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A cluster randomised controlled trial of a consumer behaviour intervention to improve healthy food purchases from online canteens: Study Protocol

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3 1 **A cluster randomised controlled trial of a consumer behaviour intervention to**
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5 2 **improve healthy food purchases from online canteens: Study Protocol**
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For peer review only

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3 28 **ABSTRACT**
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6 29 **Introduction:** School canteens represent an opportune setting in which to deliver public
7
8 30 health nutrition strategies given their wide reach, and frequent use by children. Online lunch
9
10 31 ordering services in school canteens provides an avenue to improve healthy canteen
11
12 32 purchases through the application of consumer behaviour strategies that impact on
13
14 33 purchasing decisions. The aim of this study is to assess the efficacy of a consumer
15
16 34 behaviour intervention implemented in an online school canteen ordering system in reducing
17
18 35 the kilojoule, saturated fat, sugar and sodium content of primary student lunch orders.
19

20
21 36 **Methods and analysis:** The study will employ a cluster randomised controlled trial design.
22
23 37 Ten primary schools in New South Wales, Australia currently using an online canteen
24
25 38 ordering system will be randomised in a 1:1 ratio to receive either the intervention (enhanced
26
27 39 system) or control (standard online ordering only). The intervention will include evidence-
28
29 40 based strategies shown to influence healthy food purchasing (strategies targeting
30
31 41 availability, menu labelling, placement and prompting). The primary outcomes of the trial will
32
33 42 be the mean content per student online lunch order of i) energy (kilojoules), ii) saturated fat
34
35 43 (grams) iii) sugar (grams), and iv) sodium (milligrams). The impact of the intervention will be
36
37 44 determined by between group assessment of the nutritional content of lunch purchases over
38
39 45 a 2-month period post-intervention commencement.
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41

42 46 **Ethics and dissemination:** The study was approved by the Hunter New England Human
43
44 47 Research Ethics Committee, University of Newcastle Human Research Ethics Committee
45
46 48 and New South Wales Department of Education and School Communities. Study findings
47
48 49 will be disseminated widely through peer-reviewed publications and relevant presentations in
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50 50 international conferences and to stakeholders.
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3 52 **STRENGTHS & LIMITATIONS**
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6 53 • The study is the first trial globally of an intervention to improve online food purchases
7
8 54 from primary school canteens. It represents a highly significant advance in
9
10 55 knowledge in the field of school-based public health nutrition and provides seminal
11
12 56 research for future work in the setting.
13
14 57 • The study is highly innovative and introduces a number of new approaches to
15
16 58 improving healthy food purchases from school canteens that could transform public
17
18 59 health intervention.
19
20 60 • The trial utilises the most internally valid research design (RCT), includes objective
21
22 61 measures of trial outcomes, and has been powered to detect small but meaningful
23
24 62 population-level intervention effects.
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63 BACKGROUND

64 Globally, poor diet (including excess intake of foods high in energy, saturated fat, added
65 sugars and salt) is one of the leading causes of non-communicable diseases including
66 cardiovascular disease, type 2 diabetes and cancer.¹⁻² Given that dietary behaviours in
67 childhood track into adulthood and are predictive of future non-communicable disease risk³,
68 improving child nutrition is a public health priority in Australia and internationally.^{1 4}

69 Schools are a promising setting to improve child nutrition^{1 5} as they provide prolonged,
70 centralised access to almost every child in high income countries. Australian children
71 consume almost 40% of their recommended energy intake while at school,⁴ with up to 72%
72 of primary-school aged children purchasing their lunch from school canteens at least
73 weekly.⁶ The foods ordered from such canteens however are typically high in energy, fat,
74 sugar and salt, from products such as pies and sausage rolls (consumed regularly by 54% of
75 students), pizza products (30%), processed chicken (29%) and hot dogs (18%).⁷ Therefore,
76 interventions to improve the nutritional quality of foods purchased at school canteens are a
77 key opportunity to improve child nutrition.⁵

78
79 Findings of a recent systematic review of 18 school food environment studies suggest that
80 modifying the relative availability of food for sale from school food services is associated with
81 improvements in the purchase or consumption of healthy foods by students.⁸ Similarly,
82 school based research in the U.S. has found that a number of point of purchase strategies to
83 influence consumer behaviour such as nutrition labelling⁹; prompting¹⁰ and the placement of
84 menu items (including the order, prominence and access of items)^{11 12} are associated with
85 the selection, purchase or consumption of healthier foods by students.

86
87 Online school canteen ordering systems, which enable students to order their lunch meals
88 from the school canteen via the web, are becoming increasingly common in Australia.¹³⁻¹⁵
89 Such systems provide a platform to implement evidence-based consumer behaviour change

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3 90 strategies to support healthy purchasing choices by students and parents. Specifically, the
4
5 91 online environment of these systems provides a controlled but dynamic infrastructure that
6
7 92 enables implementation of a range of strategies that can reach large numbers of individuals
8
9 93 at a relatively low cost.¹⁶ For example, point of purchase nutrition labelling, product
10
11 94 placement and prompts, strategies that are routinely used by online food retailers to
12
13 95 influence purchase decisions of consumers¹⁷ can be readily deployed to influence the
14
15 96 purchase choices of a large number of students and parents. Despite the potential benefits
16
17 97 of implementing these strategies to promote healthy online school canteen purchases, there
18
19 98 have been no previous trials of their application to online school canteen ordering systems.
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22 99 **Study Aim**

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25 100 In this context, the purpose of this study is to assess the efficacy of a consumer behaviour
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27 101 intervention implemented in an online school canteen ordering system in reducing the
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29 102 kilojoule, saturated fat, sugar and sodium content of primary student lunch orders.
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31 103

32 33 34 104 **METHODS**

35 36 37 105 **Trial Design**

38
39 106 The cohort study will employ a parallel group, cluster randomised trial design. Ten primary
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41 107 schools located in New South Wales (NSW) Australia with an existing online canteen
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43 108 ordering system will be randomised to receive either a 2-month consumer behaviour
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45 109 intervention (enhanced system) or control (standard online ordering only). The efficacy of the
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47 110 intervention will be determined by assessing between group differences at follow up in the
48
49 111 average i) energy (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium
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51 112 (milligrams) content of a cohort of students who had made an online lunch order during the
52
53 113 baseline period. Student purchase data will be automatically collected by the online canteen
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55 114 system. Outcome data will be assessed at baseline and for the 2-month period following
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57 115 introduction of the intervention.
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3 116 **Setting**
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6 117 The study will take place in the state of New South Wales, Australia, a geographically large
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8 118 state including large metropolitan and non-metropolitan areas with a demographically and
9
10 119 socioeconomically diverse population of approximately 455,000 primary aged children and
11
12 120 1,600 government primary schools.¹⁸ Children attend primary school from the age of 5 to
13
14 121 the age of 12, with government schools being the major provider of school education
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16 122 (65.2%).¹⁹
17

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19 123 **Participants**
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22 124 *Schools*
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24 125 To be eligible, schools must be a government primary school in NSW with an operational
25
26 126 canteen that has been using the online lunch ordering system supplied by a single specific
27
28 127 provider (henceforth referred to as 'the provider') for at least 6 months. In addition, schools
29
30 128 must process a minimum of 50 student online lunch orders per month. Special purpose
31
32 129 schools that exclusively enrol students with special needs, juvenile justice schools, schools
33
34 130 serving hospitalised children or schools with externally licensed canteens will be excluded
35
36 131 due to the potential differences in the provision of foods in these settings. A research
37
38 132 assistant will screen the school's online menu, and any school already employing point of
39
40 133 purchase nutrition labelling strategies (same as that of intervention) will be excluded.
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43 134 *Students*
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46 135 All users of the online school canteen ordering system (e.g. children or parents ordering on
47
48 136 behalf of their children) who place an online lunch order during the 2-month baseline data
49
50 137 collection period will be eligible for study inclusion. Other users of the school's online
51
52 138 canteen ordering system such as teaching staff, as identified by the online provider, will be
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54 139 excluded.
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140 **Recruitment Procedures**

141 A list of schools will be supplied by the provider and screened for eligibility by the research
142 team. A convenience sample of schools will be invited to participate via mail and telephone
143 with recruitment continuing until the required sample of schools consent to participate. The
144 recruitment strategy will employ effective recruitment practices within the school setting.²⁰
145 Specifically, one member of the research team will act as a dedicated recruitment
146 coordinator. The coordinator will manage the recruitment of schools into the trial and monitor
147 consent rates. Schools will be provided with the direct phone number of the trial manager
148 for any enquiries regarding the research. Study information statements will be mailed to
149 school Principals inviting study participation. Specifically, consent will be sought for
150 permission for the research team to access de-identified data regarding canteen lunch order
151 purchases, user demographics and usage characteristics of the online ordering system. As
152 de-identified student purchase data is accessed via a school controlled database, all data
153 will be utilised and individual student consent will not be sought. Two weeks after sending
154 the information statements, a research assistant will make multiple attempts to contact
155 schools via the phone to confirm eligibility, answer any questions regarding the trial, and
156 invite participation. Following consent, the online provider will supply baseline lunch order
157 purchase data (the 2-month operational period immediately preceding intervention
158 commencement) of students, in a non-identifiable format, to the research team to assess the
159 primary trial outcomes.

160 **Randomisation and blinding**

161 Following school recruitment, an independent statistician will use a computerised random
162 number function in Microsoft Excel to randomise schools to either an intervention or a control
163 group. Randomisation will occur at the unit of the school in a 1:1 (intervention: control) ratio
164 in randomly sequenced blocks of two and four to ensure the number of schools allocated to
165 each group remains approximately equal (see Figure 1).²¹ Given evidence that
166 socioeconomic status of the locality may be associated with the relative healthiness of

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2
3 167 student purchasing patterns⁷, randomisation will be stratified by the socioeconomic status of
4
5 168 a school locality based on school postcode.²² Due to the difficulty in blinding the users of the
6
7 169 online system to the changes introduced, the study will be conducted as an open trial
8
9 170 however parent and student users will not specifically be informed of the experimental
10
11 171 manipulation of the study. Furthermore, the study statistician undertaking the primary
12
13 172 analyses will be blinded to group allocation.

14 15 16 173 **Intervention Development and Theoretical framework**

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18
19 174 A consumer behaviour intervention will be integrated into the existing schools online canteen
20
21 175 ordering system operated by the provider. The intervention draws on the principles of choice
22
23 176 architecture.²³ This approach posits that consumer behaviour is influenced by social and
24
25 177 physical environments through conscious (e.g. reflective) and unconscious (automatic)
26
27 178 processes.²³ Choice architecture strategies alter the environments in which decisions are
28
29 179 made, in this case, to cue healthier purchasing choices. Consumer behaviour interventions,
30
31 180 based on choice architecture, typically require minimal conscious engagement by the
32
33 181 consumer and can include: the provision of information (prompting, labelling, feedback);
34
35 182 altering of the physical environment (e.g. altering the placement of products including
36
37 183 accessibility, position or proximity, lighting, décor etc) or the properties of products or stimuli
38
39 184 within an environment (packaging, presentation, functionality) to cue desirable behaviour.²³
40
41 185 ²⁴ The intervention component selection for this study was guided by the choice architecture
42
43 186 typology proposed by Holland et al.²³ Intervention selection was developed in consultation
44
45 187 with a multi-disciplinary team of experts including; health behaviour scientists, dietitians,
46
47 188 canteen staff, parents, software providers and developers. The consumer behaviour
48
49 189 strategies were included in the intervention if they were i) supported by empirical evidence of
50
51 190 beneficial effect in food-service settings;^{10 25 26} ii) considered appropriate and acceptable to
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53 191 school principals²⁷ and parents²⁸ and iii) able to be feasibly operationalised within the
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55 192 providers online ordering system.
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3 193 **Intervention strategies**
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6 194 The intervention seeks to encourage consumer purchase of healthier foods and beverages
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8 195 for school lunch orders, that is, food items lower in energy, saturated fat, sugar, and/or
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10 196 sodium. All users of the online canteen ordering system at intervention schools will be
11
12 197 exposed to the intervention. Contamination of intervention components between groups will
13
14 198 be minimised by randomisation at the school level, and by the provider preventing user
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16 199 access to the intervention by control group schools. The intervention incorporates the
17
18 200 following evidence based strategies that have previously been associated with healthier
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20 201 consumer choices in analogous settings.^{10 25 26}
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22
23 202 **Availability:** Canteen managers will be supported by the research team to improve the
24
25 203 relative availability of healthier items listed on their online canteen menu. Research in the
26
27 204 school food setting has found a positive association between increased availability of healthy
28
29 205 foods and improved purchasing behaviour of students.²⁹ Therefore, a trained dietitian,
30
31 206 experienced in canteen menu assessment, will classify all foods and beverages listed on the
32
33 207 canteen menu as 'red' (low in nutritional value), 'amber' (moderate nutritional value) or
34
35 208 'green' (high nutritional value) according to the NSW government school canteen policy
36
37 209 'Fresh Tastes @ School'.³⁰ The dietitian will prepare and provide a comprehensive menu
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39 210 feedback report to schools encouraging canteen managers to improve the relative
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41 211 availability of healthy items by increasing the proportion of 'green' menu items or removing
42
43 212 'red' menu items.^{31 32} These reports will be distributed once via email to both the canteen
44
45 213 manager and Principal, immediately prior to the redesigned canteen menu being uploaded
46
47 214 online. A brief phone call (of approximately 15 minutes) will be made to the canteen
48
49 215 manager and/or Principal to discuss contents of the feedback report.
50

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53 217 **Labelling:** Labelling involves the application of written or graphical feedback or information
54
55 218 endorsing a product at the point of purchase or point of choice.²³ This strategy will comprise
56
57 219 of the following components within the online system:
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3 220 *Traffic light labels* – A single red, amber or green circle will be added beside each menu
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5 221 item.²⁵ The traffic light label will be based on Fresh Tastes @ School.³⁰ Traffic light labels,
6
7 222 compared to other forms of labelling (e.g. nutrient labelling), are more likely to be noticed by
8
9 223 parents when making purchase decisions for their children from food settings.³³
10
11 224 Furthermore, compared to other labelling systems, traffic light labels are preferred by both
12
13 225 adults and children,³⁴ are more easily understood and more effective in helping consumers
14
15 226 to correctly identify healthier food products.³⁵

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18 227 *Label Guide* – An explanation of the relative healthiness of ‘green’, ‘amber’ and ‘red’ foods²⁵
19
20 228 ³⁶ will appear at the top of the online canteen website and will pop up when a user hovers
21
22 229 their cursor over each traffic light label.

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25 230 *Descriptions* – ‘Green’ menu items that require onsite preparation (e.g. salads, sandwiches,
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27 231 homemade hot meals) will receive an appealing description directly under item name (eg
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29 232 “super salad tub”). Research in the restaurant setting has demonstrated that creative
30
31 233 descriptions applied to menu items have been associated with an increase in sales by up to
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33 234 27%.³⁷ Research in the school setting has similarly shown that adding creative names to
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35 235 healthy food items (eg “x-ray vision carrots”) is associated with increases in children’s
36
37 236 consumption of the item.⁹

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40 237 **Placement:** Placement strategies will be employed to alter i) the position of menu items to
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42 238 make them appear more immediately prominent and ii) the accessibility of menu items to
43
44 239 make healthier choices easier to select and less healthy choices harder to select.²³

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46 240 Evidence suggests that items that are placed at the beginning or the end of the menu
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48 241 section were selected up to twice as frequently as when they were placed in the centre of
49
50 242 the list.²⁶ Therefore, healthier menu categories (i.e. fruit, sandwiches, salads) and items
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52 243 within categories will be ordered to give healthy items positions of greatest prominence; i.e.
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54 244 ‘green’ items will be positioned first; ‘red’ items will be located in the middle; and ‘amber’
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56 245 items will be positioned last in a food list. Where there are multiple flavours of a ‘red’ or
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3 246 'amber' food, users will be required to first 'click' on the category before the full list of items
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5 247 are displayed. For example, for a user to select a flavour of potato crisps they will first be
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7 248 required to click on that product category ('crisps') then select their preferred flavour in a
8
9 249 separate pop up box. Conversely, all available flavours of 'green' items will appear in the
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11 250 main website interface without requiring further selection actions.

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14 251 **Prompting:** Standardised written and graphical information intended to promote or raise the
15
16 252 awareness of, or the motivation for a given behaviour will be included in the online menu.
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18 253 Motivational written and graphical prompts will be used to promote and encourage selection
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20 254 of healthy items. For example, healthier menu categories (i.e. sandwiches, salads, fruit) will
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22 255 be accompanied by positive purchase prompts (e.g. "This is a good choice") and an
23
24 256 appealing image representing the category.¹⁰ When users select a red or amber hot food
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26 257 item they will also be prompted with a list of green menu items, 'meal extras', which typically
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28 258 include bottled water, fresh fruit or vegetable pieces, to add to their order.
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31 259 Once implemented the intervention will remain operational across the entire study period.
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260 **Table 1.** Intervention strategies informed by Choice Architecture Framework proposed by Hollands et al²³

| Strategy | Description | Application |
|---------------|---|---|
| Availability* | Schools will receive a comprehensive feedback report including strategies to improve the relative availability of healthy foods including: <ul style="list-style-type: none"> • A colour-coded copy of their menu, • Graphical feedback comparing their menu to the 'Fresh Tastes' target of >50% green and 0% red • Tailored advice for how to amend the menu to be compliant with the policy • Web links for additional support. | If availability of items are modified by the school or canteen this changes the capacity for user (parent or child) to select healthy vs less healthy foods |
| Labelling | Each menu item will display a single round traffic light label | Provides nutritional information about the food at point of purchase Promotes awareness of and thus motivation for a making a healthy purchase |
| | The menu will include information on how to use the label when selecting menu items (eg 'best choice', 'select carefully', 'select occasionally") | Facilitates interpretation of label Provides easily understood information about the healthiest choice |
| | Healthy menu items will include a hedonic description directly under the item name. | Provides incidental cues to induce non-conscious behavioural response (makes product more appealing) Makes healthy menu items more salient |
| Placement | Healthy menu categories (e.g. fruit, sandwiches, salads) and 'green' items within a category will be listed first. | Makes healthy menu items more salient, convenient and maximises opportunity for engagement with these items. |
| | Healthy items (green) will be listed in main website interface | Facilitates engagement with behavioural options by making healthy food more convenient/accessible |
| | Placement: Amber and red menu items with multiple flavours will require users to 'click' / explode the item before the full list of flavours are displayed. | Makes less healthy menu items harder to engage with therefore less convenient/accessible |
| Prompting | Amber and red hot item will include a prompt to add a healthy drink (water) or snack (fruit and/or veg) to the lunch order | Raises awareness of a given behaviour Makes it easier to access healthy food options |
| | Healthy food categories (eg sandwiches, salad, fruit) will appear in bold font, have an image, and a positive food prompt eg 'this is a good choice' | Provides general encouragement Promotes motivation for a given behaviour |

261 *This strategy aims to increasing healthy foods and involves providing the school with feedback on how to restrict availability of unhealthy foods in line with

262 Fresh Tastes @ School policy

263 **Intervention Integrity**

264 A dietitian will use the colour coded menu items to redesign the menu for online display
265 using a standardised template ('menu template'). This template has been pilot tested and
266 refined based on feedback by the dietitian and the provider. The completed menu template
267 will be sent via email to the provider who will 'upload' the schools online menu as per
268 specifications in the menu template. This process will be managed centrally by the online
269 provider. After the menu is uploaded but prior to being operationalised, the research team
270 will be able to view the redesigned menu in order to confirm that the strategies have been
271 applied and uploaded correctly. In order to monitor and manage intervention integrity, once
272 the redesigned menu is operational, the online provider will supply the research team with 2
273 reports (start and mid-intervention) listing any changes that have been made to the online
274 menu by the school. These reports will enable the research team to identify new menu items
275 that have been added. The research team will then label and position new menu items
276 according to the menu template and contact the provider to make the required changes.

277 **Control Group**

278 Schools allocated to the control group will continue to receive the standard online lunch
279 ordering service and will not have access to the intervention until after follow-up data
280 collection at which point they will be offered access to supportive strategies.

281 **DATA COLLECTION PROCEDURES & MEASURES**

282 **Primary Outcomes:**

283 The primary trial outcomes are: the mean content per student online lunch order of i) energy
284 (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium (milligrams). Given the
285 effect of similar interventions have been reported to be immediate,³⁸ the primary trial
286 endpoint is two months post intervention commencement (during which the canteen is
287 operational). Primary trial outcomes will be collected at baseline (the 2-month operational

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3 288 period immediately preceding intervention commencement) and follow-up (the 2-month
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5 289 period operational period post-intervention commencement). Data from all purchases
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7 290 occurring during the baseline and follow-up assessment periods for the cohort of students
8
9 291 will be used to determine the trial outcomes.

10
11 292 Data collection procedures will be in accordance with previous canteen trials conducted by
12
13 293 the research team.³¹⁻³² Specifically, a dietitian will contact the canteen manager over the
14
15 294 phone to obtain nutrition information of canteen menu items available online. For pre-
16
17 295 packaged menu items the canteen manager will be asked to specify brand name, product
18
19 296 name and serve size. The nutritional profile of each pre-packaged item will be obtained by
20
21 297 searching the 'brand', 'product name' and 'serve size' in a canteen product database
22
23 298 consisting of over 1,300 commonly stocked school canteen items developed by the research
24
25 299 team.³⁹ If the menu item is not listed in the canteen product database, the dietitian will use a
26
27 300 publicly available database of commercial items (Foodswitch ®) to obtain the nutrition
28
29 301 information panel.⁴⁰ If the item cannot be located in either database the dietitian will contact
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31 302 the manufacturer to obtain the nutrition information panel. If the dietitian cannot obtain the
32
33 303 nutrition information panel from the manufacturer a 'generic' nutrient profile will be assigned
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35 304 using a commercial equivalent found in the canteen product database.

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39 305 For menu items that are not packaged (e.g. freshly made foods such as sandwiches,
40
41 306 canteen made hot foods and snacks), dietitians will request a copy of the recipe from the
42
43 307 canteen manager including recipe yield, ingredients and serve size. Dietitians will then use a
44
45 308 commercially available Australian nutrition database (Foodworks®)⁴¹ to create a nutrient
46
47 309 profile for this item (e.g. a ham, cheese and tomato sandwich). In the absence of a complete
48
49 310 recipe, a 'generic' nutrient profile will be created using a commercial equivalent found in the
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51 311 canteen product database.
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3 312 Using the nutritional profile data, a dietitian will determine the nutrient profile (kilojoules,
4 313 saturated fat, sugar, sodium) and *Fresh Tastes* classification (red, amber, green)³⁰ for each
5
6 314 menu item.
7
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9
10 315 To enable calculation of the primary trial outcomes, the nutrition profile for each menu item
11 316 will be applied to purchasing data obtained by the provider to generate a nutritional profile for
12 317 each individual order placed. A unique de-identified numerical identifier by the provider will
13 318 be used to link student orders across and within baseline and follow-up data collection
14 319 periods.
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21 320 **Secondary Outcomes:**
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23 321 *Nutrition quality:* 1) The proportion of all student lunch orders that are i) green and ii) red;
24 322 and 2) the mean percent of energy of lunch orders from i) sugar; and ii) saturated fat per
25 323 student online lunch order will be collected at baseline (the 2-month operational period
26 324 immediately preceding intervention commencement) and follow up (the 2-month operational
27 325 period post-intervention commencement) and compared between groups at follow up. The
28 326 colour code and percent energy from saturated fat and sugar will be based on the dietitian's
29 327 nutritional assessment of the purchasing data recorded by the online ordering system
30 328 (described above). Conversion of sugar and saturated fat to energy will be based on
31 329 internationally accepted conversion factors of 17kj per gram and 37kj per gram
32 330 respectively.⁴²
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44 331 *Revenue:* Revenue data will be automatically collected and supplied by the online provider.
45 332 The average weekly online canteen revenue will be assessed at baseline (the 2-month
46 333 operational period immediately preceding intervention commencement) and follow-up (the 2-
47 334 month operational period post-intervention commencement). The average weekly online
48 335 canteen revenue will be compared between groups to assess any detrimental or beneficial
49 336 impact of the intervention on school revenue that may affect the sustainability of the
50 337 intervention.
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3 338 **Other data:**

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5 339 *School Characteristics:* School level data including school size (number of enrolments), year
6
7 340 range (e.g. Kindergarten to grade 6), and school postcode will be collected from the 'My
8
9 341 School' website.⁴³

10
11
12 342 *User characteristics:* Child school grade, and the recorded user (parent or child) will be
13
14 343 collected from the online ordering system. Online canteen usage data (e.g. frequency of
15
16 344 placing an order, the device used to place the order, the time taken to place the order) is
17
18 345 automatically collected by the system, and will also be accessed by the research team.

19
20
21 346 *Canteen Manager Survey:* After the collection of follow-up purchasing data (2 months
22
23 347 operational period post-intervention), canteen managers will be contacted to take part in a
24
25 348 telephone survey to determine i) canteen characteristics (type of canteen operation (leased,
26
27 349 P&C run, school run); staffing (paid or unpaid), profit and; ii) the acceptability of the
28
29 350 intervention strategies.

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32 351 School characteristics, user characteristics and canteen manager survey data will be
33
34 352 collected and used for descriptive purposes.

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37 353 *Availability of menu items:* 1) The proportion 'green' items available on the menu and 2) The
38
39 354 proportion of 'red' items available on the menu will be assessed at baseline (immediately
40
41 355 prior to intervention commencement) and follow-up (2-months post-intervention
42
43 356 commencement). Copies of each school's canteen menu will be obtained during baseline
44
45 357 data collection period (immediately after the school consents into the trial) and on the last
46
47 358 day of the follow-up data collection period. Each menu will be independently audited by two
48
49 359 dietitians consistent with previous studies.^{31 32} The menu audit procedure will involve
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51 360 assigning each item a colour-code (as per the Fresh Tastes @ School guidelines) and
52
53 361 calculating the proportion of each colour on the menu, in accordance to procedures
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55 362 previously described elsewhere.^{31 32 39}

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3 363 **ANALYSIS & SAMPLE SIZE**
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6 364 **Analysis:**
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9 365 The analyses will be undertaken by a statistician blinded to group allocation, with no other
10 366 involvement in the trial. Intervention effectiveness will be assessed using a separate linear
11 367 mixed model⁴⁴ for each primary outcome under an intention to treat approach⁴⁵: energy
12 368 (kilojoules), saturated fat (grams), sodium (milligrams), and sugar (grams). The average
13 369 nutritional content (e.g. mean kilojoule content) will be calculated across all online lunch
14 370 orders placed by a student during the follow-up data collection period and compared
15 371 between intervention and control groups, adjusting for clustering at the school level and
16 372 controlling for baseline values. The mixed model will account for repeated measures of the
17 373 trial outcome at the student and school level. All students that place an order during the
18 374 baseline period will be included in the primary analysis. Missing data could arise at follow up
19 375 due to a student not placing an online lunch order during the follow up period. Multiple
20 376 imputation will be used for any missing data at follow-up as recommended by White and
21 377 colleagues as part of a sensitivity analysis.⁴⁶ Exploratory sub-group analyses will also be
22 378 conducted, testing for treatment group interactions by demographic (i.e. student grade) and
23 379 purchasing characteristics of the sample.
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41 380 The trial data will be reported in adherence with the CONSORT 2010 guidelines for reporting
42 381 clustered randomised controlled trials. The trial has been prospectively registered with the
43 382 Australian New Zealand Clinical Trials Registry ACTRN12616000499482
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48 383 **Sample size calculation:**
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51 384 Given there are dose response relationships between intake of saturated fat⁴⁷, sugar⁴⁸, and
52 385 sodium⁴⁹ and important clinical health outcomes, including precursors for chronic disease
53 386 (such as blood pressure) the sample size calculation was conducted based on estimated
54 387 changes in energy intake between groups where a reduction of a defined magnitude is
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3 388 required to accrue health benefit at the population level. Specifically, at a population level,
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5 389 reductions in energy intake of just 172kJ have been estimated to offset unhealthy weight
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7 390 gain among children⁵⁰ and in doing so reduce population level risk for chronic disease.
8
9 391 Assuming that 104 students per school, place at least one online lunch order over the data
10
11 392 collection period, and assuming that a standard student lunch order contains 1729kJ
12
13 393 (sd=700) (unpublished data from research team) with an ICC of 0.05, the participation of 10
14
15 394 schools (5 each arm) in the trial would enable detection of a 303kJ, difference between
16
17 395 groups at follow-up with 80% power at the 0.05 significance level. A change of this
18
19 396 magnitude is considered clinically meaningful to detect a change in population body
20
21 397 weight.^{50 51}

24 398 **DISCUSSION**

27 399 This will be the first study to examine the efficacy of a consumer behaviour intervention on
28
29 400 purchasing behaviour from primary school canteens and will represent a substantial advance
30
31 401 in knowledge in the field of school-based public health nutrition. The results from this trial will
32
33 402 inform policy makers and practitioners working in the field of child nutrition and public health.

37 403 **ETHICS & DISSEMINATION**

39 404 Ethical approval to conduct the study has been obtained from the Hunter New England
40
41 405 Human Research Ethics Committee (reference: 06/07/26/4.04) University of Newcastle (Ref.
42
43 406 No. H-2008-0343), NSW Department of Education and Communities (SERAP 2012277).
44
45 407 Evaluation data and process data collected as part of the study may be presented at
46
47 408 scientific conferences, be published within scientific journals, form part of student theses.
48
49 409 Participant's confidentiality will be maintained.

53 410 **AUTHORS CONTRIBUTION**

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2
3 411 TD led the development of this manuscript. RW, TD, LW conceived the intervention concept.
4
5 412 JW, LW, RW, RS, SLY, KC, KB, CR, TD contributed to research design and trial
6
7 413 methodology. All authors contributed to and approved final version of this manuscript.
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9

10 414 **FUNDING STATEMENT**

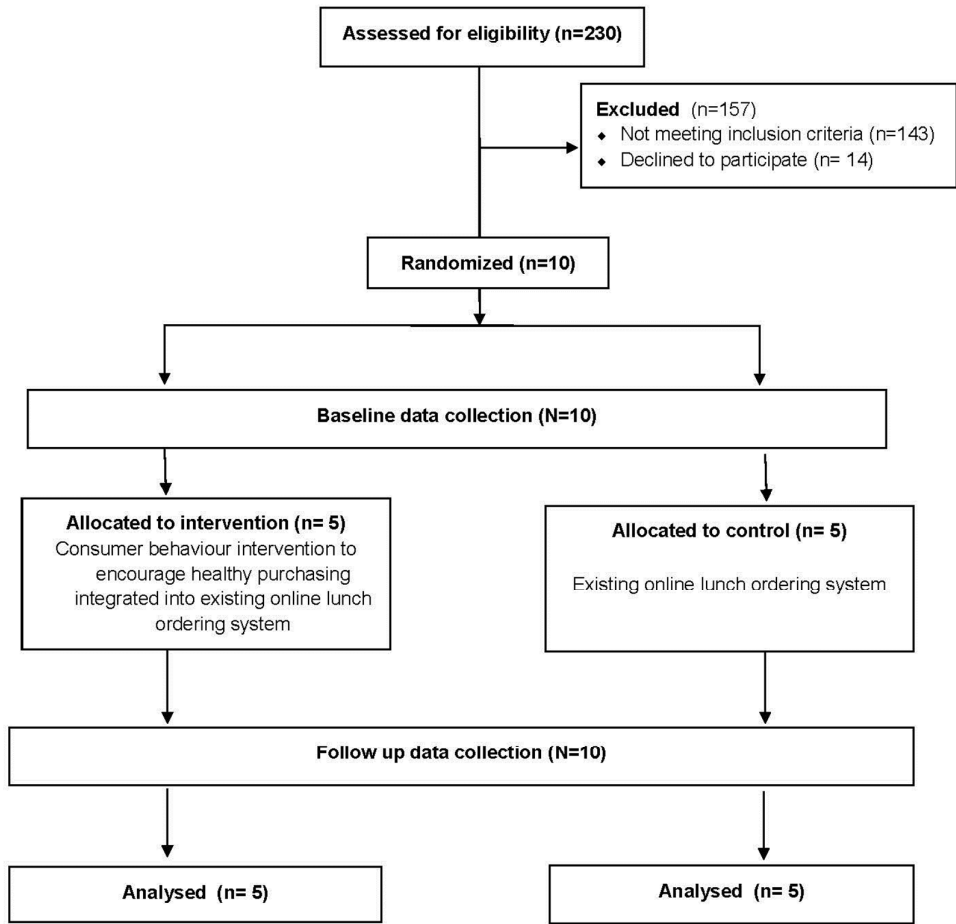
11
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17
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21
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23
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27
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29
30 424 this manuscript are the responsibility of the authors and do not reflect the views of the
31
32 425 NHMRC.
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36 426 **COMPETING INTERESTS**

37
38 427 The online provider (Flexischools) was selected through a competitive tender process.
39
40 428 Flexischools is a commercial organization which provided online canteen ordering
41
42 429 infrastructure to schools included in the study. Flexischools had no role in the study design,
43
44 430 data analysis, data interpretation, or writing of the manuscript.
45
46

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48
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50
51 433 Flexischools for enabling the research to be undertaken using their online canteen ordering
52
53 434 infrastructure.
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436 **Figure 1.** Estimated participant flow through trial. Numbers based on best available
437 information at time of submission

Peer Review Only

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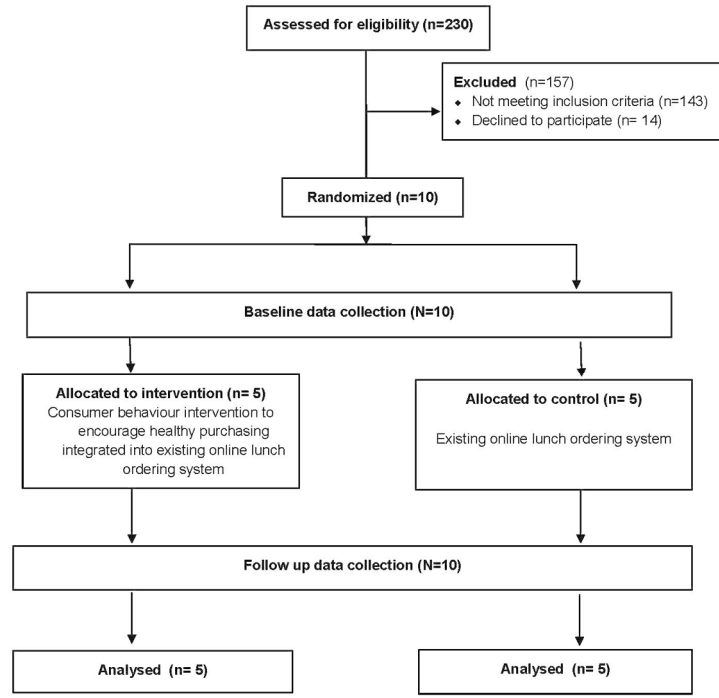


Figure 1. Estimated participant flow through trial. Numbers based on best available information at time of submission

Figure 1
210x297mm (200 x 200 DPI)



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 | 1 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | N/A |
| Protocol version | 3 | Date and version identifier | 2 |
| Funding | 4 | Sources and types of financial, material, and other support | 19 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 |
| | 5b | Name and contact information for the trial sponsor | 1, 18-19 |
| | 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) | N/A |

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 | 4-5 |
| | 6b | Explanation for choice of comparators | N/A |
| Objectives | 7 | Specific objectives or hypotheses | 5 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 5 |

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 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 8-13 |
| | 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) | N/A |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 13 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | |
| 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) | 20 |

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| 1 | | | | |
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| 3 | 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 | 17-18 |
| 4 | | | | |
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| 6 | Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 |
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8 **Methods: Assignment of interventions (for controlled trials)**

9 Allocation:

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| 12 | Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 7-8 |
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| 18 | 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 | 7-8 |
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| 22 | Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 7-8 |
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| 25 | Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 7-8 |
| 26 | | | | |
| 27 | | | | |
| 28 | | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | N/A |
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32 **Methods: Data collection, management, and analysis**

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| 33 | | | | |
| 34 | 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 | 13-15 |
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| 39 | | 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 |
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| 3 | 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 | N/A |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | 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 | 17 |
| 8 | | | | |
| 9 | | | | |
| 10 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 17 |
| 11 | | | | |
| 12 | | 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) | 17 |
| 13 | | | | |
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| 16 | Methods: Monitoring | | | |
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| 18 | 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 | |
| 19 | | | | |
| 20 | | | | |
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| 23 | | 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 | 17 |
| 24 | | | | |
| 25 | | | | |
| 26 | 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 | |
| 27 | | | | |
| 28 | | | | |
| 29 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | |
| 30 | | | | |
| 31 | | | | |
| 32 | | | | |
| 33 | Ethics and dissemination | | | |
| 34 | | | | |
| 35 | Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 18 |
| 36 | | | | |
| 37 | | | | |
| 38 | 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) | 18 |
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|----|-------------------------------|-----|---|-----|
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| 3 | Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 7 |
| 4 | | | | |
| 5 | | | | |
| 6 | | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
| 7 | | | | |
| 8 | | | | |
| 9 | 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 | 7 |
| 10 | | | | |
| 11 | | | | |
| 12 | Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 19 |
| 13 | | | | |
| 14 | | | | |
| 15 | 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 | 7-8 |
| 16 | | | | |
| 17 | | | | |
| 18 | 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 | N/A |
| 19 | | | | |
| 20 | | | | |
| 21 | 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 |
| 22 | | | | |
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| 26 | | 31b | Authorship eligibility guidelines and any intended use of professional writers | 18 |
| 27 | | | | |
| 28 | | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 18 |
| 29 | | | | |
| 30 | Appendices | | | |
| 31 | | | | |
| 32 | Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | N/A |
| 33 | | | | |
| 34 | | | | |
| 35 | 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 | N/A |
| 36 | | | | |
| 37 | | | | |

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

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A cluster randomised controlled trial of a consumer behaviour intervention to improve healthy food purchases from online canteens: Study Protocol

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Manuscripts

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3 1 **A cluster randomised controlled trial of a consumer behaviour intervention to**
4
5 2 **improve healthy food purchases from online canteens: Study Protocol**
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3 28 **ABSTRACT**
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6 29 **Introduction:** School canteens represent an opportune setting in which to deliver public
7
8 30 health nutrition strategies given their wide reach, and frequent use by children. Online school
9
10 31 canteen ordering systems, where students order and pay for their lunch online, provide an
11
12 32 avenue to improve healthy canteen purchases through the application of consumer
13
14 33 behaviour strategies that impact on purchasing decisions. The aim of this study is to assess
15
16 34 the efficacy of a consumer behaviour intervention implemented in an online school canteen
17
18 35 ordering system in reducing the kilojoule, saturated fat, sugar and sodium content of primary
19
20 36 student lunch orders.
21

22
23 37 **Methods and analysis:** The study will employ a cluster randomised controlled trial design.
24
25 38 Approximately one thousand and forty students (aged 5-12 years) from ten primary schools
26
27 39 in New South Wales, Australia currently using an online canteen ordering system will be
28
29 40 invited to participate. Schools will be randomised in a 1:1 ratio to receive either the
30
31 41 intervention (enhanced system) or control (standard online ordering only). The intervention
32
33 42 will include evidence-based strategies shown to influence healthy food purchasing
34
35 43 (strategies targeting availability, menu labelling, placement and prompting). The primary
36
37 44 outcomes of the trial will be the mean content per student online lunch order of i) energy
38
39 45 (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium (milligrams). The
40
41 46 impact of the intervention will be determined by between group assessment of the nutritional
42
43 47 content of lunch purchases over a 2-month period post-intervention commencement.
44
45

46 48 **Ethics and dissemination:** The study was approved by the Hunter New England Human
47
48 49 Research Ethics Committee, University of Newcastle Human Research Ethics Committee
49
50 50 and New South Wales Department of Education and School Communities. Study findings
51
52 51 will be disseminated widely through peer-reviewed publications and relevant presentations in
53
54 52 international conferences and to stakeholders.
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3 54 **STRENGTHS & LIMITATIONS**
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- 6 55 • The trial utilises the most internally valid research design (RCT), includes objective
7
8 56 measures of trial outcomes, central randomisation to groups and has been powered
9
10 57 to detect small but meaningful population-level intervention effects.
11
12 58 • The analysis of trial outcomes will be conducted by a statistician blinded to group
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14 59 allocation
15
16 60 • The external validity of the findings may be limited given the convenience sampling
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18 61 procedure and as the trial will be conducted in 10 schools from one Australian state
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62 BACKGROUND

63 Globally, poor diet (including excess intake of foods high in energy, saturated fat, added
64 sugars and salt) is one of the leading causes of non-communicable diseases including
65 cardiovascular disease, type 2 diabetes and cancer.^{1 2} Given that dietary behaviours in
66 childhood track into adulthood and are predictive of future non-communicable disease risk³,
67 improving child nutrition is a public health priority in Australia and internationally.^{1 4}

68 Schools are a promising setting to improve child nutrition^{1 5} as they provide prolonged,
69 centralised access to almost every child in high income countries. Australian children
70 consume almost 40% of their recommended energy intake while at school,⁴ with up to 72%
71 of primary-school aged children purchasing their lunch from school canteens at least
72 weekly.⁶ The foods ordered from such canteens however are typically high in energy, fat,
73 sugar and salt, from products such as pies and sausage rolls (consumed regularly by 54% of
74 students), pizza products (30%), processed chicken (29%) and hot dogs (18%).⁷ Therefore,
75 interventions to improve the nutritional quality of foods purchased at school canteens are a
76 key opportunity to improve child nutrition.⁵

77
78 Findings of a recent systematic review of 18 school food environment studies suggest that
79 modifying the relative availability of food for sale from school food services is associated with
80 improvements in the purchase or consumption of healthy foods by students.⁸ Similarly,
81 school based research in the U.S. has found that a number of point of purchase strategies to
82 influence consumer behaviour such as nutrition labelling⁹; prompting¹⁰ and the placement of
83 menu items (including the order, prominence and access of items)^{11 12} are associated with
84 the selection, purchase or consumption of healthier foods by students.

85
86 Online school ordering systems, which enable student school lunches to be ordered and
87 paid for via the web, are becoming increasingly common in countries including Australia^{13 14}
88 and the U.S.^{15 16}. Such systems provide a platform to implement evidence-based consumer

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3 89 behaviour change strategies to support healthy purchasing choices by students and parents.
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5 90 Specifically, the online environment of these systems provides a controlled but dynamic
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7 91 infrastructure that enables implementation of a range of strategies that can reach large
8
9 92 numbers of individuals at a relatively low cost.¹⁷ For example, point of purchase nutrition
10
11 93 labelling, product placement and prompts, strategies that are routinely used by online food
12
13 94 retailers to influence purchase decisions of consumers¹⁸ can be readily deployed to influence
14
15 95 the purchase choices of a large number of students and parents. Despite the potential
16
17 96 benefits of implementing these strategies to promote healthy online school canteen
18
19 97 purchases, there have been no previous trials of their application to online school canteen
20
21 98 ordering systems.

22 23 24 99 **Study Aim**

25
26
27 100 In this context, the purpose of this study is to assess the efficacy of a consumer behaviour
28
29 101 intervention implemented in an online school canteen ordering system in reducing the
30
31 102 kilojoule, saturated fat, sugar and sodium content of primary student lunch orders.
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33 103

34 35 36 104 **METHODS**

37 38 39 105 **Trial Design**

40
41 106 The cohort study will employ a parallel group, cluster randomised trial design. Ten primary
42
43 107 schools located in New South Wales (NSW) Australia with an existing online canteen
44
45 108 ordering system will be randomised to receive either a 2-month consumer behaviour
46
47 109 intervention (enhanced system) or control (standard online ordering only). The efficacy of the
48
49 110 intervention will be determined by assessing between group differences at follow up in the
50
51 111 average i) energy (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium
52
53 112 (milligrams) content of a cohort of students who had made an online lunch order during the
54
55 113 baseline period. Student purchase data will be automatically collected by the online canteen
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3 114 system. Outcome data will be assessed at baseline and for the 2-month period following
4
5 115 introduction of the intervention.
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8 116 **Setting**

9
10 117 The study will take place in the state of New South Wales, Australia, a geographically large
11
12 118 state including large metropolitan and non-metropolitan areas with a demographically and
13
14 119 socioeconomically diverse population of approximately 455,000 primary aged children and
15
16 120 1,600 government primary schools.¹⁹ Children attend primary school from the age of 5 to the
17
18 121 age of 12, with government schools being the major provider of school education (65.2%).²⁰
19
20

21 122 **Participants**

22 123 *Schools*

23
24 124 To be eligible, schools must be a government primary school in NSW with an operational
25
26 125 canteen that has been using the online canteen ordering system supplied by a single
27
28 126 specific provider (services approximately 11% of New South Wales government school
29
30 127 canteens [unpublished data] and henceforth referred to as 'the provider') for at least 6
31
32 128 months. In addition, schools must process a minimum of 50 student online lunch orders per
33
34 129 month. Special purpose schools that exclusively enrol students with special needs, juvenile
35
36 130 justice schools, schools serving hospitalised children or schools with externally licensed
37
38 131 canteens will be excluded due to the potential differences in the provision of foods in these
39
40 132 settings. A research assistant will screen the school's online menu, and any school already
41
42 133 employing point of purchase nutrition labelling strategies (same as that of intervention) will
43
44 134 be excluded.
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47
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49 135 *Students*

50
51 136 All users of the online school canteen ordering system (e.g. children or parents ordering on
52
53 137 behalf of their children) who place an online lunch order during the 2-month baseline data
54
55 138 collection period will be eligible for study inclusion. Other users of the school's online
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3 139 canteen ordering system such as teaching staff, as identified by the online provider, will be
4
5 140 excluded.

7 141 **Recruitment Procedures**

9 142 A list of schools will be supplied by the provider and screened for eligibility by the research
10
11 143 team. A convenience sample of approximately 50 schools currently using the online
12
13 144 providers system will be invited to participate via mail and telephone with recruitment
14
15 145 continuing until the required sample of schools (N=10) consent to participate. Schools that
16
17 146 had been invited but were not the within the first 10 schools to consent will not participate in
18
19 147 the trial. The recruitment strategy will employ effective recruitment practices within the
20
21 148 school setting.²¹ Specifically, one member of the research team will act as a dedicated
22
23 149 recruitment coordinator. The coordinator will manage the recruitment of schools into the trial
24
25 150 and monitor consent rates. Schools will be provided with the direct phone number of the trial
26
27 151 manager for any enquiries regarding the research. Study information statements will be
28
29 152 mailed to school Principals inviting study participation. Specifically, consent will be sought
30
31 153 from the Principal for permission for the research team to access de-identified data
32
33 154 regarding canteen lunch order purchases, user demographics and usage characteristics of
34
35 155 the online ordering system. As de-identified student purchase data is accessed via a school
36
37 156 controlled database, all data will be utilised and individual student consent will not be sought.
38
39 157 Two weeks after sending the information statements, a research assistant will make multiple
40
41 158 attempts to contact schools via the phone to confirm eligibility, answer any questions
42
43 159 regarding the trial, and invite participation. Following consent, the online provider will supply
44
45 160 baseline lunch order purchase data (the 2-month operational period immediately preceding
46
47 161 intervention commencement) of students, in a non-identifiable format, to the research team
48
49 162 to assess the primary trial outcomes.

53 163 **Randomisation and blinding**

1
2
3 164 Following school recruitment, an independent statistician will use a computerised random
4
5 165 number function in Microsoft Excel to randomise schools to either an intervention or a control
6
7 166 group. Randomisation will occur at the unit of the school in a 1:1 (intervention: control) ratio
8
9 167 in randomly sequenced blocks of two and four to ensure the number of schools allocated to
10
11 168 each group remains approximately equal (see Figure 1).²²⁻²⁴ Given evidence that
12
13 169 socioeconomic status of the locality may be associated with the relative healthiness of
14
15 170 student purchasing patterns⁷, randomisation will be stratified by the socioeconomic status of
16
17 171 a school locality based on school postcode.²⁵ Due to the difficulty in blinding the users of the
18
19 172 online system to the changes introduced, the study will be conducted as an open trial
20
21 173 however parent and student users will not specifically be informed of the experimental
22
23 174 manipulation of the study. Furthermore, the study statistician undertaking the primary
24
25 175 analyses will be blinded to group allocation.

27 28 176 **Intervention**

29
30
31 177 A consumer behaviour intervention will be integrated into the existing schools online canteen
32
33 178 ordering system operated by the provider. Online canteen ordering systems allow users
34
35 179 (students, or a parent on behalf of a student) to login to a website to access their school's
36
37 180 lunch menu. Users are then able to select, order and pay for lunch items which are then
38
39 181 processed by the canteen and supplied to students during their meal break. Research in
40
41 182 food service settings suggests that decisions regarding food ordered for school aged
42
43 183 children are typically made jointly by parents and children.²⁶ As such the intervention seeks
44
45 184 to encourage consumer (parent or child) purchase of healthier foods and beverages for
46
47 185 school lunch orders, that is, food items lower in energy, saturated fat, sugar, and/or sodium.
48
49 186 All users of the online canteen ordering system at intervention schools will be exposed to the
50
51 187 intervention. Contamination of intervention components between groups will be minimised by
52
53 188 randomisation at the school level, and by the provider preventing user access to the
54
55 189 intervention by control group schools.
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190 **Intervention Development and Theoretical framework**

191 The intervention draws on the principles of choice architecture.²⁷ This approach posits that
192 consumer behaviour is influenced by social and physical environments through conscious
193 (e.g. reflective) and unconscious (automatic) processes.²⁷ Choice architecture strategies
194 alter the environments in which decisions are made, in this case, to cue healthier purchasing
195 choices. Consumer behaviour interventions, based on choice architecture, typically require
196 minimal conscious engagement by the consumer and can include: the provision of
197 information (prompting, labelling, feedback); altering of the physical environment (e.g.
198 altering the placement of products including accessibility, position or proximity, lighting,
199 décor etc) or the properties of products or stimuli within an environment (packaging,
200 presentation, functionality) to cue desirable behaviour.^{27 28} The intervention component
201 selection for this study was guided by the choice architecture typology proposed by Holland
202 et al.²⁷ Intervention selection was developed in consultation with a multi-disciplinary team of
203 experts including; health behaviour scientists, dietitians, canteen staff, parents, software
204 providers and developers. The consumer behaviour strategies were included in the
205 intervention if they were i) supported by empirical evidence of beneficial effect in food-
206 service settings^{10 29 30}; ii) considered appropriate and acceptable to school principals¹⁴ and
207 parents³¹ and iii) able to be feasibly operationalised within the providers online ordering
208 system.

209 **Intervention strategies**

210 The online provider will modify the display of the online ordering system to include the
211 following evidence based strategies that have previously been associated with healthier
212 consumer choices in analogous settings.^{10 29 30}

213 **Availability:** Canteen managers will be supported by the research team to improve the
214 relative availability of healthier items listed on their online canteen menu. Research in the
215 school food setting has found a positive association between increased availability of healthy

1
2
3 216 foods and improved purchasing behaviour of students.³² Therefore, a trained dietitian,
4
5 217 experienced in canteen menu assessment, will classify all foods and beverages listed on the
6
7 218 canteen menu as 'red' (low in nutritional value), 'amber' (moderate nutritional value) or
8
9 219 'green' (high nutritional value) according to the NSW government school canteen policy
10
11 220 'Fresh Tastes @ School'.³³ The dietitian will prepare and provide a comprehensive menu
12
13 221 feedback report to schools encouraging canteen managers to improve the relative
14
15 222 availability of healthy items by increasing the proportion of 'green' menu items (to greater
16
17 223 than 50% of total items) or removing 'red' menu items.^{34 35} Such strategies have been found
18
19 224 to be effective in improving the relative availability of healthy items by school canteens.^{36 37}
20
21 225 These reports will be distributed once via email to both the canteen manager and Principal,
22
23 226 immediately prior to the redesigned canteen menu being uploaded online. A brief phone call
24
25 227 (of approximately 15 minutes) will be made to the canteen manager and/or Principal to
26
27 228 discuss contents of the feedback report.
28

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31 229

32 **Labelling:** Labelling involves the application of written or graphical feedback or information
33
34 231 endorsing a product at the point of purchase or point of choice.²⁷ This strategy will comprise
35
36 232 of the following components within the online system:

37
38 233 *Traffic light labels* – A single red, amber or green circle will be added beside each menu
39
40 234 item.³⁸ The traffic light label will be based on Fresh Tastes @ School.³³ The application of
41
42 235 traffic light labels in hospital cafeterias has been shown to significantly decrease sale of less
43
44 236 healthy and increase sale of healthier menu items.³⁸ Traffic light labels, compared to other
45
46 237 forms of labelling (e.g. nutrient labelling), are more likely to be noticed by parents when
47
48 238 making purchase decisions for their children from food settings.³⁹ Furthermore, compared to
49
50 239 other labelling systems, traffic light labels are preferred by both adults and children,⁴⁰ are
51
52 240 more easily understood and more effective in helping consumers to correctly identify
53
54 241 healthier food products.⁴¹
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3 242 *Label Guide* – An explanation of the relative healthiness of ‘green’, ‘amber’ and ‘red’ foods²⁹
4
5 243 ³⁸ will appear at the top of the online canteen website and will pop up when a user hovers
6
7 244 their cursor over each traffic light label.

8
9
10 245 *Descriptions* – ‘Green’ menu items that require onsite preparation (e.g. salads, sandwiches,
11
12 246 homemade hot meals) will receive an appealing description directly under item name (eg
13
14 247 “super salad tub”). Research in the restaurant setting has demonstrated that creative
15
16 248 descriptions applied to menu items have been associated with an increase in sales by up to
17
18 249 27%.⁴² Research in the school setting has similarly shown that adding creative names to
19
20 250 healthy food items (eg “x-ray vision carrots”) is associated with increases in children’s
21
22 251 consumption of the item.⁹

23
24
25 252 **Placement:** Placement strategies will be employed to alter i) the position of menu items to
26
27 253 make them appear more immediately prominent and ii) the accessibility of menu items to
28
29 254 make healthier choices easier to select and less healthy choices harder to select.²⁷ Evidence
30
31 255 suggests that items that are placed at the beginning or the end of the menu section were
32
33 256 selected up to twice as frequently as when they were placed in the centre of the list.³⁰
34
35 257 Therefore, healthier menu categories (i.e. fruit, sandwiches, salads) and items within
36
37 258 categories will be ordered to give healthy items positions of greatest prominence; i.e. ‘green’
38
39 259 items will be positioned first; ‘red’ items will be located in the middle; and ‘amber’ items will
40
41 260 be positioned last in a food list. Where there are multiple flavours of a ‘red’ or ‘amber’ food,
42
43 261 users will be required to first ‘click’ on the category before the full list of items are displayed.
44
45 262 For example, for a user to select a flavour of potato crisps they will first be required to click
46
47 263 on that product category (‘crisps’) then select their preferred flavour in a separate pop up
48
49 264 box. Conversely, all available flavours of ‘green’ items will appear in the main website
50
51 265 interface without requiring further selection actions.

52
53
54 266 **Prompting:** Standardised written and graphical information intended to promote or raise the
55
56 267 awareness of, or the motivation for a given behaviour will be included in the online menu.

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2
3 268 Motivational written and graphical prompts will be used to promote and encourage selection
4
5 269 of healthy items. For example, healthier menu categories (i.e. sandwiches, salads, fruit) will
6
7 270 be accompanied by positive purchase prompts (e.g. “This is a good choice”) and an
8
9 271 appealing image representing the category.¹⁰ When users select a red or amber hot food
10
11 272 item they will also be prompted with a list of green menu items, ‘meal extras’, which typically
12
13 273 include bottled water, fresh fruit or vegetable pieces, to add to their order.
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15
16 274 Once implemented the intervention will remain operational across the entire study period.
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275 **Table 1.** Intervention strategies informed by Choice Architecture Framework proposed by Hollands et al.²⁷

| Strategy | Description | Application |
|---------------|---|---|
| Availability* | Schools will receive a comprehensive feedback report including strategies to improve the relative availability of healthy foods including: <ul style="list-style-type: none"> • A colour-coded copy of their menu, • Graphical feedback comparing their menu to the 'Fresh Tastes' target of >50% green and 0% red • Tailored advice for how to amend the menu to be compliant with the policy • Web links for additional support. | If availability of items are modified by the school or canteen this changes the capacity for user (parent or child) to select healthy vs less healthy foods |
| Labelling | Each menu item will display a single round traffic light label | Provides nutritional information about the food at point of purchase Promotes awareness of and thus motivation for a making a healthy purchase |
| | The menu will include information on how to use the label when selecting menu items (eg 'best choice', 'select carefully', 'select occasionally") | Facilitates interpretation of label Provides easily understood information about the healthiest choice |
| | Healthy menu items will include a hedonic description directly under the item name. | Provides incidental cues to induce non-conscious behavioural response (makes product more appealing) Makes healthy menu items more salient |
| Placement | Healthy menu categories (e.g. fruit, sandwiches, salads) and 'green' items within a category will be listed first. | Makes healthy menu items more salient, convenient and maximises opportunity for engagement with these items. |
| | Healthy items (green) will be listed in main website interface | Facilitates engagement with behavioural options by making healthy food more convenient/accessible |
| | Placement: Amber and red menu items with multiple flavours will require users to 'click' / explode the item before the full list of flavours are displayed. | Makes less healthy menu items harder to engage with therefore less convenient/accessible |
| Prompting | Amber and red hot item will include a prompt to add a healthy drink (water) or snack (fruit and/or veg) to the lunch order | Raises awareness of a given behaviour Makes it easier to access healthy food options |
| | Healthy food categories (eg sandwiches, salad, fruit) will appear in bold font, have an image, and a positive food prompt eg 'this is a good choice' | Provides general encouragement Promotes motivation for a given behaviour |

276 *This strategy aims to increasing healthy foods and involves providing the school with feedback on how to restrict availability of unhealthy foods in line with

277 Fresh Tastes @ School policy

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3 278 **Intervention Integrity**

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5 279 A dietitian will use the colour coded menu items to redesign the menu for online display
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7 280 using a standardised template ('menu template'). This template has been pilot tested and
8
9 281 refined based on feedback by the dietitian and the provider of the online lunch ordering
10
11 282 system. The completed menu template will be sent via email to the provider who will 'upload'
12
13 283 the schools online menu as per specifications in the menu template. This process will be
14
15 284 managed centrally by the provider. After the menu is uploaded but prior to being
16
17 285 operationalised, the research team will be able to view the redesigned menu in order to
18
19 286 confirm that the strategies have been applied and uploaded correctly. In order to monitor and
20
21 287 manage intervention integrity, once the redesigned menu is operational, the provider will
22
23 288 supply the research team with 2 reports (start and mid-intervention) listing any changes that
24
25 289 have been made to the online menu by the school. These reports will enable the research
26
27 290 team to identify new menu items that have been added. The research team will then label
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29 291 and position new menu items according to the menu template and contact the provider to
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31 292 make the required changes.
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35 293 **Control Group**

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38 294 Schools allocated to the control group will continue to receive the standard online lunch
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40 295 ordering service and will not have access to the intervention until after follow-up data
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42 296 collection at which point they will be offered access to supportive strategies.
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45 297 **DATA COLLECTION PROCEDURES & MEASURES**

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48 298 **Primary Outcomes:**

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51 299 The primary trial outcomes are: the mean content per student online lunch order of i) energy
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53 300 (kilojoules), ii) saturated fat (grams) iii) sugar (grams), and iv) sodium (milligrams). Given the
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55 301 effect of similar interventions have been reported to be immediate.⁴³ the primary trial
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57 302 endpoint is two months post intervention commencement (during which the canteen is
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3 303 operational). Primary trial outcomes will be collected at baseline (the 2-month operational
4 304 period immediately preceding intervention commencement) and follow-up (the 2-month
5 305 period operational period post-intervention commencement). Data from all purchases
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7 306 occurring during the baseline and follow-up assessment periods for the cohort of students
8
9 307 will be used to determine the trial outcomes. No assessment of plate waste will be
10
11 308 conducted. Purchase data has been shown to be highly correlated with food consumed.⁴⁴
12
13 309 Data collection procedures will be in accordance with previous canteen trials conducted by
14
15 310 the research team.^{34 35} Specifically, a dietitian will contact the canteen manager over the
16
17 311 phone to obtain nutrition information of canteen menu items available online. For pre-
18
19 312 packaged menu items the canteen manager will be asked to specify brand name, product
20
21 313 name and serve size. The nutritional profile of each pre-packaged item will be obtained by
22
23 314 searching the 'brand', 'product name' and 'serve size' in a canteen product database
24
25 315 consisting of over 1,300 commonly stocked school canteen items developed by the research
26
27 316 team.⁴⁵ If the menu item is not listed in the canteen product database, the dietitian will use a
28
29 317 publicly available database of commercial items (Foodswitch®) to obtain the nutrition
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31 318 information panel.⁴⁶ If the item cannot be located in either database the dietitian will contact
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33 319 the manufacturer to obtain the nutrition information panel. If the dietitian cannot obtain the
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35 320 nutrition information panel from the manufacturer a 'generic' nutrient profile will be assigned
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37 321 using a commercial equivalent found in the canteen product database.
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39 322 For menu items that are not packaged (e.g. freshly made foods such as sandwiches,
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41 323 canteen made hot foods and snacks), dietitians will request a copy of the recipe from the
42
43 324 canteen manager including recipe yield, ingredients and serve size. Dietitians will then use a
44
45 325 commercially available Australian nutrition database (Foodworks®)⁴⁷ to create a nutrient
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47 326 profile for this item (e.g. a ham, cheese and tomato sandwich). In the absence of a complete
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49 327 recipe, a 'generic' nutrient profile will be created using a commercial equivalent found in the
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51 328 canteen product database. Detailed records will be maintained for all items (pre-packaged
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53 329 and freshly prepared) that required a 'generic' nutrient profile to be assigned.
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3 330 Using the nutritional profile data, a dietitian will determine the nutrient profile (kilojoules,
4 331 saturated fat, sugar, sodium) and *Fresh Tastes* classification (red, amber, green)³³ for each
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6 332 menu item.
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9
10 333 To enable calculation of the primary trial outcomes, the nutrition profile for each menu item
11 334 will be applied to purchasing data obtained by the provider to generate a nutritional profile for
12 335 each individual order placed. A unique de-identified numerical identifier by the provider will
13 336 be used to link student orders across and within baseline and follow-up data collection
14 337 periods.
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21 338 **Secondary Outcomes:**
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23 339 *Nutrition quality:* 1) The proportion of all student lunch orders that are i) green and ii) red;
24 340 and 2) the mean percent of energy of lunch orders from i) sugar; and ii) saturated fat per
25 341 student online lunch order will be collected at baseline (the 2-month operational period
26 342 immediately preceding intervention commencement) and follow up (the 2-month operational
27 343 period post-intervention commencement) and compared between groups at follow up. The
28 344 colour code and percent energy from saturated fat and sugar will be based on the dietitian's
29 345 nutritional assessment of the purchasing data recorded by the online ordering system
30 346 (described above). Conversion of sugar and saturated fat to energy will be based on
31 347 internationally accepted conversion factors of 17kj per gram and 37kj per gram
32 348 respectively.⁴⁸
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45 349 *Revenue:* Revenue data will be automatically collected and supplied by the online provider.
46 350 The average weekly online canteen revenue will be assessed at baseline (the 2-month
47 351 operational period immediately preceding intervention commencement) and follow-up (the 2-
48 352 month operational period post-intervention commencement). The average weekly online
49 353 canteen revenue will be compared between groups to assess any detrimental or beneficial
50 354 impact of the intervention on school revenue that may affect the sustainability of the
51 355 intervention.
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3 356 **Other data:**

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6 357 *School Characteristics:* School level data including school size (number of enrolments), year
7
8 358 range (e.g. Kindergarten to grade 6), and school postcode will be collected from the 'My
9
10 359 School' website.⁴⁹

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12 360 *User characteristics:* Child school grade, and the recorded user (parent or child) will be
13
14 361 collected from the online ordering system. Online canteen usage data (e.g. frequency of
15
16 362 placing an order, the device used to place the order, the time taken to place the order) is
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18 363 automatically collected by the system, and will also be accessed by the research team.

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21 364 *Canteen Manager Survey:* After the collection of follow-up purchasing data (2 months
22
23 365 operational period post-intervention), canteen managers will be contacted to take part in a
24
25 366 telephone survey to determine i) canteen characteristics (type of canteen operation (leased,
26
27 367 P&C run, school run); staffing (paid or unpaid), profit and; ii) the acceptability of the
28
29 368 intervention strategies using a 4 point Likert scale from 'strongly agree' to 'strongly disagree'.

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32 369 School characteristics, user characteristics and canteen manager survey data will be
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34 370 collected and used for descriptive purposes.

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37 371 *Availability of menu items:* 1) The proportion 'green' items available on the menu and 2) The
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39 372 proportion of 'red' items available on the menu will be assessed at baseline (immediately
40
41 373 prior to intervention commencement) and follow-up (2-months post-intervention
42
43 374 commencement). Copies of each school's canteen menu will be obtained during baseline
44
45 375 data collection period (immediately after the school consents into the trial) and on the last
46
47 376 day of the follow-up data collection period. Each menu will be independently audited by two
48
49 377 dietitians consistent with previous studies.^{34 35} The menu audit procedure will involve
50
51 378 assigning each item a colour-code (as per the Fresh Tastes @ School guidelines) and
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53 379 calculating the proportion of each colour on the menu, in accordance to procedures
54
55 380 previously described elsewhere.^{34 35 45} Any discrepancies between dietitians in assigning a

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3 381 colour code or calculating the proportion of green or red items available on the menu will be
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5 382 resolved through consensus processes.
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8 383 **ANALYSIS & SAMPLE SIZE**

9 10 11 384 **Analysis:**

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13
14 385 The analyses will be undertaken by a statistician blinded to group allocation, with no other
15
16 386 involvement in the trial. Intervention effectiveness will be assessed using a separate linear
17
18 387 mixed model⁵⁰ for each primary outcome under an intention to treat approach⁵¹ energy
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20 388 (kilojoules), saturated fat (grams), sodium (milligrams), and sugar (grams). The analysis of
21
22 389 primary outcomes will be conducted only after completion of final follow up data collection
23
24 390 and no interim analyses of trial outcomes will be performed. The average nutritional content
25
26 391 (e.g. mean kilojoule content) will be calculated across all online lunch orders placed by a
27
28 392 student during the follow-up data collection period and compared between intervention and
29
30 393 control groups, adjusting for clustering at the school level and controlling for baseline values.
31
32 394 The mixed model will account for repeated measures of the trial outcome at the student and
33
34 395 school level. Adjusting for baseline will control for known and unknown potential confounders
35
36 396 as any differences in prognostic factors at baseline will be captured in the baseline values for
37
38 397 energy, fat, sugar and sodium. All students that place an order during the baseline period
39
40 398 will be included in the primary analysis. Missing data could arise at follow up due to a
41
42 399 student not placing an online lunch order during the follow up period. Multiple imputation will
43
44 400 be used for any missing data at follow-up as recommended by White and colleagues as part
45
46 401 of a sensitivity analysis.⁵² Exploratory sub-group analyses will also be conducted, testing for
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48 402 treatment group interactions by demographic (i.e. student grade) and purchasing
49
50 403 characteristics of the sample.
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54 404 The trial data will be reported in adherence with the CONSORT 2010 guidelines for reporting
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56 405 clustered randomised controlled trials. The trial has been prospectively registered with the
57
58 406 Australian New Zealand Clinical Trials Registry ACTRN12616000499482
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3 407 **Sample size calculation:**
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6 408 Given there are dose response relationships between intake of saturated fat⁵³, sugar⁵⁴, and
7
8 409 sodium⁵⁵ and important clinical health outcomes, including precursors for chronic disease
9
10 410 (such as blood pressure) the sample size calculation was conducted based on estimated
11
12 411 changes in energy intake between groups where a reduction of a defined magnitude is
13
14 412 required to accrue health benefit at the population level. Specifically, a reduction of 192kJ-
15
16 413 300kJ of energy per day is estimated to offset overweight in children⁵⁶ and in doing so
17
18 414 reduce population level risk for chronic disease. Assuming that 104 students per school,
19
20 415 place at least one online lunch order over the data collection period, and assuming that a
21
22 416 standard student lunch order contains 1729kJ (approximately 25% total daily energy intake⁴)
23
24 417 (sd=700) (unpublished data from research team) with an ICC of 0.05, the participation of 10
25
26 418 schools (5 each arm) in the trial would enable detection of approximately 300kJ, difference
27
28 419 between groups at follow-up with 80% power at the 0.05 significance level. A change of this
29
30 420 magnitude is considered clinically meaningful to detect a change in population body
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32 421 weight.^{56 57 58}
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36 422 **DISCUSSION**
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39 423 This will be the first study to examine the efficacy of a consumer behaviour intervention
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41 424 implemented in an online school canteen ordering system on purchasing behaviour from
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43 425 primary school canteens and will represent a substantial advance in knowledge in the field of
44
45 426 school-based public health nutrition. Further, given that online interventions can be
46
47 427 delivered to large numbers of community members at relatively low cost, the intervention, if
48
49 428 effective, may represent an attractive strategy to contribute to improvements in child health
50
51 429 and reductions in chronic disease risk.
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54 430 While the trial will provide useful information for policy makers and practitioners, and
55
56 431 valuable data for future studies examining technology based nutrition interventions in the
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3 432 school setting, there are a number of study limitations. First, the trial utilises convenience
4
5 433 sampling methods, and is conducted using one provider of online school canteen ordering
6
7 434 systems in Australia, limiting the external validity of trial findings. Furthermore, the trial tests
8
9 435 a complex public health intervention and is not designed to assess the independent effects
10
11 436 of individual strategies utilised in the intervention. Future research using factorial designs
12
13 437 would be warranted if the intervention is found to improve child diet in order to understand
14
15 438 intervention mechanisms and to design more efficient interventions in the future.
16
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18 439 **ETHICS & DISSEMINATION**

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21 440 Ethical approval to conduct the study has been obtained from the Hunter New England
22
23 441 Human Research Ethics Committee (reference: 06/07/26/4.04) University of Newcastle (Ref.
24
25 442 No. H-2008-0343), NSW Department of Education and Communities (SERAP 2012277).
26
27 443 Modifications to the trial protocol will be made via the Australian and New Zealand Clinical
28
29 444 Trials Registry and outlined in the final publication. Evaluation data and process data
30
31 445 collected as part of the study may be presented at scientific conferences, be published within
32
33 446 scientific journals and form part of student theses. Participant's confidentiality will be
34
35 447 maintained.
36
37

38 448 **AUTHORS CONTRIBUTION**

39
40
41 449 TD led the development of this manuscript. RW, TD, LW conceived the intervention concept.
42
43 450 JW, LW, RW, RS, SLY, KC, KB, CR, TD contributed to research design and trial
44
45 451 methodology. All authors contributed to and approved final version of this manuscript.
46
47

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49
50
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59
60

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12
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14
15 463 NHMRC.

16 17 18 464 **COMPETING INTERESTS**

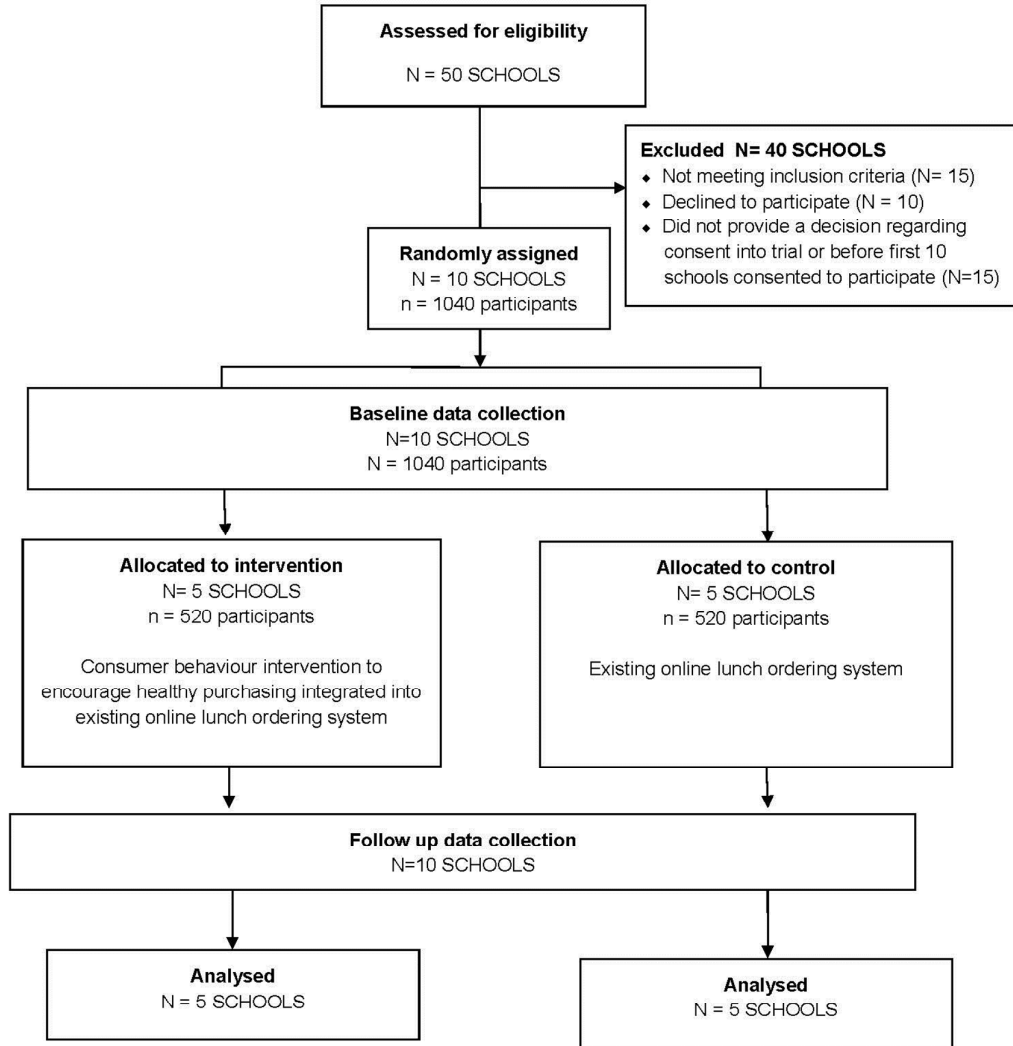
19
20
21 465 The online provider (Flexischools) was selected through a competitive tender process.
22
23 466 Flexischools is a commercial organization which provided online canteen ordering
24
25 467 infrastructure to schools included in the study. Flexischools had no role in the study design,
26
27 468 data analysis, data interpretation, or writing of the manuscript.

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31
32
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34
35 471 Flexischools for enabling the research to be undertaken using their online canteen ordering
36
37 472 infrastructure.

38 39 40 473 **DATA SHARING**

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42
43 474 Ultimate authority over the publication rests with the primary author. Access to the trial
44
45 475 dataset and full protocol will be available after publication of the study findings and on
46
47 476 request to the primary author



477

478 **Figure 1.** Estimated participant flow through trial. Numbers based on best available

479 information at time of submission

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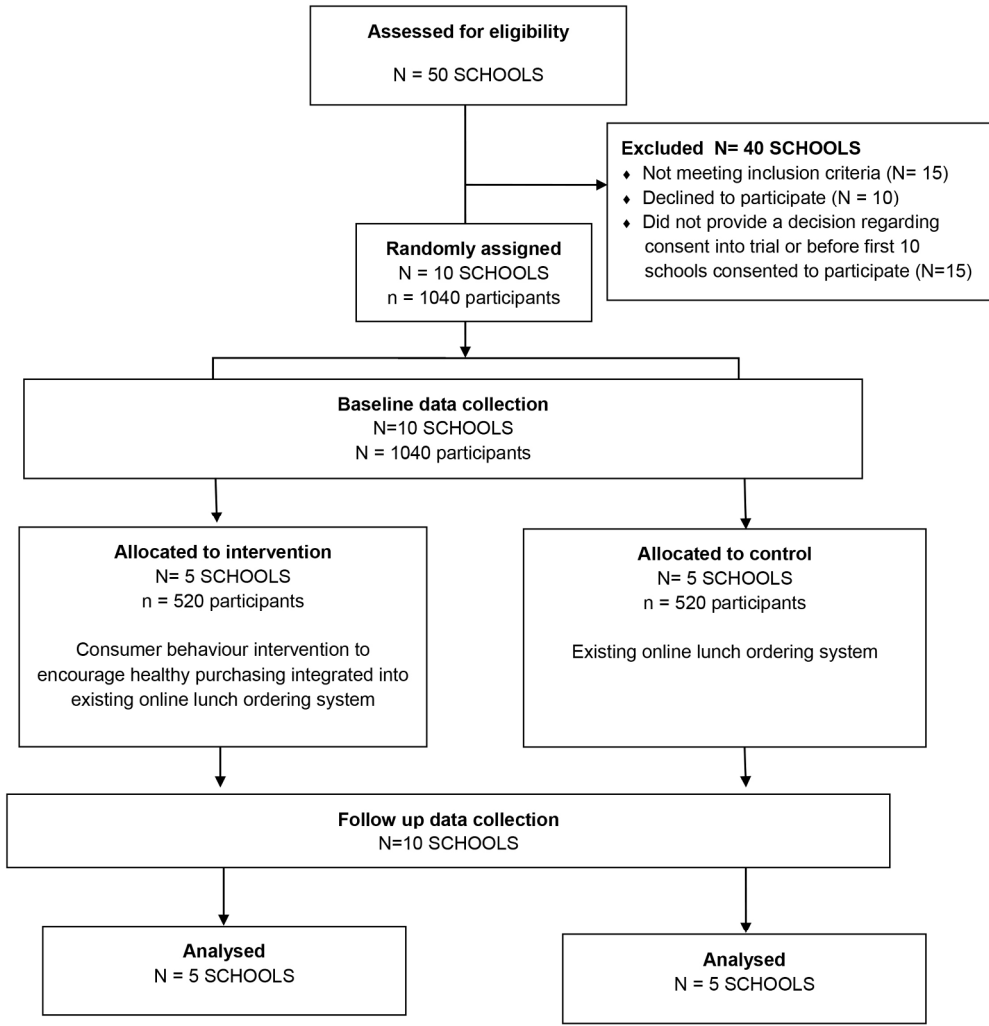
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Caption : Figure 1. Estimated participant flow through trial. Numbers based on best available information at time of submission

190x196mm (300 x 300 DPI)





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 | 2 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | N/A |
| Protocol version | 3 | Date and version identifier | 2 |
| Funding | 4 | Sources and types of financial, material, and other support | 21 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 |
| | 5b | Name and contact information for the trial sponsor | 1, 21-22 |
| | 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 | 21-22 |
| | 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) | N/A |

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2
3 **Introduction**
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|----|----------------|----|---|-----|
| 5 | Background and | 6a | Description of research question and justification for undertaking the trial, including summary of relevant | 5-6 |
| 6 | rationale | | studies (published and unpublished) examining benefits and harms for each intervention | |
| 8 | | 6b | Explanation for choice of comparators | N/A |
| 10 | Objectives | 7 | Specific objectives or hypotheses | 6 |
| 12 | Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), | 6 |
| 13 | | | allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | |

15
16 **Methods: Participants, interventions, and outcomes**
17

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|----|----------------------|-----|---|-------|
| 18 | Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data | 7 |
| 19 | | | will be collected. Reference to where list of study sites can be obtained | |
| 21 | Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and | 7 |
| 22 | | | individuals who will perform the interventions (eg, surgeons, psychotherapists) | |
| 24 | Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be | 9-15 |
| 25 | | | administered | |
| 27 | | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose | N/A |
| 28 | | | change in response to harms, participant request, or improving/worsening disease) | |
| 30 | | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence | 15 |
| 31 | | | (eg, drug tablet return, laboratory tests) | |
| 33 | | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | |
| 35 | Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood | 15-17 |
| 36 | | | pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation | |
| 37 | | | (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of | |
| 38 | | | chosen efficacy and harm outcomes is strongly recommended | |
| 40 | Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits | 23 |
| 41 | | | for participants. A schematic diagram is highly recommended (see Figure) | |

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|---|-------------|----|---|----|
| 1 | | | | |
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| 3 | 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 | 20 |
| 4 | | | | |
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| 6 | Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| 7 | | | | |

8 **Methods: Assignment of interventions (for controlled trials)**

9 Allocation:

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| 10 | | | | |
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| 12 | 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 | 9 |
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| 18 | 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 | 9 |
| 19 | | | | |
| 20 | | | | |
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| 22 | Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| 23 | | | | |
| 24 | | | | |
| 25 | Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| 26 | | | | |
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| 28 | | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | N/A |
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32 **Methods: Data collection, management, and analysis**

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| 33 | | | | |
| 34 | 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 | 15-18 |
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| 39 | | 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 |
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| 3 | 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 | N/A |
| 4 | | | | |
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| 7 | 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 | 19 |
| 8 | | | | |
| 9 | | | | |
| 10 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 19 |
| 11 | | | | |
| 12 | | 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) | 19 |
| 13 | | | | |
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| 16 | Methods: Monitoring | | | |
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| 18 | 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 | |
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| 23 | | 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 | 19 |
| 24 | | | | |
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| 26 | 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 | |
| 27 | | | | |
| 28 | | | | |
| 29 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | |
| 30 | | | | |
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| 33 | Ethics and dissemination | | | |
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| 35 | Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 21 |
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| 37 | | | | |
| 38 | 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) | 21 |
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| 3 | Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 |
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| 6 | | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
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| 9 | 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 | 8 |
| 10 | | | | |
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| 12 | Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 21-22 |
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| 15 | 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 | 22 |
| 16 | | | | |
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| 18 | 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 | N/A |
| 19 | | | | |
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| 21 | 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 | 21 |
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| 26 | | 31b | Authorship eligibility guidelines and any intended use of professional writers | 21 |
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| 28 | | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 22 |
| 29 | | | | |
| 30 | Appendices | | | |
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| 32 | Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | N/A |
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| 35 | 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 | N/A |
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*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.