The effectiveness of a multi-strategy behavioral intervention to increase the nutritional quality of primary school students’ online canteen lunch orders: The ‘Click & Crunch’ cluster randomized controlled trial

CONSORT-EHEALTH Checklist V1.6.2 Report
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1.6].

Date completed 12/7/2020 0:52:40
by Fiona Stacey

The intervention is a “multi-strategy behavioral intervention”

1a-i) Identify the mode of delivery in the title
The intervention is a “multi-strategy behavioral intervention”

1a-iii) Non-web-based components or important co-interventions in title
The intervention is a “multi-strategy behavioral intervention”

1a-iii) Primary condition or target group in the title
Included in title “increase the nutritional quality”

ABSTRACT

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT
Yes

“Schools with an online canteen lunch ordering system were randomly assigned to receive either a multi-strategy behavioral intervention which included choice-architecture strategies (menu-labeling, positioning, prompting, feedback and incentives) embedded in the online system (N=9 schools) or a control which received the standard online ordering system only (N=8 schools).”* 1b-ii) Level of human involvement in the METHODS section of the ABSTRACT
Yes

This study used a parallel group, cohort, cluster RCT design

2a-i) Problem and the type of system/solution
Yes - see paragraphs 2 & 3 in the introduction.

2a-iii) Scientific background, rationale: What is known about the (type of) system
Yes - see paragraphs 3 & 4 in the introduction.

Does your paper address CONSORT subitem 2b? Yes

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio
Yes

“Schools with an online canteen lunch ordering system were randomly assigned to receive either a multi-strategy behavioral intervention which included choice-architecture strategies (menu-labeling, positioning, prompting, feedback and incentives) embedded in the online system (N=9 schools) or a control which received the standard online ordering system only (N=8 schools).”* 3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Yes

“Although it was originally intended that government schools would be included, extensive delays in obtaining ethical approval meant that these schools were excluded, as the timeframe of intervention exposure would have been too short to warrant inclusion”.

3b-i) Bug fixes, Downtimes, Content Changes
Yes

There were initial issues with applying the ‘Healthy add-ons’ strategy, whereby users were overcharged for add-ons when the chosen menu item was ordered in multiples. This strategy was removed from all intervention menus for items that were commonly ordered in multiples (ie, chicken nuggets).

4a) CONSORT: Eligibility criteria for participants
Yes

“Schools were eligible if they used the Flexischools online canteen service and had done so for at least a month prior to recruitment.”* “Any student from kindergarten through to grade 5 who placed an online lunch order in the baseline data collection period was included in the study.”

4a-ii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT
Yes

“Schools were eligible if they used the Flexischools online canteen service and had done so for at least a month prior to recruitment.”*

4b) CONSORT: Settings and locations where the data were collected
Yes

“Online canteen lunch ordering systems were used as the basis for evaluation.”*

4b-i) Report if outcomes were (self-)assessed through online questionnaires
Yes

Outcomes were purchasing data automatically collected by the Flexischools system used as the basis for evaluation.

4b-ii) Report how institutional affiliations are displayed
Consent was provided at the school level. Affiliations were not displayed to parents or students.

5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered

3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Yes

“Although it was originally intended that government schools would be included, extensive delays in obtaining ethical approval meant that these schools were excluded, as the timeframe of intervention exposure would have been too short to warrant inclusion”.

5-i) Description of the intervention
Yes

The intervention being tested was embedded within an existing online system that was already in use. The number of children, orders, and items at each time-point is reported in the results section of the manuscript.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used
This is not possible as the intervention was embedded in an existing system. Screenshots and a description of the intervention components has been provided.
5-vi) Digital preservation
The intervention is not publicly available.

5-vii) Access
Yes. "Schools were eligible if they used the 'Flexischools' online canteen service and had done so for at least a month prior to recruitment. Flexischools is the largest provider of online canteen services in Australia, servicing over 1,200 schools, and processing over 13 million lunch orders a year [21]."

5-viii) Mode of delivery, features/functionality/components of the intervention and comparator, and the theoretical framework
Yes. See 'Intervention' section of the Methods.

5-ix) Describe use parameters
The intervention was applied to all items in the online ordering system.

5-x) Clarify the level of human involvement
The intervention is reported in full in the previously published protocol (Wyse et al 2019 http://dx.doi.org/10.1136/bmjopen-2019-030538).

5-xi) Report any prompts/reminders used
There are no prompts or reminders as part of the study.

5-xii) Describe any co-interventions (incl. training/support)
Yes. ‘An audit and feedback report was emailed to canteen managers and principals classifying each menu item as per the NSW Strategy (i.e. ‘Everyday’, ‘Occasional’, etc), and providing general information about pricing items to encourage healthy purchases [6].’

6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
Yes. Data is reported in the methods. "Student purchasing data automatically collected by the Flexischools system was used as the basis for evaluation. Data were collected at the same time for all schools, over two 8-week periods, 12-months apart (Term 2, 2018 and Term 2, 2019)." "The primary outcomes were the mean lunch order content of energy (kJ/kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams)." Secondary outcomes were: "The proportion of all lunch order items that were ‘Everyday’, ‘Occasional’, and ‘Caution’ was calculated by a dietitian using the criteria underpinning the NSW Strategy. The mean proportion of energy within lunch orders that was derived from: saturated fat; and sugar.”

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored
Not applicable

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained
Not applicable

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons
Yes. "Non-government (Catholic and Independent) primary schools within NSW, Australia were approached to participate by mail and telephone. “Student purchasing data automatically collected by the Flexischools system was used as the basis for evaluation.”

7a) CONSORT: How sample size was determined
Yes. "Recruitment of 26 schools and 194 students per school (allowing for 86% follow-up and 70% of orders placed using a mobile devices)”

7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines
Yes. Data is reported in the methods. "Student purchasing data automatically collected by the Flexischools system was used as the basis for evaluation. Data were collected at the same time for all schools, over two 8-week periods, 12-months apart (Term 2, 2018 and Term 2, 2019)." "The primary outcomes were the mean lunch order content of energy (kJ/kilojoules), saturated fat (grams), sugar (grams), and sodium (milligrams)." Secondary outcomes were: "The proportion of all lunch order items that were ‘Everyday’, ‘Occasional’, and ‘Caution’ was calculated by a dietitian using the criteria underpinning the NSW Strategy. The mean proportion of energy within lunch orders that was derived from: saturated fat; and sugar.”

8a) CONSORT: Method used to generate the random allocation sequence
Yes. "Following provision of principal (cluster) consent, and after the completion of the baseline menu assessment, an independent statistician used Microsoft Excel to randomize schools to an intervention or control group in a 1:1 ratio.”

8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)
Yes. "Using block randomization with block size between 2 and 4. Randomization was stratified by school sector (ie, Independent schools, and Catholic schools) and the socioeconomic status based on school postcode using Socio-Economic Indexes for Areas (SEIFA) [29]."" 

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Yes. "Using a randomised number function in Microsoft Excel in a 1:1 ratio” (reported in the previously published protocol: Wyse et al 2019 http://dx.doi.org/10.1136/bmjopen-2019-030538).

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Yes. "Following provision of principal (cluster) consent, and after the completion of the baseline menu assessment, an independent statistician used Microsoft Excel to randomize schools to an intervention or control group in a 1:1 ratio.”

11a) CONSORT: Blinding - if done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
11a-i) Specify who was blinded, and who wasn’t
Schools and parents were not blinded. "Due to the difficulty in blinding participants, this was run as an open trial.”

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”
Intervention schools were aware of the changes applied to their online system. "Control schools received no change to their online canteen menu and no audit and feedback report.”

11b) CONSORT: If relevant, description of the similarity of interventions
Not applicable

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes
Yes, clustering was accounted for in the analysis "Recruitment of 26 schools and 194 students per school (allowing for 86% follow-up and 70% of orders placed using a mobile devices)”

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses
A per-protocol and pre-specified sub-group analyses were undertaken "A per-protocol analysis was conducted to determine the effect on energy content (kJ) and proportion of ‘everyday’ foods when the intervention was applied in full. Schools were included if they had >80% of verifiable strategies correctly applied at follow-up, and if the incentive strategy was reported as present in the canteen manager survey. Pre-specified sub-group analyses were conducted based on energy content (kJ), student grade (kindergarten - grade 2 vs grade 3 - grade 5); school sector (Catholic vs Independent); and order frequency (≤ 1 order/week vs > 1 order/week)." Statistical analyses were performed using Statistical Analysis System (SAS) version 9.3 (SAS Institute, Cary, North Carolina, United States)."

13a) CONSORT: For each group, the number of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
Yes. "A total of nine schools were randomized to the intervention group and eight schools were randomized to the control. At baseline, the intervention group had 1,135 children; N=77,726 orders; N=23,526 items. At baseline, the control group had N=848 children; N=6,279 orders; N=1,14,124 items.

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons
Yes. "None of the schools dropped out of the study.”

13b-i) Attrition diagram
This information is not applicable

14a) CONSORT: Dates defining the periods of recruitment and follow-up
"Recruitment took place from May to September 2018 (17 weeks)."

14a-i) Indicate if critical “secular events” fell into the study period
Not applicable

14b) CONSORT: Why the trial ended or was stopped (early)
"None of the schools dropped out of the study.”

15) CONSORT: A table showing baseline demographic and clinical characteristics for each group
Reported in Table 1. Characteristics of the sample

15-i) Report demographics associated with digital divide issues
Not applicable
We did not collect any identifying information about individual participants. We have reported the socioeconomic status and proportion of Aboriginal and Torres Strait Islander enrolments for participating schools.

16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16b) Report multiple "denominators" and provide definitions

This is reported in Table 2. CONSORT diagram.

16c) Primary analysis should be intent-to-treat

"We adopted an intention-to-treat approach whereby all student orders and schools were analyzed based on the groups to which they were originally allocated, and included data from all students that had baseline purchasing data."

A per-protocol analysis was conducted to determine the effect on energy content (kJ) and proportion of 'Everyday' foods when the intervention was applied in full. Schools were included if they had >80% of verifiable strategies correctly applied at follow-up, and if the incentive strategy was reported as present in the canteen manager survey.

17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

These statistics are reported in Table 2. Primary and secondary outcomes in intervention and control groups from baseline to follow-up.

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended

"Yes. "From baseline to follow-up, relative to control schools, intervention schools had significantly higher purchases of 'Everyday' items purchased (OR: 1.7; P<0.001) corresponding to a 9.8% increase in 'Everyday' items, and lower odds of having 'Occasional' items purchased (OR: 0.7; P=0.001) corresponding to a 7.7% decrease in 'Occasional' items."

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Yes, a per-protocol and pre-specified subgroup analyses are reported.

- **There were no differences in intervention effectiveness with respect to energy content across: student grade, school sector or frequency of order (see Table 3).**

18b) Subgroup analysis of comparing only users

Yes "The per-protocol analysis of the five intervention schools that implemented the intervention in full, relative to control schools, showed larger significant effects for those of the four primary outcomes (-89.4kJ energy P=0.007, -0.7 grams of saturated fat P=0.001, -29.9 mg sodium P=0.0405) (See Table 2)."

19) CONSORT: All important harms or unintended effects in each group

Yes, revenue was examined as a potential adverse effect. "There was no between-group difference in the average weekly revenue from online canteen purchases over time (P=0.364)."

20) CONSORT: Qualitative feedback from participants or observations from staff/researchers

Not applicable

21) CONSORT: Generalisability (external validity, applicability of the trial findings)

Given evidence of its effectiveness, acceptability and wide reach, this intervention has potential to influence dietary choices at a population level. As such, further research is warranted to determine its impact in primary schools when implemented at scale, and to investigate its application in other online food ordering systems, such as secondary schools, workplaces, hospitals, and online-ordered home-delivered food.

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

"This trial investigated the effect of 'Click & Crunch' on the nutritional quality of students' online lunch orders. Intervention schools had significantly higher energy and saturated fat content relative to controls, but there was no significant difference in sugar or sodium content. Intervention schools had significantly greater odds of having 'Everyday' items purchased, and corresponding to a 9.8% increase in 'Everyday' items, and a 7.7% decrease in 'Occasional' items respectively. There was no impact on canteen revenue."

23) CONSORT: All unanswered new questions, suggest future research

"Given its effectiveness, acceptability and wide reach, this intervention has potential to influence dietary choices at a population level. As such, further research is warranted to determine its impact in primary schools when implemented at scale, and to investigate its application in other online food ordering systems (such as secondary schools, workplaces, hospitals, and online-ordered home-delivered food)."

24) CONSORT: Where the full trial protocol can be accessed, if available

https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618000855224

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

"The authors declare they have no conflicts of interest to report. This work is supported by the NHMRc, grant number APP1120233. In-kind support is provided by Hunter New England Population Health and the Hunter Medical Research Institute. RW is supported by a Heart Foundation Postdoctoral Fellowship (ID: 102165). LW receives salary support from a NHMRC Career Development Fellowship (ID: APP1128348) and Heart Foundation Future Leader Fellowship (ID: 101175). Neither the NHMRc nor the Heart Foundation had any role in the design of the study, data collection, analysis or interpretation, or dissemination of these findings. The protocol of this study was pre-specified and was selected through a competitive tender process. Flexischools is a commercial organization that provided the online canteen ordering infrastructure to schools that were included in the study. Flexischools had no role in the study design, data analysis, data interpretation or writing of the manuscript."

X26-ii) Outline informed consent procedures

The recruitment and consent process is reported in full. The protocol was pre-specified and was selected through a competitive tender process. Flexischools is a commercial organization that provided the online canteen ordering infrastructure to schools that were included in the study. Flexischools had no role in the study design, data analysis, data interpretation or writing of the manuscript.

X26-iii) Safety and security procedures

Purchasing data did not include any parent or child identifying details, and as such, there did not appear to be any reasonable expectation of harm.