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A CLUSTER RANDOMISED CONTROLLED TRIAL OF AN ONLINE INTERVENTION TO IMPROVE HEALTHY FOOD PURCHASES FROM PRIMARY SCHOOL CANTEENS: A STUDY PROTOCOL OF THE 'CLICK & CRUNCH' TRIAL

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PUBLIC TITLE: CLICK & CRUNCH: AN ONLINE INTERVENTION TO IMPROVE HEALTHY FOOD PURCHASES FROM PRIMARY SCHOOL CANTEENS

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ABSTRACT

Introduction

School canteens are the most frequently accessed take-away food outlet by Australian children. The rapid development of online lunch ordering systems from school canteens presents new opportunities to deliver novel public health nutrition interventions to school-aged children. This study aims to assess the effectiveness and cost-effectiveness of a behavioural intervention in reducing the energy, saturated fat, sugar and sodium content of online canteen lunch orders for primary school children.

Methods and analysis

The study will employ a cluster randomised controlled trial design. Twenty-six primary schools in New South Wales, Australia, that have an existing online canteen ordering system will be randomised to receive either a multi-strategy behavioural intervention or a control (the standard online canteen ordering system). The intervention will be integrated into the existing online canteen system and will seek to encourage the purchase of healthier food and drinks for school lunch orders (i.e. items lower in energy, saturated fat, sugar, and sodium). The behavioural intervention will use evidence-based choice architecture strategies to redesign the online menu and ordering system including: menu labelling, placement, prompting, and provision of feedback and incentives. The primary trial outcomes will be the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of lunch orders placed via the online system, and will be assessed 9 months after baseline data collection.

Ethics and dissemination

The study was approved by the ethics committees of the University of Newcastle (H-2017-0402) and the New South Wales Department of Education and Communities (SERAP 2018065), and the Catholic Education Office Dioceses of Sydney, Parramatta, Lismore, Maitland-Newcastle, Bathurst, Canberra-Goulburn, Wollongong, Wagga Wagga and Wilcannia-Forbes. Study results will be disseminated through peer-reviewed publications, reports, presentations at relevant national and international conferences and via briefings to key stakeholders. Results will be used to inform future implementation of public health nutrition interventions through school canteens, and may be transferrable to other food settings or online systems for ordering food.

Registration details

This trial was prospectively registered with the Australian and New Zealand Clinical Trials Register on 22/5/18 (ACTRN12618000855224).

Strengths and limitations of this study

- This study will use a cluster randomised controlled trial design, a rigorous research design for

assessing intervention effectiveness.

- The evidence-based choice architecture intervention is embedded within an existing online canteen ordering system that is used by over 1,200 schools across Australia, and processes over 13 million lunch orders per year.
- The cost and cost-effectiveness of the intervention will be determined from a societal perspective giving transparency to the cost of implementation, providing policy makers with critical data to inform decision-making.
- Actual food consumption will not be assessed; purchase data will serve as a proxy for food consumption.

Key Words

Intervention, RCT, Nutrition, Obesity, Primary School, Canteen

INTRODUCTION

Dietary risk factors are a leading cause of death and disability internationally.[1] Given dietary behaviours in childhood track into adulthood and are predictive of future chronic disease,[2] improving child nutrition is a health priority in Australia and internationally.[3,4] Schools provide an important setting for promoting healthy food consumption to children as they provide centralised access to almost every Australian child for prolonged periods, with children consuming almost 40% of their recommended energy intake while at school.[5] Schools also represent a significant food provider. In New South Wales (NSW), 95% of primary-aged children attend a school with a canteen[6] and 55% of students order their lunch from the canteen at least weekly, compared with 23% of students that eat a meal or snack from a fast-food outlet each week.[6] The most frequently purchased menu items from canteens are often high in fat, sugar and salt[7] with canteen purchases contributing an additional 200kJ to energy consumed at school, compared to foods brought from home.[5]

While previous attempts to improve the school food environment have focused on changing the relative availability of unhealthy foods for sale at school,[8–12] modifying other drivers of consumer behaviour represents an additional opportunity to improve children's diet. For example, previous research has demonstrated that point-of-purchase interventions that involve nutrition labelling[13]; manipulating the placement of menu items[14]; and the provision of purchasing prompts[15]; nutritional feedback[16] and incentives[17], can influence the purchase of foods and drinks among children and adults. Despite the potential of behavioural strategies to encourage healthy purchasing, national and international studies of (non-online) canteens and cafeterias indicate that such strategies are under-utilised in schools. The United States (U.S.) School Health Policies and Practices Study of 544 elementary schools found few school cafeterias used strategies such as provision of nutritional feedback (60%) or item placement (10-26%), or incentives (16-17%) to encourage healthy purchasing.[18] Furthermore, an Australian study of 203 primary schools found that only 43% reported labelling their canteen menus to identify healthy options.[19]

Canteen online ordering systems allow users to view, select and purchase food and drink menu items online, and represent a new approach for children to access food at school. They are becoming increasingly popular in Australia,[20] with the leading supplier servicing over 1,200 schools nationally and processing over 13 million lunch orders per year.[21] These systems represent an attractive opportunity to apply a range of behavioural strategies that can reach large numbers of individuals at relatively low cost.[22] Strategies including menu or product labelling, product placement, and the provision of prompts and incentives are routinely used to influence purchase decisions by food retailers online.[23] Furthermore, given these systems are centrally administrated, interventions delivered via these means may be more resistant to the transient nature of local canteen staffing, a common barrier to sustainable implementation of nutrition guidelines and interventions

in this setting[24].

We recently conducted a pilot trial that evaluated the use of strategies including traffic light menu-labelling, prominent placement of healthy menu items, provision of prompts to select healthy menu items, and reduced accessibility of less healthy items[25] integrated into an online school canteen ordering system. The trial was undertaken in ten NSW primary schools over a 2-month intervention period and found that, compared to controls, intervention lunch orders were significantly lower in energy (-567kJ), saturated fat (-2.37g), and sodium (-228mg) (all $p<0.001$).[26] Given these promising findings, a larger trial is proposed and described in this protocol, which tests a greater range of intervention strategies, using a larger study sample and longer period of follow-up.

STUDY AIM

The aim of the study is to assess the effectiveness and cost-effectiveness of an online multi-strategy behavioural intervention in reducing the energy, saturated fat, sugar and sodium content of primary school students' online canteen lunch orders.

METHODS AND ANALYSIS

Study design and setting

The study will be conducted in Government, Independent and Catholic schools in NSW, Australia, and will use a cluster randomised controlled trial design. Schools that currently use the 'Flexischools' online canteen ordering system will be randomised to either an intervention or usual practice control group. Intervention effectiveness will be assessed by comparing between-group differences at follow-up in the mean i) energy (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium (milligrams) contained in students' online lunch orders, based on purchasing data that is automatically collected by the online canteen system. Both baseline and follow-up assessment periods will be conducted over one school term, of approximately 10 weeks' duration, one calendar year apart.

Participants and recruitment

Schools: All NSW primary schools currently using the 'Flexischools' online canteen system[27] will serve as the sampling frame (n=481). A list of all such schools has been supplied by the provider of the online canteen ordering system (here-after referred to as the 'provider') servicing over 1,200 schools across Australia.[21] One member of the research team will act as the recruitment coordinator and will manage recruitment and consent into the trial. Study information and consent forms will be mailed to the school principal and canteen manager at all potentially eligible schools from the sampling frame. Approximately one to two weeks later,

the recruitment coordinator will make a follow-up phone call to speak with the school principal and/or canteen manager about the research and confirm school eligibility using procedures previously undertaken by the research team. Principal consent will be required to enable school participation in the trial and to enable the researchers to access the school's canteen purchasing data from the provider. Principals will retain the right to discontinue their participation in the study and withdraw the school from the trial at any point.

School eligibility criteria: Given canteen guidelines differ from state to state and between primary and secondary schools, only NSW primary schools (serviced by the provider) will be included in the study. Schools will be approached via mail and telephone to participate. Schools that can be identified (i.e. from a published list or where reliable data can be sourced about their operation) as having an externally licensed commercial canteen operator will be removed from the sample due to the potential for contamination between schools. Schools that enrol both primary (Kindergarten to Grade 6) and secondary (Grade 7 to 12) school students will only be included where there is a separate canteen menu for primary school students, due to differences in the NSW canteen guidelines for primary versus secondary schools.

Users: Users of the online canteen system could be students or parents/carers who place orders on behalf of their children. Schools that use an online canteen system can also choose to retain the traditional method for placing lunch orders (i.e. writing the lunch order on a paper bag and submitting directly to the canteen) in addition to offering online ordering. To submit an online order, users access the provider's website from their mobile device or computer. They then select the day and meal for which they want to make place an order (e.g. Tuesday, lunchtime), and they are then shown the full list of food and drink menu items that are available for that meal. To order, users click on menu items and then pay via a credit or debit card or PayPal. Data supplied from the provider suggests that on average, 30-40% of students in schools they service have an account set up to enable online canteen ordering and have ordered within the last 30 days.

User eligibility criteria: Students who have an online lunch order submitted during the baseline data collection period are eligible for inclusion in the trial. As the follow-up data collection period occurs in the subsequent school year, only students in Kindergarten to Grade 5 (ages 5-11) will be included at baseline, in order to ensure they are available for follow-up. Given not all schools offer online ordering for recess foods, recess purchases will not be included in the analysis. Furthermore, only lunch orders submitted via mobile devices (approximately 70%) will be included in the analysis as the desktop version is due to be phased out by the provider. As such orders submitted via the desktop website, or orders submitted at the canteen will not be included in the analysis.

Randomisation and blinding

Following school recruitment and baseline data collection, schools will be randomised by an independent statistician using a randomised number function in Microsoft Excel in a 1:1 ratio to either an intervention or control group (see Figure 1). Block randomisation will be employed to ensure group allocation is approximately equal, with block size randomly varying between 2 and 4. Given evidence that there are differences in the implementation of canteen guidelines between more and less advantaged areas and between Government and non-Government school sectors,[28] the randomisation procedure will be stratified by the socioeconomic status of a school locality (based on postcode and dichotomised into most vs least advantaged), and by school sector (Government vs Catholic vs Independent). Following random allocation to either intervention or control group, the online strategies will be applied to the canteen menus of each intervention school by accessing the canteen manager portal within the online canteen system. A research assistant will perform a quality check on the live website to ensure all strategies have been correctly applied. Due to the difficulty in blinding users to the changes introduced as part of the intervention, the study will be conducted as an open trial. However, the dietitians conducting the menu assessment will be blind to group allocation via the removal of all identifiable information from menus prior to assessment.

INSERT FIGURE 1 HERE

Intervention

A multi-strategy behavioural intervention will be integrated into the existing online canteen system[27] of intervention schools as described below. The intervention seeks to encourage the purchase of healthier foods and drinks for school canteen lunch orders, that is, items lower in energy, saturated fat, sugar, and/or sodium, consistent with the NSW Healthy School Canteen Strategy. The intervention will be operational across the entire study period until the end of follow-up data collection (9 months post baseline). Research assistants will be responsible for managing the delivery of the online strategy to the intervention group, liaising with schools and communicating any necessary changes throughout the study. All users of the online canteen ordering system at intervention schools will be exposed to the intervention. Controlled access to the intervention strategies by the provider will prevent potential intervention contamination between groups.

Intervention conceptual framework

The intervention is based on the principles of choice architecture, which suggests that behaviour can be influenced by the environment in which choices are made,[29] with choice architecture interventions typically altering micro-environments (e.g. online applications / 'apps') in order to cue healthier choices.[30] The intervention for this trial was guided by the choice architecture typology proposed by Hollands and colleagues.[29] Strategies that performed well against the following criteria were included in the intervention:

i) strategies that were supported by evidence of effectiveness from food-service settings (including the pilot trial[26]); ii) strategies that were considered effective and acceptable in surveys of school stakeholders including principals and parents[31,32]; iii) strategies that were able to be feasibly operationalised in an online environment; and vi) strategies that were amenable to implementation at scale (i.e. low cost and high reach). Furthermore, given research suggests that parents are involved in 68% of fast food purchase decisions for their children,[33] a strategy was deliberately included that targeted child users of the system (incentives).

Intervention strategies

The strategies that form the intervention have all been shown to support healthier choices in food-service settings.[13–17,34] The choice architecture strategies from the pilot trial will be retained[25] and additional strategies, including provision of feedback and incentives will be added. Based on feedback from the pilot trial, availability (menu composition) and pricing strategies will be included to support the canteen manager to apply the NSW Healthy School Canteen Strategy and to allay any concerns that implementing the intervention will undermine canteen revenue. These strategies will be delivered via a tailored feedback report that will be sent to both the canteen manager and school principal and discussed in a brief feedback call from the research assistant with the canteen manager. The written and verbal feedback will be provided at one time point, immediately prior to the application of the choice architecture strategies within the online canteen system.

Availability of healthy foods (Menu composition):[35]

In 2017, the NSW Healthy School Canteen Strategy was revised and the classification system used to indicate the relative healthiness of canteen foods and drinks was changed. Classification thresholds were set for the menu item content of energy, saturated fat, sugar, and sodium, as well as serving sizes,[36] with all menu items classified as either 'Everyday', 'Occasional', or 'Should Not Be Sold'.[37] The canteen manager at each intervention school will receive a tailored feedback report summarising the results of an assessment of their online canteen menu against the 'NSW Healthy School Canteen Strategy: Food and Drink Criteria', conducted by a trained dietitian. The report will contain a copy of their online menu with all items classified as 'Everyday', 'Occasional' or 'Should Not Be Sold' and graphical feedback comparing their menu to the recommendations of the criteria (i.e. 'Everyday' foods should compromise at least 75% of the menu, and 'Should Not Be Sold' foods should be removed from the menu). The report will also contain suggestions for how to better align their menu with the Food and Drink Criteria, ways of increasing the proportion of 'Everyday' items and suggestions for alternatives to menu items classified as 'Should Not Be Sold'.

Pricing:[38]

Price is a key driver of child and adult consumer choice.[38] However, typically the prices of Australian canteen

foods do not encourage healthy purchasing, with the average price of healthier items exceeding less healthy items.[39] While the pricing of menu items will be at the discretion of each participating school, canteen managers will receive pricing feedback in their tailored feedback report. Specifically, a bar graph will display the average prices of 'Everyday', 'Occasional' and 'Should Not Be Sold' foods and drinks within the following menu categories; main meals, snacks and drinks). This section will contain general advice to price 'Everyday' foods and drinks more competitively, whilst providing additional advice on ways to maintain canteen profitability e.g. "Consider applying a larger mark up for 'Occasional' and 'Should Not Be Sold' foods than for 'Everyday' items").

Menu Labelling:[40]

i) Labels: Coloured symbols will be visible at the point-of-purchase (see Figure 2). One symbol will be placed next to every food or drink item on the online menu. Labels, symbols and colours will be assigned according to the NSW Healthy School Canteen Strategy[36] currently implemented in NSW primary schools. Food and drink items will be categorised as either a) 'Everyday'; b) 'Occasional' or c) 'Caution – consider switching' and be labelled with green dots, grey dots or red exclamation marks respectively. The terminology of the Healthy School Canteen Strategy has been designed for use by canteen managers, rather than parents and/or children. As such, it was determined through expert consultation that 'Should Not Be Sold' was an inappropriate and potentially confusing label for consumers, and 'Caution – consider switching' provided a behavioural action which would be more appropriate. Previous research has found simplified traffic light labelling similar to the one used in this study is highly likely to be noticed by parents when making purchase decisions for their children, with 96% of parents assigned to a traffic-light labelling menu condition reporting noticing the labelling system.[41]

INSERT FIGURE 2 HERE

ii) Key to labels: Once a user selects a food category from the menu (e.g. Sandwiches), a key explaining the labelling symbols will appear at the top of the page. The key contains the following text: (Everyday) "Choose everyday for Happy Healthy Kids"; (Occasional) "Occasional – choose occasionally"; "Caution – Consider switching" (see Figure 2).

Placement:[14]

i) Menu category: Menu items will be arranged to place healthy food items and healthy food categories in positions of greatest prominence. Consistent with the NSW Healthy School Canteen Strategy, the following categories are considered to be healthier and will be positioned first within the menu: Fresh Fruit, Sandwiches/Rolls/Wraps/Toasties, and Salads. The following categories are considered to be less healthy and

will be positioned lower on the menu: Hot food, Daily Specials, Meal deals, Frozen Ice Snacks, Snacks, Drinks, Sauces.

ii) Menu Item: Within each menu category 'Everyday' items will be positioned first and 'Occasional' items will be positioned last, with 'Should Not Be Sold' and unclassified items located in the middle (see Figure 2). Research suggests that items at the beginning and end of each product category are purchased twice as frequently as items in the middle.[14]

iii) Accessibility (proximity): Where a menu contains multiple flavours of an 'Occasional' or 'Should Not Be Sold' item, such as multiple flavours of potato crisps, users will be required to 'click' through to a different screen in order to see the full list of flavours. In contrast, all flavours of 'Everyday' items will be listed in the main interface. Similar strategies have been shown to encourage the purchase of more accessible menu items from printed menus.[42]

Prompting:[42]

i) 'Add-ons': If a user selects a main meal 'Occasional' or 'Should Not Be Sold' item from the Hot Food category a pop-up message will appear prompting users to select a healthy drink and/or healthy snack option called 'meal deal add-ons' (see Figure 2). The exact items included in 'meal deal add-ons' will depend on each school's menu but will typically include a bottle of water and a fresh fruit and/or vegetable snack. This will be accompanied by text encouraging the purchase of 'Everyday' items – "Try adding some everyday items for a balanced meal". Due to programming constraints, this will apply only to hot food items that are typically sold as a single item (e.g. hot dog, meat pie, chicken burger), rather than as multiple items (e.g. chicken nuggets).

ii) Text prompts: A different text prompt encouraging the selection of healthy items will appear each week in the ordering system.[43] These will include: '*Everyday' lunches = better focus; How balanced is your lunch? Add an 'Everyday' item; 'Everyday' foods help make balanced lunches; Discover new 'Everyday' tastes and flavours; Browse our 'everyday' foods & –try something new!; 'Everyday' foods – Fresh, Flavoursome, Fun!; Choose 'Everyday' items for happy, healthy kids; Hungry? 'Everyday' foods are good tummy fillers!; 'Everyday' foods are great for you!; Order all 'Everyday' foods & earn a lunch bag buddy; Have you tried a new 'Everyday' snack this week?* These prompts will appear at the top of the menu and will be rotated each week according to a pre-determined schedule.

iii) Categories: All healthy food categories will be labelled with appealing names and prompts[44] ("This is a good choice"), and be accompanied by a coloured image of the item. Less healthy categories (see 'Menu Category' above) will not be accompanied by any image or prompt.

Feedback:[16]

Prior to each lunch order being confirmed and submitted for payment, the user will receive graphical feedback[45] in the form of a pie chart, displaying the proportion of 'Everyday', 'Occasional' and 'Caution – consider switching' items contained within the lunch order (see Figure 2). Users will have the option of amending their order at this point. The graph is dynamic, so if menu items are removed from the order, the graph will change to reflect the updated selection. In addition, a tailored message will appear under the chart, providing feedback on the lunch order. The content of the tailored message will be based on the proportion of 'Everyday' items within the lunch order:

i. 100% Everyday: "Excellent Choice! You have earnt a lunch bag buddy!"
ii. 50-99% Everyday: "Nice Choice – select all 'Everyday' items for a lunch bag buddy"
iii. 1-49% Everyday: "Good start – add some more 'Everyday' items for a more balanced meal"
iv. 0% Everyday: "Try adding some 'Everyday' items for a more balanced meal"

Incentives:[17]

Lunch orders that contain 100% "Everyday" items will have a reward symbol printed on the label that is stuck on the paper bag in which the ordered items are delivered to the student. Tangible non-food rewards, such as stickers have been shown to increase children's liking and consumption of healthy food.[46] Reward symbols will rotate every week within the school term. They will contain cartoon fruit and vegetable characters and will contain the text "Congratulations - Healthy Lunch!"

Where possible, strategies will be automated by the provider, i.e. automatically applied once the menus items are entered into the online system as 'Everyday', 'Occasional' or 'Caution'. Otherwise, strategies will be manually applied by accessing the canteen manager portal within the online canteen system and manually altering the presentation of menu items.

Control

Schools allocated to the control group will only have access to the standard online canteen system without any of the above strategies.

Fidelity check

Once per term following the implementation of the intervention, a research assistant will check each school's online menu to ensure that any new items are correctly classified and the intervention strategies are applied accordingly. If there is insufficient information on the online menu to classify the new items according to the Healthy School Canteen Strategy, a research assistant will call the canteen manager to collect brand, portion

or recipe information as needed. The research assistant will also ask whether any portion sizes, ingredients or brands have changed. The intervention strategies will then be applied to the new items.

Public Involvement: The public were not involved in the development of the research questions, the study design or recruitment to the trial.

DATA COLLECTION MEASURES AND PROCEDURES

Primary outcomes

The primary trial outcomes are the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of online canteen lunch order purchases for each student within the defined baseline and follow-up data collection periods. The primary trial end-point is approximately 9 months post-baseline. This is to enable baseline and follow-up data collection to occur within the same term, 1 year apart. The intervention will still be operational during follow-up data collection for the intervention group. Assessment of primary trial outcomes will be based on lunch order purchase data from the cohort of students who place an order during the baseline period. Data from the pilot trial indicated that 82-91% of students for whom a lunch is ordered during one term will also order lunch during a subsequent term.[26]

Menu Assessment Process: Trained research assistants with Nutrition and Dietetics qualifications will conduct a menu assessment for each participating school and will classify each menu item as 'Everyday', 'Occasional' or 'Caution' and will record the nutrition information for each product. Where additional information is required beyond what is listed on the canteen menu, the school canteen manager will be phoned to collect brand and product name and serve size or recipe, including yield. For commercial (e.g. packaged products) and assembled (e.g. sandwiches) items research assistants will use a database of commonly stocked canteen products to obtain the nutrition information panel. The canteen product database was established in 2015 and was generated based on data collected from 38 schools and includes over 2,000 commonly stocked canteen items. It was used as the basis for nutritional information classification in the pilot study[25] and has been regularly updated. The canteen product database contains the nutrient panel information for all items, which includes the brand, serve size, and energy, saturated fat, sugar and sodium content per serve and per 100g. If the item is not listed in the canteen product database, two additional sources will be searched: 1. The FoodFinder Database - a list of common canteen foods classified under the NSW Healthy Canteen Strategy supplied by the NSW Ministry of Health[47], and 2. The FoodSwitch website – a list of supermarket products maintained by the George Institute for Global Health.[48] If the item cannot be located in any database, the research assistant will search for the nutrient panel online, and if it cannot be located, a 'generic' nutrient profile will be assigned using a commercial equivalent found in the canteen product database. For canteen-made items (e.g. muffins) the recipe will be entered into nutrition analysis software (FoodWorks Version 9)[49] to obtain the nutrient profile. FoodWorks is a commercially available software

program that contains the latest and most comprehensive Australian and New Zealand food data and is the industry standard in nutritional analysis software for dietitians and researchers.[49] A quality assurance process will be adopted as part of the menu assessments, whereby one dietitian will conduct the assessment and a second dietitian will confirm each item classification. Any discrepancies will be resolved between the two dietitians, and if needed a third dietitian will be consulted to settle the discrepancy. The proposed process is consistent with menu assessment procedures used in a number of previous studies conducted by the research team.[26,35,49]

Lunch order purchasing data: The purchasing data that is automatically collected by the online canteen system during the baseline and follow-up period will be supplied to the researchers by the provider in a de-identified format. Each menu item in the online canteen system is assigned a unique product ID code. This ID code will be matched to the product's nutritional profile determined in the menu assessment process outlined above, allowing for the calculation of the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of online canteen lunch order purchases for each student. For each school, a second research assistant will perform a quality assurance check of approximately 10% of the canteen menu items, to ensure that the nutrition profile has been correctly matched to the purchasing data. Special event orders (e.g. end of term pizza lunch) will be excluded from analysis, given canteen managers typically create a new menu for these events, which may not have the intervention strategies applied. Similarly, recurring orders (i.e. orders placed ahead of time to be repeated regularly without the need for the user to subsequently engage with the online canteen system) will be excluded from analysis as the user may not have been exposed to the intervention strategies.

Secondary outcomes

a) *Adverse outcome: Change in canteen revenue*

In order to determine whether the intervention has any adverse impact on school canteen revenue, the mean weekly canteen revenue from online orders at baseline and follow-up will be compared between intervention and control groups. Revenue data automatically collected by the online system will be supplied to the research team by the provider.

b) *Nutritional quality*

The overall nutritional quality of lunch order purchases during the baseline and follow-up periods will be compared between groups by calculating the total proportion of 1) 'Everyday' items, 2) 'Occasional' items and 3) 'Should Not Be Sold' items that are purchased per student over each data collection period. Trained research assistants with Nutrition and Dietetics qualifications and blinded to group allocation will classify each menu item based on the NSW Healthy School Canteen Strategy: Food and Drink Criteria.[37]

c) Intervention effect over time:

To explore the trajectory of the intervention effect over the course of the 9-month intervention period, time-series analysis will be conducted. The semi-continuous data collection will allow for such trends to be explored across all study sites. The functional form of the trajectory will be explored once data is collected.

d) Intervention cost, cost consequence and cost-effectiveness:

A trial-based economic evaluation involving costing, cost-consequence analysis and, subject to assessment of effectiveness, cost-effectiveness analysis, will be undertaken. Cost data will be collected using a specifically designed template, supported by detailed project management records.

Process Measures

The following process measures will be collected to determine any changes in availability and price of menu items, as well as intervention acceptability.

Change in availability: At baseline and follow-up, an experienced dietitian will use the assessment of Nutrition quality (above) to calculate the proportion of 'Everyday' items, 'Occasional' items and 'Should Not Be Sold' items within each menu, to compare against the "NSW Healthy School Canteen Strategy: Food and Drink Criteria" which state that at least 75% of the menu should be 'Everyday' items and no more than 25% should be 'Occasional' items. The proportion of schools meeting the criteria at baseline and follow-up will be reported per group to determine if changes to the availability of healthier items were made.

Change in pricing: At baseline and follow-up, a research assistant will calculate the average price of 'Everyday', 'Occasional' and 'Should Not Be Sold' items to determine if changes to the price levels of items were made.

Intervention Acceptability: Intervention acceptability will be assessed using a series of questions about functionality and useability using Likert scales (strongly agree to strongly disagree). This data will be collected from all canteen managers at intervention schools as part of the canteen manager survey administered at follow-up.

Additional support received: Given the NSW Healthy School Canteen Strategy was launched in 2017,[36] and that NSW Local Health Districts are mandated to support schools within their boundaries to submit their canteen menu for assessment against the new criteria[51], measurement of the receipt and timing of such additional support will be assessed at follow up via a canteen manager survey. Given the random assignment of school to intervention and control groups, it is anticipated that this support will be evenly distributed across the sample.

Other data

Student grade (Kindergarten to Grade 5) will be automatically collected by the online canteen system. School level data including size (number of enrolments) and sector, grades enrolled (e.g. Kindergarten to Grade 6) and percent of students who identify as Aboriginal or Torres Strait Islander will be collected from the 'My School' website.[52] School socio-economic index (SEIFA[53]) and school location (metropolitan, provincial, remote and very remote[54]) will be calculated based on school postcode, taken from the 'My School' website.[52] Data regarding canteen operations (e.g. number of days open, model of operation, paid canteen manager) will be collected during the canteen manager survey at follow-up. Analytics data that are automatically collected by the online canteen system (e.g. frequency of use, time taken to place the order) will be supplied by the provider.

Data quality and integrity

The purchasing data that are automatically collected by the online canteen system and used in the assessment of trial outcomes will undergo independent verification by the research team to ensure its integrity. Specifically, in a random sample of approximately 20% of participating schools, research assistants will visit the school canteen for one day and will record: all items ordered through the online canteen system; all items provided to students in the lunch order bags; and all product substitutions made by the canteen manager prior to foodservice (i.e. products that have been ordered for students, but are out of stock on the day and are replaced with a similar item). This information will be collected from the lunch order labels, as generated by the online system, verified against the contents of each student lunch order (i.e. the contents of each made up lunch bag will be checked) and cross-referenced with the purchasing data supplied by the provider.

Dissemination

Dissemination of the trial results will be in summary form only; no identifying information about schools or individual participants will be available. Dissemination of the research findings could involve peer-reviewed scientific publications, reports, presentations at national or international conferences, or part of student research theses.

Analysis

Statistical analysis: Each primary trial outcome will be assessed using a separate linear mixed model under an intention-to-treat framework. The mean nutritional content (i.e. energy, saturated fat, sugar and sodium) of online lunch orders placed for an individual student will be compared between intervention and control groups at follow-up, adjusting for baseline values, and clustering within school (using a random school-level intercept). The linear mixed model will account for repeated measures of the trial outcome at the student

and school level. To account for elevated type 1 error from multiple primary outcomes, a Holm-Bonferroni procedure will be used. A per protocol analysis will also be conducted to determine the effect of the intervention strategies being partially applied. Exploratory sub-group analyses will also be conducted, testing the average energy content per student lunch order for treatment group interactions by demographic characteristics (i.e. student grade – infants vs primary; and school sector) and purchasing characteristics (i.e. 1/+ orders per week vs <1 order per week). The trial data will be reported in adherence with the CONSORT 2010 guidelines[55] for reporting cluster randomised controlled trials.

Sample size calculation

As dose-response relationships exist between three of the four primary outcomes (saturated fat[56], sugar[57] and sodium[58]) and dietary related clinical health outcomes, the sample size calculation was based on the estimated between group differences in daily energy intake that would be required to offset unhealthy weight gain.[59] It is expected that approximately 194 students at each school will place at least one online lunch order during the baseline data collection period, and that 86% of those of students will order within the follow-up data collection period, and that 70% of orders are placed using a mobile device (and will be included in the analysis). Assuming that a standard lunch order has a standard deviation of 616kJ, and assuming an ICC of 0.05, the participation of 26 schools (13 each arm) would enable detection of a 195kJ difference between groups at follow-up with 80% power at the Bonferroni adjusted level of 0.0125 significance level (preserving a family-wise type 1 error rate of 5%).

Economic analysis

A trial-based economic evaluation involving costing, cost-consequence analysis and, subject to assessment of effectiveness, cost-effectiveness analysis, will be undertaken. The intervention will be compared against the control group (usual-practice) from a societal perspective. Resource use will be identified, measured and valued for the intervention development, implementation and sustainability stages. It will be assumed that control schools will incur no additional costs beyond the use of the online ordering system (i.e. usual practice). The costs of the intervention will be reported as the difference in mean total costs between the intervention schools and control schools. Costs will further be reported to give transparency to the intervention cost profile at different stages (development, implementation and sustainability) and by stakeholder. An incremental cost-effectiveness ratio (ICER) will be calculated as the difference in mean total cost divided by the observed difference in the primary outcome of kilojoules. Uncertainty analysis will be undertaken using non-parametric bootstrapping to derive uncertainty intervals (UIs) around the key variables. Sensitivity and scenario analysis will be undertaken to test the impact of changing key design features of the intervention and scale-up of the implementation model.

DISCUSSION

This trial adopts a rigorous cluster randomised controlled design and tests the effectiveness of an intervention that is integrated into an existing online canteen system with wide reach throughout Australian schools. The intervention will be evaluated using routinely collected lunch order purchasing data from thousands of primary school students. The results should be considered in the context of the strengths and limitations of the research. The external validity of the findings may be limited given the application of this intervention only to primary schools from one Australian state, although the inclusion of all school types across socioeconomic strata is a strength. Furthermore, study findings may be limited due to the use of purchasing data as opposed to consumption data, and an inability to identify the person placing the order (i.e. a student ordering for themselves or a parent ordering on behalf of a student). Notwithstanding these limitations, it is anticipated that the trial results will be used to inform future implementation of public health nutrition interventions through school canteens and may be transferrable to other online systems for ordering food.

ETHICS AND DISSEMINATION

The study was approved by the University of Newcastle Human Research Ethics Committee (H-2017-0402), the NSW Department of Education and Communities (SERAP), and the Catholic Education Office Dioceses of Sydney, Parramatta, Lismore, Maitland-Newcastle, Bathurst, Canberra-Goulburn, Wagga Wagga, Wollongong and Wilcannia-Forbes. Study information statements and consent forms are available from the authors on request. Study results will be disseminated through presentations at relevant national and international conferences and to key stakeholders.

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AUTHOR'S CONTRIBUTIONS

Author RW led the development of this manuscript. Authors RW, LW, KB, KC, JW and CR secured the funding source. Authors RW, TD, and LW developed the intervention strategies. Authors TD, RW and LW determined the measures to be used, and authors JA, CO, RW and LW determined the analyses to be conducted. All authors contributed to the research design and trial methodology and contributed to, read and approved the final version of this manuscript.

COMPETING INTERESTS

The authors have no competing interests to declare.

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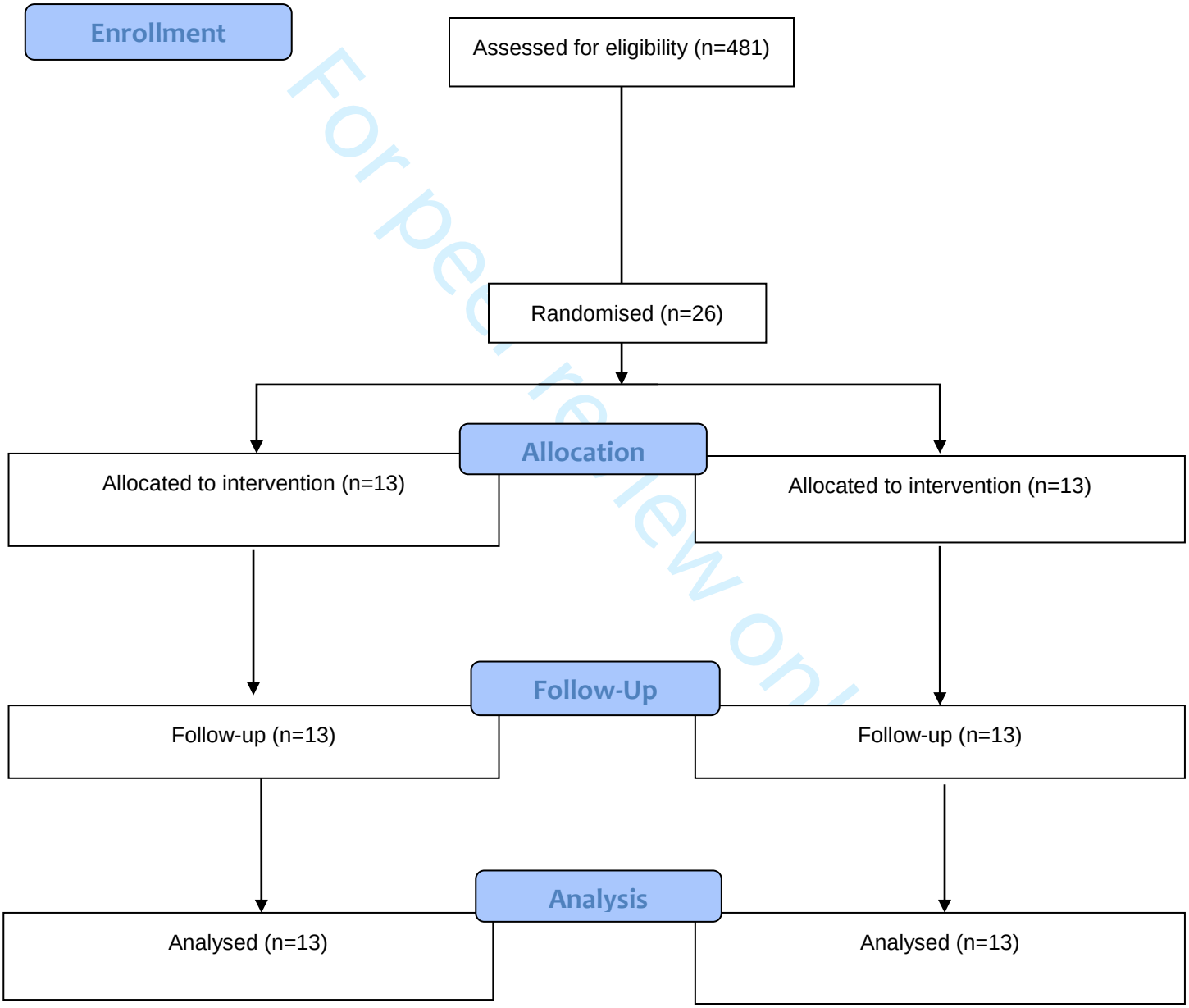

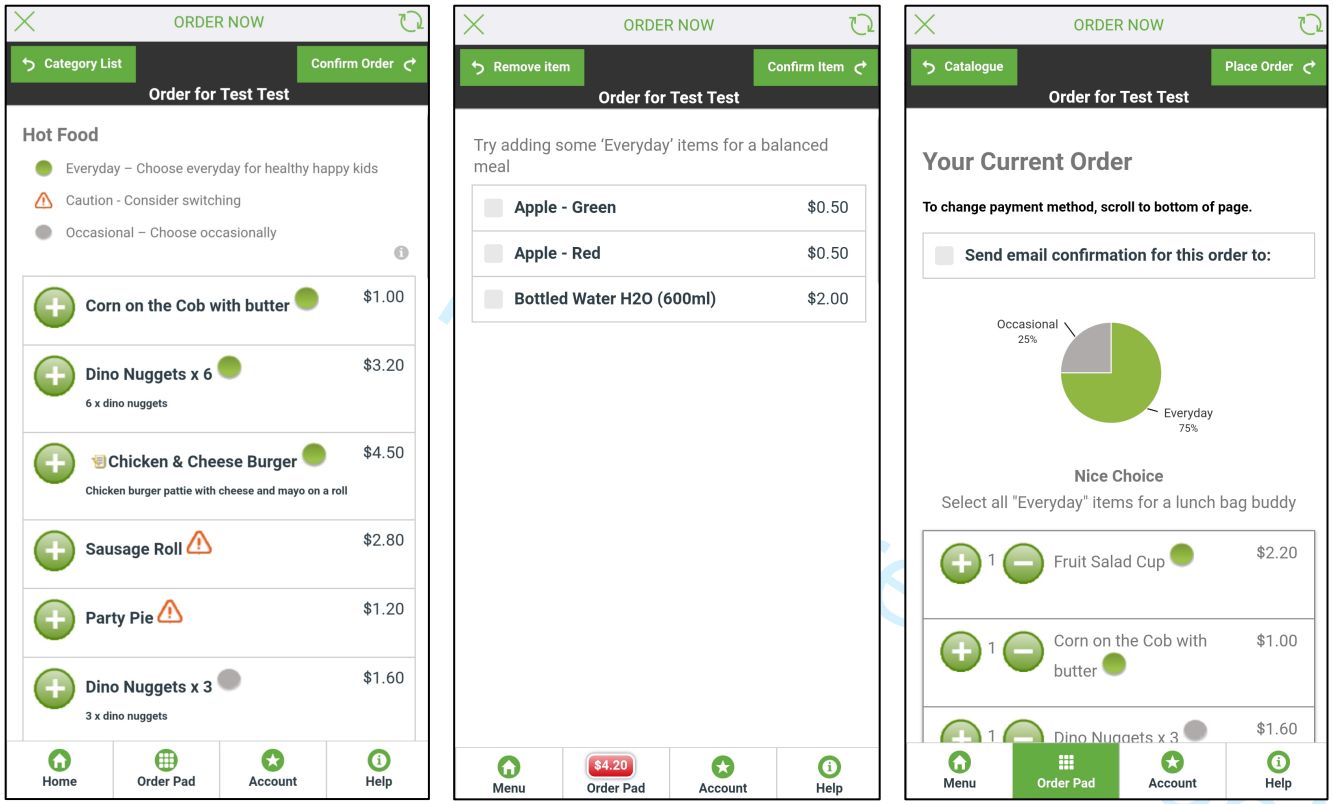

Figure 2. Screenshots from the Online Canteen Ordering System showing A) Menu labelling strategy & Placement strategy ('Everyday' first, 'Caution' middle, 'Occasional' last); B) Prompting – 'Add ons' for 'Occasional' or 'Caution' hot food items; C) Feedback – pie chart displaying the proportion of 'Everyday', 'Occasional' and 'Caution – consider switching' items contained within the lunch order.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
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	_3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_1-15_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_18-19_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1_____
	5b	Name and contact information for the trial sponsor	_NA_____
	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	_18-19_____
	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)	_18-19_____

Introduction			
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	__5-6_____
	6b	Explanation for choice of comparators	__6_____
Objectives	7	Specific objectives or hypotheses	__6_____
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, noninferiority, exploratory)	__6_____
Methods: Participants, interventions, and outcomes			
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	__6_____
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)	__6-7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__8-12_____
	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)	__6_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_12-13_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___9,14-15_____
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	__13-15_____
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)	___8_____

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	___17_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___6-7_____
Methods: Assignment of interventions (for controlled trials)			
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	__8_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	__8_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	__8_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___8,13_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___NA_____
Methods: Data collection, management, and analysis			
Data collection methods	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	8,14-16
	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	____N/A_____

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	___15_____
Statistical methods	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	____16-17_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__16-17_____
	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)	____16-17_____
Methods: Monitoring			
Data monitoring	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_____ _
	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	_____N/A_____
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	_____14_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___12-13_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___18_____
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)	___9_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7
	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	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
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	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	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants andauthorised surrogates	Appendices
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

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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A CLUSTER RANDOMISED CONTROLLED TRIAL OF AN ONLINE INTERVENTION TO IMPROVE HEALTHY FOOD PURCHASES FROM PRIMARY SCHOOL CANTEENS: A STUDY PROTOCOL OF THE 'CLICK & CRUNCH' TRIAL

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SCIENTIFIC TITLE: A CLUSTER RANDOMISED CONTROLLED TRIAL OF AN ONLINE INTERVENTION TO IMPROVE HEALTHY FOOD PURCHASES FROM PRIMARY SCHOOL CANTEENS: A STUDY PROTOCOL OF THE 'CLICK & CRUNCH' TRIAL

PUBLIC TITLE: CLICK & CRUNCH: AN ONLINE INTERVENTION TO IMPROVE HEALTHY FOOD PURCHASES FROM PRIMARY SCHOOL CANTEENS

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ABSTRACT

Introduction

School canteens are the most frequently accessed take-away food outlet by Australian children. The rapid development of online lunch ordering systems from school canteens presents new opportunities to deliver novel public health nutrition interventions to school-aged children. This study aims to assess the effectiveness and cost-effectiveness of a behavioural intervention in reducing the energy, saturated fat, sugar and sodium content of online canteen lunch orders for primary school children.

Methods and analysis

The study will employ a cluster randomised controlled trial design. Twenty-six primary schools in New South Wales, Australia, that have an existing online canteen ordering system will be randomised to receive either a multi-strategy behavioural intervention or a control (the standard online canteen ordering system). The intervention will be integrated into the existing online canteen system and will seek to encourage the purchase of healthier food and drinks for school lunch orders (i.e. items lower in energy, saturated fat, sugar, and sodium). The behavioural intervention will use evidence-based choice architecture strategies to redesign the online menu and ordering system including: menu labelling, placement, prompting, and provision of feedback and incentives. The primary trial outcomes will be the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of lunch orders placed via the online system, and will be assessed 9 months after baseline data collection.

Ethics and dissemination

The study was approved by the ethics committees of the University of Newcastle (H-2017-0402) and the New South Wales Department of Education and Communities (SERAP 2018065), and the Catholic Education Office Dioceses of Sydney, Parramatta, Lismore, Maitland-Newcastle, Bathurst, Canberra-Goulburn, Wollongong, Wagga Wagga and Wilcannia-Forbes. Study results will be disseminated through peer-reviewed publications, reports, presentations at relevant national and international conferences and via briefings to key stakeholders. Results will be used to inform future implementation of public health nutrition interventions through school canteens, and may be transferrable to other food settings or online systems for ordering food.

Registration details

This trial was prospectively registered with the Australian and New Zealand Clinical Trials Register on 22/5/18 (ACTRN12618000855224).

Strengths and limitations of this study

- This study will use a cluster randomised controlled trial design, a rigorous research design for

assessing intervention effectiveness.

- The evidence-based choice architecture intervention is embedded within an existing online canteen ordering system that is used by over 1,200 schools across Australia, and processes over 13 million lunch orders per year.
- The cost and cost-effectiveness of the intervention will be determined from a societal perspective giving transparency to the cost of implementation, providing policy makers with critical data to inform decision-making.
- Actual food consumption will not be assessed; purchase data will serve as a proxy for food consumption.

Key Words

Intervention, RCT, Nutrition, Obesity, Primary School, Canteen

INTRODUCTION

Dietary risk factors are a leading cause of death and disability internationally.[1] Given dietary behaviours in childhood track into adulthood and are predictive of future chronic disease,[2] improving child nutrition is a health priority in Australia and internationally.[3,4] Schools provide an important setting for promoting healthy food consumption to children as they provide centralised access to almost every Australian child for prolonged periods, with children consuming almost 40% of their recommended energy intake while at school.[5] Schools also represent a significant food provider. In New South Wales (NSW), 95% of primary-aged children attend a school with a canteen[6] and 55% of students order their lunch from the canteen at least weekly, compared with 23% of students that eat a meal or snack from a fast-food outlet each week.[6] The most frequently purchased menu items from canteens are often high in fat, sugar and salt[7] with canteen purchases contributing an additional 200kJ to energy consumed at school, compared to foods brought from home.[5]

While previous attempts to improve the school food environment have focused on changing the relative availability of unhealthy foods for sale at school,[8–12] modifying other drivers of consumer behaviour represents an additional opportunity to improve children's diet. For example, previous research has demonstrated that point-of-purchase interventions that involve nutrition labelling[13]; manipulating the placement of menu items[14]; and the provision of purchasing prompts[15]; nutritional feedback[16] and incentives[17], can influence the purchase of foods and drinks among children and adults. Despite the potential of behavioural strategies to encourage healthy purchasing, national and international studies of (non-online) canteens and cafeterias indicate that such strategies are under-utilised in schools. The United States (U.S.) School Health Policies and Practices Study of 544 elementary schools found few school cafeterias used strategies such as provision of nutritional feedback (60%) or item placement (10-26%), or incentives (16-17%) to encourage healthy purchasing.[18] Furthermore, an Australian study of 203 primary schools found that only 43% reported labelling their canteen menus to identify healthy options.[19]

Canteen online ordering systems allow users to view, select and purchase food and drink menu items online, and represent a new approach for children to access food at school. They are becoming increasingly popular in Australia,[20] with the leading supplier servicing over 1,200 schools nationally and processing over 13 million lunch orders per year.[21] These systems represent an attractive opportunity to apply a range of behavioural strategies that can reach large numbers of individuals at relatively low cost.[22] Strategies including menu or product labelling, product placement, and the provision of prompts and incentives are routinely used to influence purchase decisions by food retailers online.[23] Furthermore, given these systems are centrally administrated, interventions delivered via these means may be more resistant to the transient nature of local canteen staffing, a common barrier to sustainable implementation of nutrition guidelines and interventions

in this setting[24].

We recently conducted a pilot trial that evaluated the use of strategies including traffic light menu-labelling, prominent placement of healthy menu items, provision of prompts to select healthy menu items, and reduced accessibility of less healthy items[25] integrated into an online school canteen ordering system. The trial was undertaken in ten NSW primary schools over a 2-month intervention period and found that, compared to controls, intervention lunch orders were significantly lower in energy (-567kJ), saturated fat (-2.37g), and sodium (-228mg) (all $p<0.001$).[26] Given these promising findings, a larger trial is proposed and described in this protocol, which tests a greater range of intervention strategies, using a larger study sample and longer period of follow-up.

STUDY AIM

The aim of the study is to assess the effectiveness and cost-effectiveness of an online multi-strategy behavioural intervention in reducing the energy, saturated fat, sugar and sodium content of primary school students' online canteen lunch orders.

METHODS AND ANALYSIS

Study design and setting

The study will be conducted in Government, Independent and Catholic schools in NSW, Australia, and will use a cluster randomised controlled trial design. Schools that currently use the 'Flexischools' online canteen ordering system will be randomised to either an intervention or usual practice control group. Intervention effectiveness will be assessed by comparing between-group differences at follow-up in the mean i) energy (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium (milligrams) contained in students' online lunch orders, based on purchasing data that is automatically collected by the online canteen system. Both baseline and follow-up assessment periods will be conducted over one school term, of approximately 10 weeks' duration, one calendar year apart.

Participants and recruitment

Schools: All NSW primary schools currently using the 'Flexischools' online canteen system[27] will serve as the sampling frame (n=481). A list of all such schools has been supplied by the provider of the online canteen ordering system (here-after referred to as the 'provider') servicing over 1,200 schools across Australia.[21] One member of the research team will act as the recruitment coordinator and will manage recruitment and consent into the trial. Study information and consent forms will be mailed to the school principal and canteen manager at all potentially eligible schools from the sampling frame. Approximately one to two weeks later,

the recruitment coordinator will make a follow-up phone call to speak with the school principal and/or canteen manager about the research and confirm school eligibility using procedures previously undertaken by the research team. Principal consent will be required to enable school participation in the trial and to enable the researchers to access the school's canteen purchasing data from the provider. Principals will retain the right to discontinue their participation in the study and withdraw the school from the trial at any point.

School eligibility criteria: Given canteen guidelines differ from state to state and between primary and secondary schools, only NSW primary schools (serviced by the provider) will be included in the study. Schools will be approached via mail and telephone to participate. Schools that can be identified (i.e. from a published list or where reliable data can be sourced about their operation) as having an externally licensed commercial canteen operator will be removed from the sample due to the potential for contamination between schools. Schools that enrol both primary (Kindergarten to Grade 6) and secondary (Grade 7 to 12) school students will only be included where there is a separate canteen menu for primary school students, due to differences in the NSW canteen guidelines for primary versus secondary schools.

Users: Users of the online canteen system could be students or parents/carers who place orders on behalf of their children. Schools that use an online canteen system can also choose to retain the traditional method for placing lunch orders (i.e. writing the lunch order on a paper bag and submitting directly to the canteen) in addition to offering online ordering. To submit an online order, users access the provider's website from their mobile device or computer. They then select the day and meal for which they want to make place an order (e.g. Tuesday, lunchtime), and they are then shown the full list of food and drink menu items that are available for that meal. To order, users click on menu items and then pay via a credit or debit card or PayPal. Data supplied from the provider suggests that on average, 30-40% of students in schools they service have an account set up to enable online canteen ordering and have ordered within the last 30 days.

User eligibility criteria: Students who have an online lunch order submitted during the baseline data collection period are eligible for inclusion in the trial. As the follow-up data collection period occurs in the subsequent school year, only students in Kindergarten to Grade 5 (ages 5-11) will be included at baseline, in order to ensure they are available for follow-up. Given not all schools offer online ordering for recess foods, recess purchases will not be included in the analysis. Furthermore, only lunch orders submitted via mobile devices (approximately 70%) will be included in the analysis as the desktop version is due to be phased out by the provider. As such orders submitted via the desktop website, or orders submitted at the canteen will not be included in the analysis.

Randomisation and blinding

Following school recruitment and baseline data collection, schools will be randomised by an independent statistician using a randomised number function in Microsoft Excel in a 1:1 ratio to either an intervention or control group (see Figure 1). Block randomisation will be employed to ensure group allocation is approximately equal, with block size randomly varying between 2 and 4. Given evidence that there are differences in the implementation of canteen guidelines between more and less advantaged areas and between Government and non-Government school sectors,[28] the randomisation procedure will be stratified by the socioeconomic status of a school locality (based on postcode and dichotomised into most vs least advantaged), and by school sector (Government vs Catholic vs Independent). Following random allocation to either intervention or control group, the online strategies will be applied to the canteen menus of each intervention school by accessing the canteen manager portal within the online canteen system. A research assistant will perform a quality check on the live website to ensure all strategies have been correctly applied. Due to the difficulty in blinding users to the changes introduced as part of the intervention, the study will be conducted as an open trial. However, the dietitians conducting the menu assessment will be blind to group allocation via the removal of all identifiable information from menus prior to assessment.

INSERT FIGURE 1 HERE

Intervention

A multi-strategy behavioural intervention will be integrated into the existing online canteen system[27] of intervention schools as described below. The intervention seeks to encourage the purchase of healthier foods and drinks for school canteen lunch orders, that is, items lower in energy, saturated fat, sugar, and/or sodium, consistent with the NSW Healthy School Canteen Strategy. The intervention will be operational across the entire study period until the end of follow-up data collection (9 months post baseline). Research assistants will be responsible for managing the delivery of the online strategy to the intervention group, liaising with schools and communicating any necessary changes throughout the study. All users of the online canteen ordering system at intervention schools will be exposed to the intervention. Controlled access to the intervention strategies by the provider will prevent potential intervention contamination between groups.

Intervention conceptual framework

The intervention is based on the principles of choice architecture, which suggests that behaviour can be influenced by the environment in which choices are made,[29] with choice architecture interventions typically altering micro-environments (e.g. online applications / 'apps') in order to cue healthier choices.[30] The intervention for this trial was guided by the choice architecture typology proposed by Hollands and colleagues.[29] Strategies that performed well against the following criteria were included in the intervention:

i) strategies that were supported by evidence of effectiveness from food-service settings (including the pilot trial[26]); ii) strategies that were considered effective and acceptable in surveys of school stakeholders including principals and parents[31,32]; iii) strategies that were able to be feasibly operationalised in an online environment; and vi) strategies that were amenable to implementation at scale (i.e. low cost and high reach). Furthermore, given research suggests that parents are involved in 68% of fast food purchase decisions for their children,[33] a strategy was deliberately included that targeted child users of the system (incentives).

Intervention strategies

The strategies that form the intervention have all been shown to support healthier choices in food-service settings.[13–17,34] The choice architecture strategies from the pilot trial will be retained[25] and additional strategies, including provision of feedback and incentives will be added. Based on feedback from the pilot trial, availability (menu composition) and pricing strategies will be included to support the canteen manager to apply the NSW Healthy School Canteen Strategy and to allay any concerns that implementing the intervention will undermine canteen revenue. These strategies will be delivered via a tailored feedback report that will be sent to both the canteen manager and school principal and discussed in a brief feedback call from the research assistant with the canteen manager. The written and verbal feedback will be provided at one time point, immediately prior to the application of the choice architecture strategies within the online canteen system.

Availability of healthy foods (Menu composition):[35]

In 2017, the NSW Healthy School Canteen Strategy was revised and the classification system used to indicate the relative healthiness of canteen foods and drinks was changed. Classification thresholds were set for the menu item content of energy, saturated fat, sugar, and sodium, as well as serving sizes,[36] with all menu items classified as either 'Everyday', 'Occasional', or 'Should Not Be Sold'.[37] The canteen manager at each intervention school will receive a tailored feedback report summarising the results of an assessment of their online canteen menu against the 'NSW Healthy School Canteen Strategy: Food and Drink Criteria', conducted by a trained dietitian. The report will contain a copy of their online menu with all items classified as 'Everyday', 'Occasional' or 'Should Not Be Sold' and graphical feedback comparing their menu to the recommendations of the criteria (i.e. 'Everyday' foods should compromise at least 75% of the menu, and 'Should Not Be Sold' foods should be removed from the menu). The report will also contain suggestions for how to better align their menu with the Food and Drink Criteria, ways of increasing the proportion of 'Everyday' items and suggestions for alternatives to menu items classified as 'Should Not Be Sold'.

Pricing:[38]

Price is a key driver of child and adult consumer choice.[38] However, typically the prices of Australian canteen

foods do not encourage healthy purchasing, with the average price of healthier items exceeding less healthy items.[39] While the pricing of menu items will be at the discretion of each participating school, canteen managers will receive pricing feedback in their tailored feedback report. Specifically, a bar graph will display the average prices of 'Everyday', 'Occasional' and 'Should Not Be Sold' foods and drinks within the following menu categories; main meals, snacks and drinks). This section will contain general advice to price 'Everyday' foods and drinks more competitively, whilst providing additional advice on ways to maintain canteen profitability e.g. "Consider applying a larger mark up for 'Occasional' and 'Should Not Be Sold' foods than for 'Everyday' items").

Menu Labelling:[40]

i) Labels: Coloured symbols will be visible at the point-of-purchase (see Figure 2). One symbol will be placed next to every food or drink item on the online menu. Labels, symbols and colours will be assigned according to the NSW Healthy School Canteen Strategy[36] currently implemented in NSW primary schools. Food and drink items will be categorised as either a) 'Everyday'; b) 'Occasional' or c) 'Caution – consider switching' and be labelled with green dots, grey dots or red exclamation marks respectively. The terminology of the Healthy School Canteen Strategy has been designed for use by canteen managers, rather than parents and/or children. As such, it was determined through expert consultation that 'Should Not Be Sold' was an inappropriate and potentially confusing label for consumers, and 'Caution – consider switching' provided a behavioural action which would be more appropriate. Previous research has found simplified traffic light labelling similar to the one used in this study is highly likely to be noticed by parents when making purchase decisions for their children, with 96% of parents assigned to a traffic-light labelling menu condition reporting noticing the labelling system.[41]

INSERT FIGURE 2 HERE

ii) Key to labels: Once a user selects a food category from the menu (e.g. Sandwiches), a key explaining the labelling symbols will appear at the top of the page. The key contains the following text: (Everyday) "Choose everyday for Happy Healthy Kids"; (Occasional) "Occasional – choose occasionally"; "Caution – Consider switching" (see Figure 2).

Placement:[14]

i) Menu category: Menu items will be arranged to place healthy food items and healthy food categories in positions of greatest prominence. Consistent with the NSW Healthy School Canteen Strategy, the following categories are considered to be healthier and will be positioned first within the menu: Fresh Fruit, Sandwiches/Rolls/Wraps/Toasties, and Salads. The following categories are considered to be less healthy and

will be positioned lower on the menu: Hot food, Daily Specials, Meal deals, Frozen Ice Snacks, Snacks, Drinks, Sauces.

ii) Menu Item: Within each menu category 'Everyday' items will be positioned first and 'Occasional' items will be positioned last, with 'Should Not Be Sold' and unclassified items located in the middle (see Figure 2). Research suggests that items at the beginning and end of each product category are purchased twice as frequently as items in the middle.[14]

iii) Accessibility (proximity): Where a menu contains multiple flavours of an 'Occasional' or 'Should Not Be Sold' item, such as multiple flavours of potato crisps, users will be required to 'click' through to a different screen in order to see the full list of flavours. In contrast, all flavours of 'Everyday' items will be listed in the main interface. Similar strategies have been shown to encourage the purchase of more accessible menu items from printed menus.[42]

Prompting:[42]

i) 'Add-ons': If a user selects a main meal 'Occasional' or 'Should Not Be Sold' item from the Hot Food category a pop-up message will appear prompting users to select a healthy drink and/or healthy snack option called 'meal deal add-ons' (see Figure 2). The exact items included in 'meal deal add-ons' will depend on each school's menu but will typically include a bottle of water and a fresh fruit and/or vegetable snack. This will be accompanied by text encouraging the purchase of 'Everyday' items – "Try adding some everyday items for a balanced meal". Due to programming constraints, this will apply only to hot food items that are typically sold as a single item (e.g. hot dog, meat pie, chicken burger), rather than as multiple items (e.g. chicken nuggets).

ii) Text prompts: A different text prompt encouraging the selection of healthy items will appear each week in the ordering system.[43] These will include: '*Everyday' lunches = better focus; How balanced is your lunch? Add an 'Everyday' item; 'Everyday' foods help make balanced lunches; Discover new 'Everyday' tastes and flavours; Browse our 'everyday' foods & –try something new!; 'Everyday' foods – Fresh, Flavoursome, Fun!; Choose 'Everyday' items for happy, healthy kids; Hungry? 'Everyday' foods are good tummy fillers!; 'Everyday' foods are great for you!; Order all 'Everyday' foods & earn a lunch bag buddy; Have you tried a new 'Everyday' snack this week?* These prompts will appear at the top of the menu and will be rotated each week according to a pre-determined schedule.

iii) Categories: All healthy food categories will be labelled with appealing names and prompts[44] ("This is a good choice"), and be accompanied by a coloured image of the item. Less healthy categories (see 'Menu Category' above) will not be accompanied by any image or prompt.

Feedback:[16]

Prior to each lunch order being confirmed and submitted for payment, the user will receive graphical feedback[45] in the form of a pie chart, displaying the proportion of 'Everyday', 'Occasional' and 'Caution – consider switching' items contained within the lunch order (see Figure 2). Users will have the option of amending their order at this point. The graph is dynamic, so if menu items are removed from the order, the graph will change to reflect the updated selection. In addition, a tailored message will appear under the chart, providing feedback on the lunch order. The content of the tailored message will be based on the proportion of 'Everyday' items within the lunch order:

i. 100% Everyday: "Excellent Choice! You have earnt a lunch bag buddy!"

ii. 50-99% Everyday: "Nice Choice – select all 'Everyday' items for a lunch bag buddy"

iii. 1-49% Everyday: "Good start – add some more 'Everyday' items for a more balanced meal"

iv. 0% Everyday: "Try adding some 'Everyday' items for a more balanced meal"

Incentives:[17]

Lunch orders that contain 100% "Everyday" items will have a reward symbol printed on the label that is stuck on the paper bag in which the ordered items are delivered to the student. The reward symbols will automatically be printed on the student's label by the online system. Tangible non-food rewards, such as stickers have been shown to increase children's liking and consumption of healthy food.[46] Reward symbols will rotate every week within the school term. They will contain cartoon fruit and vegetable characters and will contain the text "Congratulations - Healthy Lunch!"

Where possible, strategies will be automated by the provider, i.e. automatically applied once the menus items are entered into the online system as 'Everyday', 'Occasional' or 'Caution'. Otherwise, strategies will be manually applied by accessing the canteen manager portal within the online canteen system and manually altering the presentation of menu items.

Control

Schools allocated to the control group will only have access to the standard online canteen system without any of the above strategies.

Fidelity check

Once per term following the implementation of the intervention, a research assistant will check each school's online menu to ensure that any new items are correctly classified and the intervention strategies are applied accordingly. If there is insufficient information on the online menu to classify the new items according to the

Healthy School Canteen Strategy, a research assistant will call the canteen manager to collect brand, portion or recipe information as needed. The research assistant will also ask whether any portion sizes, ingredients or brands have changed. The intervention strategies will then be applied to the new items.
The only stargey we cannot verify via onpine is the incentives and these will be verified via visist

Public Involvement: The public were not involved in the development of the research questions, the study design or recruitment to the trial.

DATA COLLECTION MEASURES AND PROCEDURES

Primary outcomes

The primary trial outcomes are the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of online canteen lunch order purchases for each student within the defined baseline and follow-up data collection periods. The primary trial end-point is approximately 9 months post-baseline. This is to enable baseline and follow-up data collection to occur within the same term, 1 year apart. The intervention will still be operational during follow-up data collection for the intervention group. Assessment of primary trial outcomes will be based on lunch order purchase data from the cohort of students who place an order during the baseline period. Data from the pilot trial indicated that 82-91% of students for whom a lunch is ordered during one term will also order lunch during a subsequent term.[26]

Menu Assessment Process: Trained research assistants with Nutrition and Dietetics qualifications will conduct a menu assessment for each participating school and will classify each menu item as 'Everyday', 'Occasional' or 'Caution' and will record the nutrition information for each product. Where additional information is required beyond what is listed on the canteen menu, the school canteen manager will be phoned to collect brand and product name and serve size or recipe, including yield. For commercial (e.g. packaged products) and assembled (e.g. sandwiches) items research assistants will use a database of commonly stocked canteen products to obtain the nutrition information panel. The canteen product database was established in 2015 and was generated based on data collected from 38 schools and includes over 2,000 commonly stocked canteen items. It was used as the basis for nutritional information classification in the pilot study[25] and has been regularly updated. The canteen product database contains the nutrient panel information for all items, which includes the brand, serve size, and energy, saturated fat, sugar and sodium content per serve and per 100g. If the item is not listed in the canteen product database, two additional sources will be searched: 1. The FoodFinder Database - a list of common canteen foods classified under the NSW Healthy Canteen Strategy supplied by the NSW Ministry of Health[47], and 2. The FoodSwitch website – a list of supermarket products maintained by the George Institute for Global Health.[48] If the item cannot be located in any database, the research assistant will search for the nutrient panel online, and if it cannot be located, a 'generic' nutrient profile will be assigned using a commercial equivalent found in the canteen product

database. For canteen-made items (e.g. muffins) the recipe will be entered into nutrition analysis software (FoodWorks Version 9)[49] to obtain the nutrient profile. FoodWorks is a commercially available software program that contains the latest and most comprehensive Australian and New Zealand food data and is the industry standard in nutritional analysis software for dietitians and researchers.[49] A quality assurance process will be adopted as part of the menu assessments, whereby one dietitian will conduct the assessment and a second dietitian will confirm each item classification. Any discrepancies will be resolved between the two dietitians, and if needed a third dietitian will be consulted to settle the discrepancy. The proposed process is consistent with menu assessment procedures used in a number of previous studies conducted by the research team.[26,35,49, 50]

Lunch order purchasing data: The purchasing data that is automatically collected by the online canteen system during the baseline and follow-up period will be supplied to the researchers by the provider in a de-identified format. One full school term (10 weeks) of purchasing data will be provided at each time point for analysis. Each menu item in the online canteen system is assigned a unique product ID code. This ID code will be matched to the product's nutritional profile determined in the menu assessment process outlined above, allowing for the calculation of the mean energy (kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams) content of online canteen lunch order purchases for each student. For each school, a second research assistant will perform a quality assurance check of approximately 10% of the canteen menu items, to ensure that the nutrition profile has been correctly matched to the purchasing data. Special event orders (e.g. end of term pizza lunch) will be excluded from analysis, given canteen managers typically create a new menu for these events, which may not have the intervention strategies applied. Similarly, recurring orders (i.e. orders placed ahead of time to be repeated regularly without the need for the user to subsequently engage with the online canteen system) will be excluded from analysis as the user may not have been exposed to the intervention strategies.

Secondary outcomes

a) *Adverse outcome: Change in canteen revenue*

In order to determine whether the intervention has any adverse impact on school canteen revenue, the mean weekly canteen revenue from online orders at baseline and follow-up will be compared between intervention and control groups. Revenue data automatically collected by the online system will be supplied to the research team by the provider.

b) *Nutritional quality*

The overall nutritional quality of lunch order purchases during the baseline and follow-up periods will be compared between groups by calculating the 1) total proportion of i) 'Everyday' items, ii) 'Occasional' items and iii) 'Should Not Be Sold' items and 2) the mean percent of energy from (i) sugar; and (ii) saturated fat

that are purchased per student over each data collection period. Trained research assistants with Nutrition and Dietetics qualifications and blinded to group allocation will classify each menu item based on the NSW Healthy School Canteen Strategy: Food and Drink Criteria.[37]

c) Intervention effect over time:

To explore the trajectory of the intervention effect over the course of the 9-month intervention period, time-series analysis will be conducted. The semi-continuous data collection will allow for such trends to be explored across all study sites. The functional form of the trajectory will be explored once data is collected.

d) Intervention cost, cost consequence and cost-effectiveness:

A trial-based economic evaluation involving costing, cost-consequence analysis and, subject to assessment of effectiveness, cost-effectiveness analysis, will be undertaken. Cost data will be collected using a specifically designed template, supported by detailed project management records.

Process Measures

The following process measures will be collected to determine any changes in availability and price of menu items, as well as intervention acceptability.

Change in availability: At baseline and follow-up, an experienced dietitian will use the assessment of Nutrition quality (above) to calculate the proportion of 'Everyday' items, 'Occasional' items and 'Should Not Be Sold' items within each menu, to compare against the "NSW Healthy School Canteen Strategy: Food and Drink Criteria" which state that at least 75% of the menu should be 'Everyday' items and no more than 25% should be 'Occasional' items. The proportion of schools meeting the criteria at baseline and follow-up will be reported per group to determine if changes to the availability of healthier items were made.

Change in pricing: At baseline and follow-up, a research assistant will calculate the average price of 'Everyday', 'Occasional' and 'Should Not Be Sold' items to determine if changes to the price levels of items were made.

Intervention Acceptability: Intervention acceptability will be assessed using a series of questions about functionality and useability using Likert scales (strongly agree to strongly disagree). This data will be collected from all canteen managers at intervention schools as part of the canteen manager survey administered at follow-up.

Additional support received: Given the NSW Healthy School Canteen Strategy was launched in 2017,[36] and that NSW Local Health Districts are mandated to support schools within their boundaries to submit their

canteen menu for assessment against the new criteria[51], measurement of the receipt and timing of such additional support will be assessed at follow up via a canteen manager survey. Given the random assignment of school to intervention and control groups, it is anticipated that this support will be evenly distributed across the sample.

Other data

Student grade (Kindergarten to Grade 5) will be automatically collected by the online canteen system. School level data including size (number of enrolments) and sector, grades enrolled (e.g. Kindergarten to Grade 6) and percent of students who identify as Aboriginal or Torres Strait Islander will be collected from the 'My School' website.[52] School socio-economic index (SEIFA[53]) and school location (metropolitan, provincial, remote and very remote[54]) will be calculated based on school postcode, taken from the 'My School' website.[52] Data regarding canteen operations (e.g. number of days open, model of operation, paid canteen manager) will be collected during the canteen manager survey at follow-up. Analytics data that are automatically collected by the online canteen system (e.g. frequency of use, time taken to place the order) will be supplied by the provider.

Data quality and integrity

The purchasing data that are automatically collected by the online canteen system and used in the assessment of trial outcomes will undergo independent verification by the research team to ensure its integrity. Specifically, in a random sample of approximately 20% of participating schools, research assistants will visit the school canteen for one day and will record: all items ordered through the online canteen system; all items provided to students in the lunch order bags; all product substitutions made by the canteen manager prior to foodservice (i.e. products that have been ordered for students, but are out of stock on the day and are replaced with a similar item); and the presence of any printed reward symbols on student lunch labels. This information will be collected from the lunch order labels, as generated by the online system, verified against the contents of each student lunch order (i.e. the contents of each made up lunch bag will be checked) and cross-referenced with the purchasing data supplied by the provider.

Dissemination

Dissemination of the trial results will be in summary form only; no identifying information about schools or individual participants will be available. Dissemination of the research findings could involve peer-reviewed scientific publications, reports, presentations at national or international conferences, or part of student research theses.

Analysis

Statistical analysis: Each primary trial outcome will be assessed using a separate linear mixed model under an intention-to-treat framework. The mean nutritional content (i.e. energy, saturated fat, sugar and sodium) of online lunch orders placed for an individual student will be compared between intervention and control groups at follow-up, adjusting for baseline values, and clustering within school (using a random school-level intercept). The linear mixed model will account for repeated measures of the trial outcome at the student and school level. To account for elevated type 1 error from multiple primary outcomes, a Holm-Bonferroni procedure will be used. A per protocol analysis will also be conducted to determine the effect of the intervention strategies being partially applied. Exploratory sub-group analyses will also be conducted, testing the average energy content per student lunch order for treatment group interactions by demographic characteristics (i.e. student grade – infants vs primary; and school sector) and purchasing characteristics (i.e. 1/+ orders per week vs <1 order per week). The trial data will be reported in adherence with the CONSORT 2010 guidelines[55] for reporting cluster randomised controlled trials.

Sample size calculation

As dose-response relationships exist between three of the four primary outcomes (saturated fat[56], sugar[57] and sodium[58]) and dietary related clinical health outcomes, the sample size calculation was based on the estimated between group differences in daily energy intake that would be required to offset unhealthy weight gain.[59] It is expected that approximately 194 students at each school will place at least one online lunch order during the baseline data collection period, and that 86% of those of students will order within the follow-up data collection period, and that 70% of orders are placed using a mobile device (and will be included in the analysis). Assuming that a standard lunch order has a standard deviation of 616kJ, and assuming an ICC of 0.05, the participation of 26 schools (13 each arm) would enable detection of a 195kJ difference between groups at follow-up with 80% power at the Bonferroni adjusted level of 0.0125 significance level (preserving a family-wise type 1 error rate of 5%).

Economic analysis

A trial-based economic evaluation involving costing, cost-consequence analysis and, subject to assessment of effectiveness, cost-effectiveness analysis, will be undertaken. The intervention will be compared against the control group (usual-practice) from a societal perspective. Resource use will be identified, measured and valued for the intervention development, implementation and sustainability stages. It will be assumed that control schools will incur no additional costs beyond the use of the online ordering system (i.e. usual practice). Micro costing will be used to calculate the system level and school level cost associated with the intervention. An incremental cost-effectiveness ratio (ICER) will be calculated as the difference in mean total cost divided by the observed difference in the primary outcome of kilojoules. Uncertainty analysis will be undertaken using non-parametric bootstrapping to derive uncertainty intervals (UIs) around the key variables as well as the cost-effectiveness acceptability curve. Sensitivity and scenario analysis will be undertaken to

test the impact of changing key design features of the intervention and scale-up of the implementation model.

DISCUSSION

This trial adopts a rigorous cluster randomised controlled design and tests the effectiveness of an intervention that is integrated into an existing online canteen system with wide reach throughout Australian schools. The intervention will be evaluated using routinely collected lunch order purchasing data from thousands of primary school students. The results should be considered in the context of the strengths and limitations of the research. The external validity of the findings may be limited given the application of this intervention only to primary schools from one Australian state, although the inclusion of all school types across socioeconomic strata is a strength. Furthermore, study findings may be limited due to the use of purchasing data as opposed to consumption data, and an inability to identify the person placing the order (i.e. a student ordering for themselves or a parent ordering on behalf of a student). Notwithstanding these limitations, it is anticipated that the trial results will be used to inform future implementation of public health nutrition interventions through school canteens and may be transferrable to other online systems for ordering food.

ETHICS AND DISSEMINATION

The study was approved by the University of Newcastle Human Research Ethics Committee (H-2017-0402), the NSW Department of Education and Communities (SERAP), and the Catholic Education Office Dioceses of Sydney, Parramatta, Lismore, Maitland-Newcastle, Bathurst, Canberra-Goulburn, Wagga Wagga, Wollongong and Wilcannia-Forbes. Study information statements and consent forms are available from the authors on request. Study results will be disseminated through presentations at relevant national and international conferences and to key stakeholders.

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AUTHOR'S CONTRIBUTIONS

Author RW led the development of this manuscript. Authors RW, LW, KB, KC, JW and CR secured the funding source. Authors RW, TD, and LW developed the intervention strategies. Authors TD, RW and LW determined the measures to be used, and authors JA, CO, RW and LW determined the analyses to be conducted. Authors (RW, TD, PG, KB, KC, SY, KS, RZ, CR, JW, JA, CO, RS, NN, KR, PR AND LW contributed to the research design and trial methodology and contributed to, read and approved the final version of this manuscript.

COMPETING INTERESTS

The authors have no competing interests to declare.

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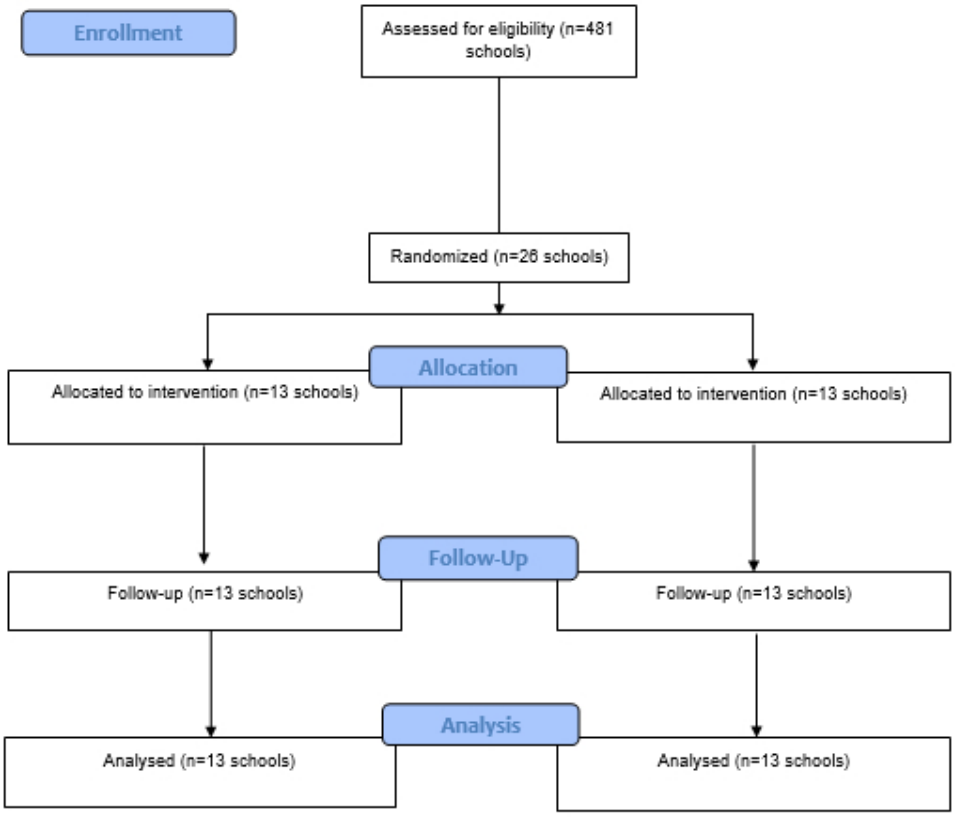
Enrollment
Assessed for eligibility (n=481 schools)
Randomized (n=26 schools)
Allocation
Allocated to intervention (n=13 schools)
Allocated to intervention (n=13 schools)
Follow-Up
Follow-up (n=13 schools)
Follow-up (n=13 schools)
Analysis
Analysed (n=13 schools)
Analysed (n=13 schools)

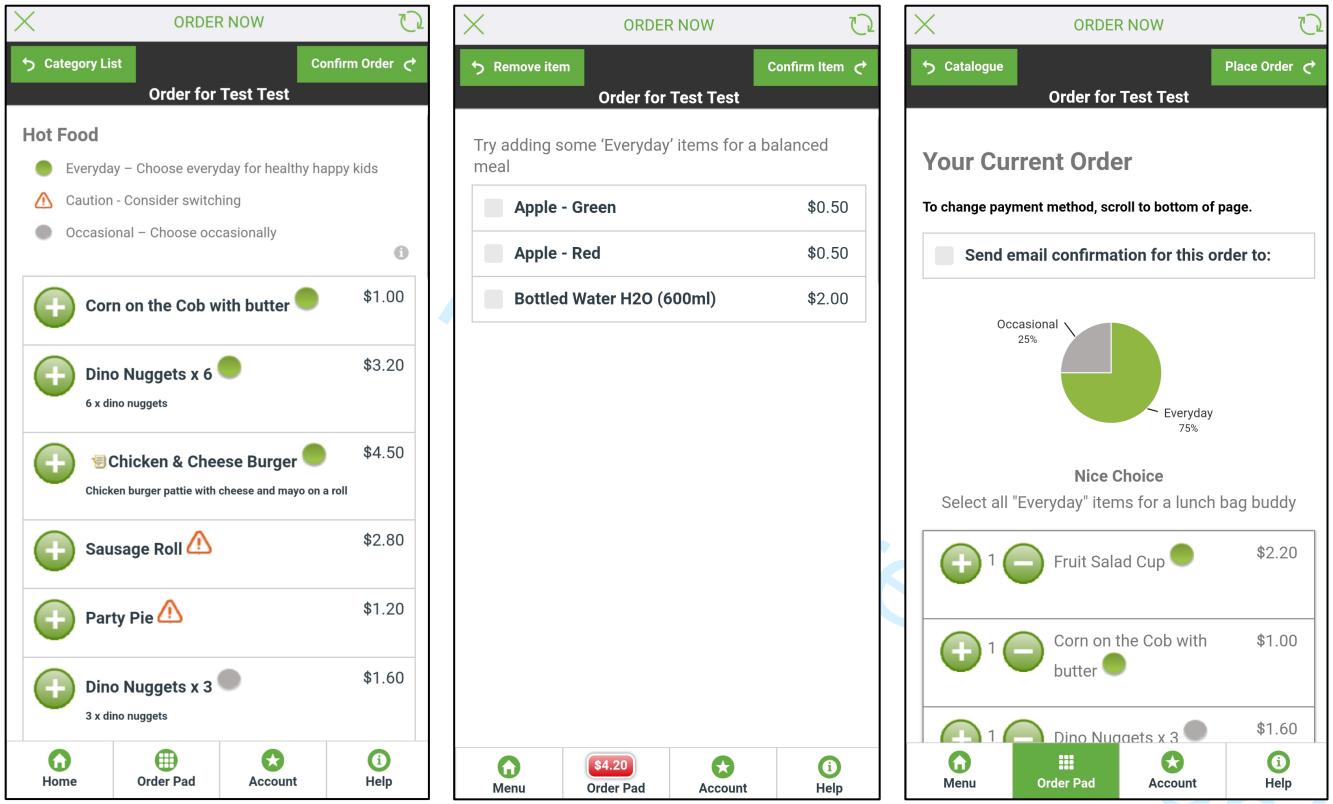

Figure 2. Screenshots from the Online Canteen Ordering System showing A) Menu labelling strategy & Placement strategy ('Everyday' first, 'Caution' middle, 'Occasional' last); B) Prompting – 'Add ons' for 'Occasional' or 'Caution' hot food items; C) Feedback – pie chart displaying the proportion of 'Everyday', 'Occasional' and 'Caution – consider switching' items contained within the lunch order.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
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	_3_____
	2b	All items from the World Health Organization Trial Registration Data Set	_1-15_____
Protocol version	3	Date and version identifier	_1_____
Funding	4	Sources and types of financial, material, and other support	_18-19_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1_____
	5b	Name and contact information for the trial sponsor	_NA_____
	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	_18-19_____
	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)	_18-19_____

Introduction			
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	__5-6_____
	6b	Explanation for choice of comparators	__6_____
Objectives	7	Specific objectives or hypotheses	__6_____
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, noninferiority, exploratory)	__6_____
Methods: Participants, interventions, and outcomes			
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	__6_____
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)	__6-7_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	__8-12_____
	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)	__6_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_12-13_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___9,14-15_____
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	__13-15_____
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)	___8_____

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	___17_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___6-7_____
Methods: Assignment of interventions (for controlled trials)			
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	__8_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	__8_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	__8_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___8,13_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___NA_____
Methods: Data collection, management, and analysis			
Data collection methods	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	8,14-16
	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	____N/A_____

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	___15_____
Statistical methods	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	____16-17_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	__16-17_____
	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)	____16-17_____
Methods: Monitoring			
Data monitoring	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_____ _
	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	_____N/A_____
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	_____14_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___12-13_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___18_____
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)	___9_____

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6-7
	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	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
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	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	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants andauthorised surrogates	Appendices
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

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.