Mean (SD) (n=1176)	Follow-up Mean (SD) (n=886)		
Mean daily energy (kJ) packed in student lunchboxes						
Primary outcome: Mean lunchbox energy (kJ) from discretionary foods ***packed*** in lunchboxes	1214.86 (876.49)	1156.77 (841.76)	1067.38 (898.82)	1105.06 (859.06)	-117.26 [-195.59; -39.83]	**<.01**
Mean lunchbox energy from everyday foods (kJ) ***packed*** in lunchboxes	1616.19 (628.34)	1610.93 (624.41)	1644.17 (621.73)	1605.81 (610.02)	32.85 [-31.61; 97.31]	.31
Mean total lunchbox energy (kJ) ***packed*** in lunchboxes	2831.05 (927.81)	2767.70 (873.52)	2711.54 (962.33)	2710.87 (878.44)	-88.38 [-172.84; -3.92]	**.04**
Mean daily lunchbox energy (kJ) consumed by students						
Mean lunchbox energy (kJ) from discretionary foods ***consumed*** from lunchboxes	901.30 (745.60)	876.70 (717.23)	744.19 (717.20)	802.75 (677.23)	-96.31 [-194.63; 2.01]	**.05**
Mean lunchbox energy from everyday foods (kJ) ***consumed*** from lunchboxes	1270.85 (631.79)	1282.56 (622.95)	1304.69 (600.58)	1341.72 (607.53)	-21.91 [-112.38; 68.56]	.62
Mean total lunchbox energy (kJ) ***consumed*** from lunchboxes	2172.15 (895.82)	2159.26 (810.78)	2048.88 (853.84)	2144.48 (743.22)	-117.17 [-233.72; -0.62]	**.05**
Percentage of lunchbox energy coming from discretionary and everyday foods						

Percentage of ***packed*** lunchbox energy from discretionary foods	40.10 (SD=23.31)	39.04 (SD=23.94)	35.84 (SD=23.69)	37.90 (SD=23.81)	-3.16 [-5.46 ; -0.86]	**.01**
Percentage of ***packed*** lunchbox energy from everyday foods	59.90 (SD=23.31)	60.96 (SD=23.94)	64.16 (SD=23.69)	62.10 (SD=23.81)	3.16 [0.86 ; 5.46]	**.01**
Total cost of lunchbox items	3.94 (1.35)	3.91 (1.36)	3.78 (1.38)	3.78 (1.32)	-0.06 [-0.18 ; 0.07]	.37

Student engagement: Table 3 outlines the student engagement measures. There were no observed differences between groups for any measure of student engagement after the six month intervention including student's total school engagement measure score (-0.08; CI=-0.18, 0.02; *P*=.1), student behaviour (-0.05; CI=-0.15, 0.04; *P*=.24), emotional (-0.08; CI=-0.2, 0.06; *P*=.26) or cognitive engagement (0.09; CI=-0.22, 0.05; *P*=.20).

Table 3. Mean School Engagement measure by group at baseline and follow-up

Mean School Engagement Score	Intervention		Control		Mean difference in engagement between groups at follow up Mean (CI)	*P* value
	Baseline Mean (SD) (n=364)	Follow-up Mean (SD) (n=309)	Baseline Mean (SD) (n=299)	Follow-up Mean (SD) (n=241)		
Behaviour Score (mean)	4.12 (SD=0.59)	4.09 (SD=0.62)	4.11 (SD=0.65)	4.14 (SD=0.66)	-0.05 (-0.15 ; 0.04)	.24
Emotion score (mean)	3.55 (SD=0.91)	3.33 (SD=0.99)	3.56 (SD=0.92)	3.40 (SD=0.98)	-0.08 (-0.22 ; 0.06)	.26
Cognitive score (mean)	2.92 (SD=0.87)	2.80 (SD=0.87)	2.87 (SD=0.83)	2.83 (SD=0.85)	-0.09 (-0.22 ; 0.05)	.20
Total school	3.44	3.31	3.42	3.35	-0.08	.10

engagement	(SD=0.66)	(SD=0.71)	(SD=0.68)	(SD=0.70)	(-0.18 ; 0.02)	

Student consumption of discretionary foods outside of school hours: There were no differences between groups in the foods consumed outside of school hours indicating no compensatory consumption of discretionary foods outside of care.

Lunchbox cost: The total cost of lunchbox foods following the intervention did not differ between groups (-$0.06AUD; CI=-0.18, 0.07; *P*=0.37). See Table 2.

Discussion

This trial investigated the effectiveness of the SWAP IT intervention, which incorporated the use of an existing school communication app directly to parents, on the energy of students' lunchbox foods, both packed and consumed. Relative to lunchboxes in the control group, the lunchboxes in the intervention group contained significantly less mean energy from discretionary foods corresponding to 117kJ per day, or a 600kJ reduction over a school week. The SWAP IT intervention also resulted in a reduction in mean energy from discretionary foods that were consumed by students (96.31kJ). The mean total lunchbox energy both packed and consumed was also significantly less in intervention lunchboxes, and the percentage of energy from discretionary foods reduced by 3.16% whilst percentage energy from everyday foods correspondingly increased. The lunchbox energy coming from everyday foods consistent with dietary guidelines did not statistically differ between groups, indicating the change in total energy observed was primarily from a reduction in discretionary foods. These favourable nutrition outcomes occurred whilst the cost of packing a lunchbox remained stable across groups, indicating the changes made to lunchboxes did not result in

additional costs. The intervention however, did not result in changes to student school engagement at school.

Although challenging to make direct comparisons, the magnitude of reduction in energy from discretionary foods appears favourable compared to previous lunchbox interventions. Of the ten included studies within a systematic review of lunchbox interventions conducted within the school and childcare environment [20], four targeted the packing of discretionary foods, with evidence for the effectiveness of interventions on what is packed in lunchboxes in relation to discretionary foods, sugar-sweetened drinks or other core foods being equivocal. Of the two studies conducted in the school environment, results were mixed, impacting on either high fat salty snacks (reduction of 2.8gm of savour snacks, p=0.04) or sweet confectionary, fruit drinks or candy (-0.43 serves, p=<0.01), but not both [20]. Furthermore, only one study within this review used a similar methodology of assessment based on lunchbox photography and observation to estimate serve size.[2] This study found no significant effect, posing this may be due to lack of power, and/or a complex information dissemination pathway of their intervention by sending messages to parents via newsletters and lessons delivered to children. To target behaviour change, our research team conducted extensive formative assessment including mapping barriers, and consulted with key stakeholders to co-design SWAP IT using a theoretical framework. The multi-component program also dually targeted both the school and parents sending messages directly to parents, which may explain the favourable intervention effect.

To improve health at a population level, interventions shown to be effective under research conditions need to be scaled-up to reach a large proportion of the population [47]. Few

school-based behavioural interventions have been suggested to be suitable for large scale dissemination as they require expertise and resources not readily available within schools, and often utilise high intensity delivery modes such as face to face training [20]. The use of digital delivery modes overcome many of these barriers, however poor adoption and ongoing engagement with new apps or websites for example, is often an impediment to population level reach, and improved health gains [48]. To address this, the SWAP IT intervention adopted a multi-component intervention design that addressed many of the existing limitations [20]. Incorporating the SWAP IT behavioural intervention components into and to complement an existing school communication app, already adopted by schools and downloaded by parents, was undertaken to overcome the challenges of both population level reach and digital engagement. Such an approach has also been utilised within another nutrition intervention embedded into an existing online school canteen ordering system, which similarly resulted in a significant intervention effect on energy, sugar and fat [49]. This suggests that embedding digital interventions within existing systems, supported by additional behaviour change strategies may be superior to developing and implementing new digital health interventions alone.

Whilst a reduction in energy from discretionary foods of 600kJ per week may appear small at an individual level, at a population level it has the potential to impact on population risk of overweight and obesity, result in a gain of health adjusted life years (HALYs) and make a significant contribution towards savings in health care costs [50]. Given the potential reach of this intervention, with 86% of students taking a packed lunch on a daily basis, 90% of those students packing at least 1 serve of discretionary food in their lunchbox, such an intervention has the potential to immensely shift the consumption of discretionary foods.

Further, as 60% to 70% [51] of schools in NSW Australia and the United States respectively already using school communication apps, interventions such as SWAP IT have the potential to reach millions of parents on a daily basis. Further investigation evaluating the cost effectiveness and implementation process of the SWAP IT intervention are needed to confirm if the SWAP IT intervention warrants large scale dissemination. Future research should focus on developing strategies that maximise the adoption or uptake of the SWAP IT intervention by schools at scale, and methods for sustaining school engagement in order to continue to impact on parent behaviour change.

The results of this trial should be interpreted within the context of its strengths and limitations. Study strengths include the experimental hybrid design, with randomised controlled trials considered gold standard for evaluating causal effects of interventions. The SWAP IT trial was also developed using behaviour change theory and utilised direct observation and validated tools to assess lunchbox contents strengthening the ability of the study to accurately measure the true impact of the study outcomes. Whilst the effect size of the SWAP IT effectiveness trial was smaller than the previous pilot [16], the significant results were replicated indicating that pending further evaluation exploring the implementation outcomes and cost effectiveness, the intervention warrants consideration for large scale dissemination. However, a number of limitations should be considered. The trial had a lower than anticipated participation and consent rate from schools and particularly parents, with only 41% of parents consenting to participate in the lunchbox observations. Upon enquiry, we believe this is primarily due to the measurement component, whereby lunchbox observations may be considered to encroach privacy [52], given acceptability of the intervention for schools and parents was high at 84% [16]. The

intervention was also multi-component, and isolating the impact of individual strategies was not possible in this trial. Whilst large scale dissemination of the electronic pushed message via the app to parents is feasible with high fidelity, implementation of the school level strategies may require additional support. This trial had a follow up period of six months, and, long term sustainability of the intervention, by both school and parents is unknown. Ongoing investigation is warranted to ensure the intervention has an ongoing desirable impact on lunchbox behaviour.

Conclusion

The SWAP IT intervention presents an effective digital behaviour change solution to a large and long standing public health problem of high consumption of discretionary foods by children while at school. Given the significant impact on lunchbox food energy that has been demonstrated by the previous pilot trial and replicated in this effectiveness trial at a larger scale, the intervention provides an attractive option to policy makers to complement existing public health programs targeting the school nutrition environment. Following further evaluation to determine its implementation process outcomes and cost effectiveness, models to further scale up and maximise the adoption of SWAP IT will ensure a public health benefit can be realised.

Declarations

Ethics approval and consent to participate

Approval to conduct this study was obtained from Hunter New England Human Research Ethics Committee (Ref. No. 06/07/26/4.04), University of Newcastle (Ref. No. H-2008-0343), and the NSW Department of Education SERAP (2018247) and was prospectively registered

with Australian New Zealand Clinical Trials Register 12618001731280. Written informed consent was obtained from all parents of students.

Consent for publication

Not applicable

Availability of data and materials

The datasets analysed during the study will be available from the corresponding author on reasonable request, following study completion. All data has been stored securely as per ethical requirements. All participants were issued a unique identification number following consent for confidentiality. The final trial dataset is stored securely and accessed only by the study statistician. Further results of this trial will be disseminated via publication in peer reviewed journal, conference presentations and reports to schools and relevant health and education departments.

Competing interests

Authors RS, NN, LW, KG, NE, and JW receive salary support from their respective Local Health Districts. Hunter New England Local Health District contributes funding to the project outlined in this protocol. None of these agencies were involved in the peer review of this grant. RS and NN are Associate Editors for BMC Public Health. All other authors declare that they have no competing interests.

Funding

This project was funded by the NSW Ministry of Health, Translational Research Grant Scheme. The NSW Ministry of Health has not had any role in the design, data collection,

analysis of data, interpretation of data and dissemination of the study. The project also received infrastructure support from the Hunter Medical Research Institute (HMRI). RS is supported by an NHMRC TRIP Fellowship (APP1150661) and a Hunter New England Clinical Research Fellowship; LW is supported by a NHMRC Career Development Fellowship (APP1128348) and Heart Foundation Future Leader Fellowship; SY is by a DECRA fellowship.

Authors' contributions

RS and AB led the development of this manuscript. RS, NN, SY, LJ and LW conceived the intervention concept. RS, LW secured funding for the study. RS, NN, LW guided the design and piloting of the intervention. RS, AB, LW, NN, LJ, JW guided the evaluation design and data collection. CO developed the analysis plan. RS, AB, NN, LJ, JW, NK, NE, CO, AS, PR, CR, BS, MD, KR, BC, KG, TM, LW are all members of the Advisory Group that oversee the program and monitor data. RR, AW, NH, AB, LJ and AC are all members of the project team that oversee the implementation and evaluation of the program. All authors contributed to developing the protocols and reviewing, editing, and approving the final version of the paper.

Acknowledgements

The authors wish to acknowledge the research assistants involved and the schools participating in this study.

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Abbreviations

ACAES Australian Child and Adolescent Eating Survey

BCW Behaviour Change Wheel

CC Central Coast

HNE Hunter New England

kJ Kilojoules

LHD Local Health District

MNC Mid North Coast

NSW New South Wales

RCT Randomised Controlled Trial

SFC School Food Checklist

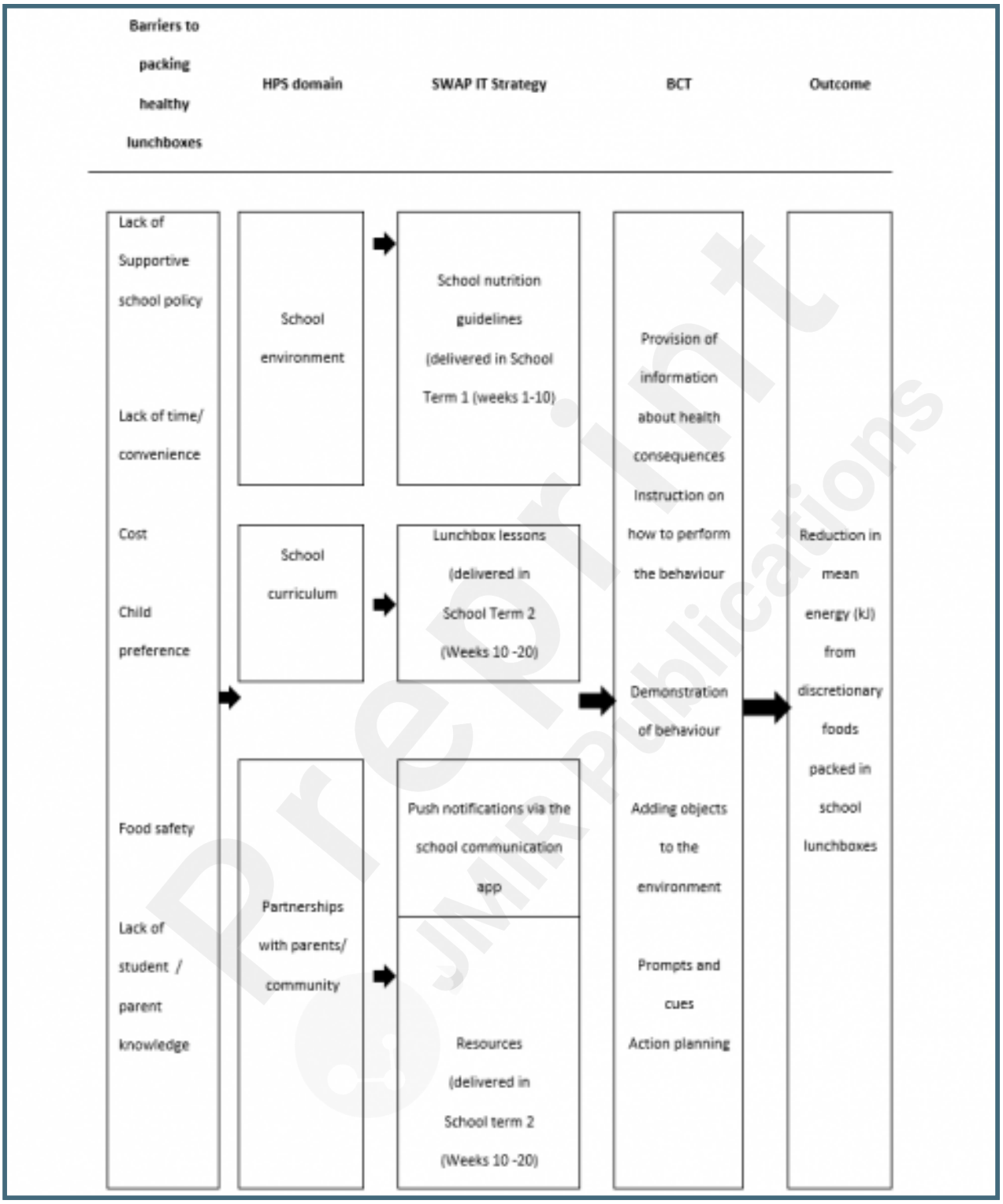
SEIFA Socio-Economic Index for Areas

Supplementary Files

Tracked version of revised manuscript.
URL: https://asset.jmir.pub/assets/d1060dc5cfced97971d9f05fab7b8e32.docx

Figures

SWAP IT logic model.



Consort flow diagram.