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Application of the Multiphase Optimization Strategy to develop an initiative package to increase children's vegetable intake in childcare

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9 3 **initiative package to increase children’s vegetable intake in childcare**
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22 ABSTRACT

23 **Introduction:** Globally, children do not eat enough foods from the five food groups, with vegetable
24 intake being persistently low. Early life is a crucial period for establishing vegetable acceptance and
25 intake. Increased reliance by families on formal childcare has led to childcare settings playing an
26 important role in shaping young children's food intake. This study will use the Multiphase
27 Optimisation Strategy to develop, optimise and evaluate the effectiveness of a multicomponent
28 initiative package to increase 2-to-5-year-old children's vegetable intake in long day care centres.

29 **Methods:** The *Preparation Phase* will use existing literature and best practice guidelines to develop
30 three initiatives which aim to: (1) increase vegetable provision at mealtimes, (2) deliver a sensory
31 vegetable-focused curriculum, and (3) use supportive mealtime practices to encourage children to
32 taste vegetables. The *Optimisation Phase* (N=32 centres) will use a 12-week, eight-condition factorial
33 experiment to test main and synergistic effects of the initiatives. The optimum combination of
34 initiatives producing the largest increase in vegetable intake will be identified. The *Evaluation Phase*
35 (N=20 centres) will test the effectiveness of the optimised package using a 12-week waitlist
36 randomised controlled trial. Primary outcomes are vegetable intake and food group intake. Secondary
37 outcomes are menu compliance with guidelines, staff knowledge and skills and reach. Process
38 evaluation data will include fidelity, acceptability, barriers and facilitators, and compatibility with
39 practice.

40 **Ethics and dissemination:** This study has received ethics approval from the Flinders University
41 Research Ethics Committee (Project No: 1873) for the Optimisation Phase. Approval for the
42 Evaluation Phase will be obtained as amendment to current approval following completion of
43 Optimisation Phase, which will identify the final optimised initiative package for evaluation. Findings
44 will be disseminated to stakeholders in childcare sectors, in particular long day care centres and
45 professional childcare bodies; as well as to researchers via peer-reviewed journals and conferences.

46 **Trial Registration Number:** Optimisation Phase - ACTRN12620001301954; Evaluation Phase –
47 trial registration under review with Australia New Zealand Clinical Trial Registry.

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2
3 48 **Keywords:** Multiphase Optimisation Strategy, Early Care and Education, childcare, nutrition,
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5 49 vegetable intake, early childhood, menu provision, feeding practices, sensory education, vegetable
6
7 50 acceptance
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- 16 53 • This study will use the Multiphase Optimisation Strategy (MOST) framework to develop,
17
18 54 optimise and evaluate a best-practice multicomponent initiative package which aims to increase
19
20 55 children's vegetable intake in long day care.
21
22 56 • The MOST framework is a novel approach for producing effective, efficient and scalable
23
24 57 multicomponent interventions, which is a more rapid and less resource intensive than classical
25
26 58 approaches using sequential pilot and RCT studies.
27
28 59 • The initiatives will equip cooks and educators with the knowledge and skills to implement the
29
30 60 intervention to ensure sustainability outside of the research setting and will be developed with an
31
32 61 adoption partner who works within the sector to provide a pathway to roll-out.
33
34 62 • Notable limitations include the inability to conceal group allocation as participating centres are
35
36 63 required to make organisational changes and possibility of contamination across centres from the
37
38 64 same childcare provider which are enrolled in different conditions.
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INTRODUCTION

48 67 Globally, children do not eat enough foods from the five food groups and overconsume
49
50 68 nutrient-poor foods and drinks.¹ In particular, intake of vegetables is persistently low. Only 6.3% of
51
52 69 Australian children eat the recommended amount of vegetables,² with similar low intake in other
53
54 70 countries.³⁻⁵ The first five years of life (i.e. early childhood) is a critical period when adequate
55
56 71 nutrition is fundamental for growth and development, influencing a child's lifelong health trajectory.⁶
57
58 72 ⁷ Early childhood is also an important period for establishing vegetable liking and acceptance, which
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2
3 73 are associated with vegetable intake.⁸⁻¹⁰ Humans are born with an innate liking for sweet taste and a
4
5 74 predisposition to reject foods with bitter flavours, such as vegetables.^{8,9} However, food preferences
6
7 75 are most malleable in early childhood when young children can learn to like a range of foods,
8
9 76 including vegetables, through a variety of mechanisms including early and repeated exposure.^{8,10,11}
10
11 77 Repeated exposure can overcome low willingness to try new foods and food rejection that occur as
12
13 78 part of child development between ages two and six years, leading to increased vegetable intake.^{8,11}
14
15 79 Parents are a key influence on children's food intake in the early years, but many young children also
16
17 80 spend considerable time in non-parental formal and informal care arrangements where food is
18
19 81 provided to them.^{12,13} Over half of 2-to-5 year old children in Australia attend formal centre-based
20
21 82 early childhood education and care, most commonly long day care (LDC),^{13,14} where children spend
22
23 83 on average three days (~30 hours) per week.¹⁵
24
25
26

27 84 LDC centres in Australia provide both full-time and part-time care to children aged six weeks
28
29 85 to six years, for up to 12 hours a day.^{13,14} LDC generally includes an education element to prepare
30
31 86 children for school and approximately 70% (variable by state and territory) of centres provide food
32
33 87 that is prepared onsite for morning snack, lunch and afternoon snack, accounting for 40-60% of
34
35 88 children's daily food intake in care.^{16,17} Many also provide breakfast and a late snack.¹⁷ Australian
36
37 89 LDC services must comply with a National Quality Framework which outlines standards for the
38
39 90 sector, including for healthy eating.¹⁸ Menu planning guidelines that guide the provision of foods
40
41 91 according to dietary guidelines are also common.¹⁹ Despite these standards, children's food intake
42
43 92 while in child care is not consistent with dietary guidelines²⁰⁻²² and menus at most LDC centres do
44
45 93 not comply with menu guidelines.^{23,24} For example, 0- 55% of centres comply with guidelines for
46
47 94 vegetable provision.^{23,25,26} Barriers reported by cooks to improving menu compliance with guidelines
48
49 95 include perceptions about children's likes and dislikes, increased cost and food wastage.²⁷ Further,
50
51 96 although educators report that promoting healthy eating is an important part of their role, use of
52
53 97 feeding practices that create a supportive mealtime environment for tasting new foods and enjoying
54
55 98 vegetables have not been consistently observed in practice.^{28,29} Given the pivotal role that early care
56
57 99 settings can play in shaping children's dietary intake and the importance of the early years for
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3 100 establishing vegetable acceptance, there is a need to better support LDC centres to provide supportive
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5 101 environments for promoting vegetable intake.
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8 102 Childcare-based nutrition promotion strategies can be effective for improving children's food
9
10 103 intake in care.^{30 31} Interventions targeting improvements in vegetable intake in childcare settings have
11
12 104 achieved small-moderate increases in intake ranging from one-quarter of a serve to 67g (1 serve =
13
14 105 75g).^{32 33} In comparison, school-based interventions with older children achieved increases of 0.07
15
16 106 servings of vegetables,³⁴ suggesting that intervening at an earlier age when vegetable preferences are
17
18 107 being formed can produce superior results. Multi-level (targeting individuals and environments) and
19
20 108 multi-component nutrition promotion approaches in child care have been most successful.^{30 32}
21
22 109 Interventions which improved children's healthy eating behaviours in care have targeted a
23
24 110 combination of nutrition policies and food provision,^{31 35} staff training,^{35 36} educators' nutrition
25
26 111 knowledge and feeding practices,^{37 38} delivery of curricula and sensory education,^{31 35 37} role-
27
28 112 modelling and observational learning.³⁹ Further, providing training and embedding interventions into
29
30 113 everyday routines of the child care centre is likely to improve the sustainability of interventions.³⁰
31
32 114 Best practice guidelines for intervention design to increase young children's vegetable intake also
33
34 115 emphasise the need for multilevel and multicomponent approaches, which target both individuals and
35
36 116 the environment, have more than one target audience (i.e. educators, children), focus on vegetables
37
38 117 and making frequent contact with participants over at least six weeks.^{32 40} Accordingly, a
39
40 118 multicomponent intervention with a strong vegetable focus, which combines strategies that target
41
42 119 children, such as education and hands-on sensory experiences, with strategies targeting educators,
43
44 120 cooks and the centre environment to support regular and repeated exposure to vegetables, is needed to
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46 121 produce optimum results for increasing vegetable intake in young children.³⁰
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51 122 Delivery and evaluation of multicomponent interventions within community settings presents
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53 123 many challenges. Traditional approaches using randomised controlled trials (RCT) to evaluate the
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55 124 performance of several intervention components are resource intensive, requiring multiple trials or
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57 125 many experimental conditions with high cost and large sample sizes. Conversely, evaluation of a
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59 126 multi-component intervention 'package' via RCT does not provide information about the relative
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3 127 effectiveness of individual intervention components or the synergy between components. To
4
5 128 overcome these limitations, the Multiphase Optimisation Strategy (MOST) uses a multi-phase
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7 129 experimental design to develop multi-component behavioural interventions.⁴¹ The MOST provides an
8
9 130 efficient approach for identifying the most effective combination of intervention components, by
10
11 131 testing main, additive and interactive effects of multiple interventions ⁴². Further, MOST embeds
12
13 132 within its design evaluation of compatibility with practice and effectiveness within real-world
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15 133 settings, supporting the development of interventions that can be more readily translated into policy
16
17 134 and practice.⁴¹

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21 135 This study will use the MOST experimental design to develop and evaluate a multicomponent
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23 136 initiative package for use in LDC centres to increase children's vegetable intake while in care. The
24
25 137 aims of this study are to 1) develop three initiatives targeting food provision, meal time practices and
26
27 138 curriculum which integrate best practice guidelines for increasing vegetable intake in LDC
28
29 139 (*preparation phase*), (2) identify the optimum combination of initiatives for increasing 2-to-5 year old
30
31 140 children's vegetable intake in LDC (*optimisation phase*), and (3) determine the effectiveness of the
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33 141 optimised initiative package for increasing children's vegetable intake in care (*evaluation phase*). We
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35 142 hypothesise that the effects of the three initiatives for increasing vegetable intake will be synergistic,
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37 143 and secondly, that the optimised initiative package will increase children's mean vegetable intake
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39 144 while in care by more than 0.5 serves.

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147 **METHODS**

148 **Trial design**

149 This project will undertake the three stages of the MOST: the preparation phase will select and
150 develop the initiatives to be tested; the optimisation phase will assess the independent and synergistic
151 effects of the initiatives to identify the optimal initiative package; and the evaluation phase will test
152 the effectiveness of the initiative package.⁴¹ The RE-AIM model will be used to evaluate the reach,
153 efficacy/effectiveness, adoption, implementation and maintenance of the initiative package across the
154 optimisation and evaluation phases.⁴³

155

156 **INSERT FIGURE 1 HERE**

157 **Preparation Phase**

158 Three initiatives will be developed which draw on evidence for effective strategies for increasing
159 vegetable intake and acceptance in the early years^{30 44} and align with best practice guidelines for
160 increasing vegetable intake in LDC^{32 40} (Table 1). The target audience of the initiatives will be
161 children, educators, and cooks. The initiatives will aim to increase educator's and cook's knowledge
162 and skills to create a supportive environment that promotes children's vegetable familiarisation,
163 acceptance, and consumption (Figure 1). Changes to food provision via increasing vegetables on the
164 menu, delivery of experiential and sensory curriculum activities and use of supportive feeding
165 practices at mealtimes will increase vegetable availability and repeated exposure to vegetables.

166 *Food provision initiative*

167 The food provision initiative will support cooks to increase the provision of vegetables across all
168 eating occasions, in the context of training to plan a menu that aligns with healthy menu guidelines.⁴⁵
169 Interventions supporting childcare centres to improve compliance with menu guidelines have
170 increased children's vegetable intake by 0.1-0.4 serves.^{25 46} Cooks will complete an online training
171 module, use an online menu planning tool to review their menu and implement the

172 **Table 1** – Description and alignment with Best Practice Guidelines of initiatives to increase 2-5-year-old children’s vegetable intake in long day care (LDC)

Initiative	LDC Staff	Description	Initiative goals and objectives	Best practice guidelines for vegetable intake in LDC(32, 40)
Food provision	Cooks	Online cook’s training module supported by online menu assessment tool to increase vegetable provision in meals and snacks.	<p>Goal: To support cooks to increase the provision of vegetables on the menu to align with guidelines and across all mealtimes</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase cook’s knowledge and skills to provide a menu in line with menu planning guidelines 2. Reduce barriers to the provision of vegetables on the menu 3. Support cooks to plan and monitor their provision of vegetables on the menu 	<p>Make vegetables the hero – have simple vegetable specific messages with a clear focus</p> <p>Coordinate sustained effort across multiple players – coordinate long-term action among key players involved in promoting & proving vegetables</p> <p>Grow knowledge and skills to support change – identify and act on gaps in knowledge and skills</p> <p>Minimise barriers to increase success – understand and identify ways to address barriers</p> <p>Plan for and commit to success – set clear and measurable vegetable-specific goals</p> <p>Create an environment that supports children to eat vegetables – make vegetables the easy choice, promote vegetable familiarisation & intake</p> <p>Monitor and provide feedback on progress – monitor progress</p>
Mealtime environment	Educator (mealtimes)	Online educator training module supported to encourage children to taste and enjoy vegetables at mealtimes.	<p>Goal: To increase the use of mealtime practices which will promote children’s vegetable acceptance and intake</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. To increase educator’s knowledge and skills to use supportive feeding practices at mealtimes to increase children’s vegetable acceptance and intake 	
Curriculum	Educator (teaching)	Lesson plans and teaching resources aligned with The Early Years Learning Framework (51), focusing on increasing vegetable liking and intake via repeated and other sensory exposure,	<p>Goal: To create an environment which supports children to enjoy, try and consume vegetables</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase children’s ability to describe their sensory perceptions when eating vegetables 2. Increase exposure to a variety of familiar and unfamiliar vegetables 	

sensory education and
experiential learning

3. Support children to enjoy vegetables and be
able to taste any vegetable

against goals at regular intervals

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3 175 revised menu. The training will take approximately 45-55 minutes to complete and covers menu
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5 176 planning, importance of healthy eating, implementing menu guidelines and overcoming common
6
7 177 barriers. Cooks will use an automated online menu assessment tool to assess compliance of their
8
9 178 menu with guidelines. There are currently no South Australian guidelines, therefore Victorian Menu
10
11 179 Planning Guidelines will be used, which align closely with previous South Australian guidelines.^{19 45}
12
13 180 Cooks will enter their current menu, recipes, and number of children for whom their menu caters and
14
15 181 will receive an overview of compliance of the menu with guidelines for each food group.
16
17 182 Recommendations by food group will be provided, identifying meal occasions (morning snack, lunch,
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19 183 and afternoon snack) and days where the menu needs to be revised to meet guidelines. According to
20
21 184 the guidelines, children should be offered 1-1.5 serves of vegetables and legumes/beans per day (1
22
23 185 serve = 75g vegetables or cooked beans, 1 cup of leafy greens), at least 2-3 different types of
24
25 186 vegetables per day and at least 5 different types per week.⁴⁵ Cooks will have four weeks to complete
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27 187 training, the menu assessment and revise their menu according to the recommendations provided
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29 188 before implementing the revised menu at their next menu change.
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190 *Mealtime environment*

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39 191 The mealtime environment initiative will support educators to use mealtime practices that promote
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41 192 children's vegetable acceptance and intake. The initiative will apply evidence for effective strategies
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43 193 that support development of vegetable acceptance development in other settings within a childcare
44
45 194 setting.^{44 47} The initiative will aim to increase educator's knowledge and skills to use feeding practices
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47 195 at mealtimes that will promote vegetable familiarisation via repeated exposure and opportunities to try
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49 196 vegetables, including the division of responsibility ('educator provides, child decides'),⁴⁸ repeated
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51 197 encouragement to try, use of neutral language, sensory tasting using the five senses and role
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53 198 modelling of vegetable intake.^{10 44 47 49} Educators will complete an interactive online training module
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55 199 (~45-55 minutes) which includes topics about the role of the educator in promoting healthy eating,
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57 200 creating supportive meal time environments, use of feeding practices, overcoming barriers related to
58
59 201 food rejection and planning and implementing a strategy within their centre. The training module will
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3 202 promote strategies to increasing vegetable acceptance and intake within the context of creating a
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5 203 mealtime environment which promotes healthy eating. Educators and teachers will then apply the
6
7 204 knowledge and strategies learnt in training during mealtimes in the eight weeks of the implementation
8
9 205 period (as described below).

11 12 206 *Curriculum*

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15 207 The curriculum initiative will consist of a lesson package for educators that aims to provide
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17 208 opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a
18
19 209 variety of familiar and unfamiliar vegetables. The curriculum is based on experiential learning,
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21 210 sensory education, and insights on vegetable preference development in children. The curriculum will
22
23 211 be adapted from the evidence-based Taste & Learn vegetable education curriculum for primary school
24
25 212 children (aged 5-12 years)⁵⁰ to be suitable for younger children and align with The Early Years
26
27 213 Learning Framework.⁵¹ Taste & Learn is effective for increasing children's vegetable knowledge,
28
29 214 verbalization skills, acceptance, and willingness to try vegetables.⁵² The curriculum will consist of the
30
31 215 following elements:

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34 216 • A series of 16 short (~10-20min) lessons and hands-on activities delivered during intentional
35
36 217 teaching time. Children will discover how to enjoy a variety of vegetables using sensory
37
38 218 education and tasting lessons that focus on fun, involvement and experiential learning.
- 39
40 219 • A series of 16 snack time occasions where vegetables will be tasted and critical strategies to
41
42 220 reinforce children's enjoyment of vegetables can be consolidated.
- 43
44 221 • Supporting resources and activities to further familiarise children with vegetables and their
45
46 222 senses (e.g. reading corner, songs) and a group reward chart to track progress of vegetables
47
48 223 tasted

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52 224 Educators will be provided with written background information and lesson plans to teach and
53
54 225 implement the program over the eight-week implementation period. The development process will
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56 226 engage early education experts to ensure that the curriculum is appropriate and aligns with usual
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58 227 teaching practice and everyday routines in LDC.
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3 228 **INSERT FIGURE 2 HERE**

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6 229 **Optimisation Phase**

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9 230 **Study design**

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11 231 The optimisation phase will use a factorial design to test the efficacy of the three initiatives for
12 232 increasing vegetable intake in LDC centres. The objectives will be to (1) evaluate the relative and
13 233 synergistic effects of three initiatives to identify the optimal package of initiatives for increasing
14 234 children's vegetable intake while in care, and (2) undertake a process evaluation to understand
15 235 acceptability and factors that influence adoption of the initiatives. LDC centres will be randomly
16 236 assigned to eight experimental conditions resulting from the crossing of the three initiatives, each of
17 237 which has two conditions (present versus not present), and reflecting all possible combinations of
18 238 initiative components, including a no-initiative control condition (Figure 2). This study design
19 239 maximises the statistical power to identify the main effect of each individual initiative, as well as to
20 240 identify which combination of these initiatives produces the largest effect for increasing children's
21 241 vegetable intake.

22 242 **Eligibility criteria**

23 243 Private (non-Government) LDC centres will be eligible if they operate for at least eight hours per
24 244 weekday (Monday to Friday), prepare food onsite, serve lunch and two between-meal snacks each day
25 245 and enrol children aged two to five years. Centres will be excluded if they cater exclusively to
26 246 children with special needs. Within participating centres, children aged 2-5 years enrolled in the
27 247 centres and present on data collection days will be eligible to participate in data collection. Children
28 248 with severe allergies or medical conditions that significantly affect their food intake and prevent them
29 249 from consuming the standard centre menu will be excluded.

30 250 **Recruitment**

31 251 LDC centres in metropolitan Adelaide, South Australia will be recruited. The majority of LDC centres
32 252 in South Australia are part of large-chain providers,⁵³ therefore private LDC providers will be

1
2
3 253 approached to provide endorsement for the study. Centres will be randomly sampled from provider
4
5 254 lists, stratified by centre size and socio-economic status using the Socio-Economic Indexes for Areas
6
7 255 (SEIFA).⁵⁴ Randomly sampled centres will be sent information about the study by email to the
8
9 256 Director. Centres will then be contacted by phone to determine interest in study participation. An
10
11 257 information session about the study will be conducted at the centre to inform all staff of what is
12
13 258 involved and allow the opportunity to ask questions. Centre directors will provide consent for their
14
15 259 centre to participate in the study, and participating cooks and educators within centres will provide
16
17 260 consent to be involved in initiatives and provide data. The standard electronic method of
18
19 261 communication (i.e. communication Apps) within participating centres will be used to distribute
20
21 262 information about the study to parents. These systems allow parents to notify the centre (via the App)
22
23 263 when forms or notices have been opened and read. Parents will indicate that they wish to exclude
24
25 264 children from data collection by electronically signing and returning the opt-out form via the App.
26
27 265 This opt-out strategy has been used successfully in a previous study in South Australian LDC centres
28
29 266 and is approved by the ethics committee.²⁵
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33 267 **Randomisation and blinding**

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35
36 268 Centres will be randomised to one of the eight experimental conditions at completion of baseline data
37
38 269 collection by a member of the research team who is not directly involved in this study. Random
39
40 270 allocation will be done using computer number sequence generation in Excel, stratified by
41
42 271 socioeconomic status determined from postcodes (zip codes) using SEIFA⁵⁴ and size of long day care
43
44 272 centre. Research staff and participating centres will be blinded to intervention group allocation at
45
46 273 baseline only.
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Table 2 – Summary of evaluation data collected using the RE-AIM framework in the Multiphase Optimisation Strategy study evaluating the effectiveness of an initiative package to increase 2-5-year-old children’s vegetable intake in long day care

	Outcome measures	OPTIMISATION PHASE			EVALUATION PHASE	
		Timepoint	Instrument	Timepoint	Instrument	
REACH	Response rate	✓	-	Study records		
	Proportion of LDC centres in state participating	✓	BL	Study records, ACECQA data	✓	Registration questionnaire, ACECQA data
	Profile of participating children (age, gender, ATSI, ethnicity)	✓	BL, 12w	Centre data	✓	BL, 12w SFS-ECEC
ADOPTION	Characteristics & representativeness of centres (type of provider, centre size, SES, location, cook & educator experience in sector, previous training)	✓	BL	Baseline questionnaire – cook, educator, Director	✓	BL Baseline questionnaire – cook, educator, Director
EFFICACY / EFFECTIVENESS - Primary outcome	Child vegetable intake in care (serves/day)	✓			✓	BL, 12w SFS-ECEC
	Child intake of other food groups – fruit, grains, dairy, meat & alternatives, extras (serves/day)	✓	BL, 12w	Plate waste		
EFFICACY / EFFECTIVENESS - Impact	Knowledge (educators and cooks)	✓	BL, 12w	TDFQ – cook, educator, teacher (curriculum)	✓	BL, 12w TDFQ – cook, educator, teacher (curriculum)
	Skills (self-report educators and cooks)	✓	BL, 12w	Menu assessment	✓	BL, 12w Website metrics
	Menu compliance with guidelines	✓	BL, 12w		✓	BL, 12w Website metrics
IMPLEMENTATION - Fidelity & dose	Initiatives delivery (fidelity):					
	Initiative completion (cook’s training, menu assessment completion, educator training)	✓	12w	Website metrics	✓	12w Website metrics
	Reasons for non-completion	✓	12w	Follow-up questionnaire		
	Initiative implementation at centre (dose):					
	Menu implementation	✓	12w	Cook self-report in follow-up questionnaire	✓	12w Cook self-report in follow-up questionnaire
	Use of feeding practices at mealtimes	✓	BL, 12w	Educator TDFQ (skills domain)	✓	BL, 12w Educator TDFQ (skills domain)
	Curriculum delivery	✓	12w	Curriculum checklist	✓	12w Curriculum checklist
Reasons for non-implementation	✓	12w	Follow-up questionnaire			
Other:						
	Contamination & co-intervention	✓	12w	Follow-up questionnaire	✓	12w Follow-up questionnaire

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	Completion rate	✓	12w	Study records	✓	-	Study records
	Reasons for withdrawal	✓	-	Study records			
IMPLEMENTATION - Process	Acceptability (training & resources)	✓	12w		✓	12w	TDFQ – cook, educator, teacher (curriculum)
	Contextual factors influencing implementation (barriers & facilitators, beliefs about benefits & disadvantages, social influences)	✓	12w	TDFQ – cook, educator, teacher (curriculum)			
	Self-efficacy (educators and cooks)	✓	12w				
	<i>Feasibility</i>	✓	-	<i>Interpretation of implementation & maintenance</i>	✓	-	<i>Interpretation of implementation & maintenance</i>
MAINTENANCE (sustainability)	Compatibility with practice (part of regular practice, professional role to implement, intention to implement)	✓	12w	TDFQ – cook, educator, teacher (curriculum)	✓	12w	TDFQ – cook, educator, teacher (curriculum)

Abbreviations: ACECQA = Australian Children’s Education & Care Quality Authority; ATSI = Aboriginal and Torres Strait Islander; BL = baseline; LDC = Long Day Care; m = month; SA = South Australia; SFS-ECEC = Short Food Survey – Early Care and Education; TDFQ – Theoretical Domains Framework Questionnaire; VIC = Victoria; w = week

281 **Study procedures**

282 Data collection will be conducted at baseline and at the conclusion of the 12-week
283 intervention period (Figure 1). The intervention period will comprise a 4-week preparation period
284 (completion of training, menu assessment and curriculum preparation) and 8-week implementation
285 period (initiative delivery to children within centres). Centres allocated to the control condition will
286 continue with their usual practice and will be offered access to intervention at the completion of
287 follow-up data collection. Data collection of primary outcome data (children's vegetable intake) will
288 be conducted by trained research assistants within centres on two days each at baseline and follow-up
289 (end of intervention period). Data collection will be undertaken on the same days of the week at
290 baseline and follow-up within each centre to control as much as possible for differences in attendance
291 patterns. Secondary data will be collected via cook and educator completed questionnaires at baseline
292 and follow-up. The baseline questionnaire (~30-items) will collect data on staff characteristics, usual
293 practices, knowledge, and skills. The follow-up questionnaire (~70-items) will collect data for
294 knowledge, skills, process and impact measures (Table 2). Staff will be able to complete
295 questionnaires online or as paper and pen questionnaires. Questionnaires will be provided on the first
296 data collection day and staff will have a period of one week to complete them. Hard copies of data
297 will be stored in locked filing cabinets in locked offices of the chief investigators at the Flinders
298 University campus and electronic data will be stored on password protected Flinders University
299 server. To protect participant confidentiality throughout the trial, LDC centres and individuals (staff
300 and children) will be assigned ID codes and all data will be identified using this number. Prior to data
301 entry, questionnaires will be coded by the chief investigator and data dictionary developed. Data from
302 questionnaires will be entered by trained research assistants and double data entry will be conducted
303 for 10% of measures.

304 *Strategies to minimise attrition and improve fidelity*

305 To minimise centre attrition and increase fidelity, 8-10 SMS messages will be sent to participating
306 educators and cooks over the 12-week intervention period, with timing of messages varying as
307 relevant to the initiative. Message content will provide a reminder to complete elements of the

1
2
3 308 initiative and reinforce key messages of the initiatives. For example, for the food provision initiative
4
5 309 messages will be sent weekly in the preparation phase when cooks are completing the training and
6
7 310 assessing their menu and then fortnightly in the eight-implementation phase once the menu is
8
9 311 implemented. Educators participating in the curriculum and mealtime environment initiatives will
10
11 312 receive messages fortnightly in the preparation period and weekly in the implementation period when
12
13 313 they are delivering the curriculum and using feeding practices at mealtimes.
14
15

16 314 **INSERT TABLE 2 HERE**

17
18
19 315 **Primary outcome measures**

20
21
22 316 *Dietary intake*

23
24
25 317 Children's vegetable intake will be assessed within the context of total food intake while in care,
26
27 318 estimated using the plate wastage method which is a standard method for assessment of food intake in
28
29 319 child care²⁵. Data will be collected from all eligible children present on the day. Prior to each
30
31 320 mealtime (morning tea, lunch, and afternoon tea) bowls/plates and cups will be labelled with ID
32
33 321 stickers and weighed. As food is served each component of the meal will be weighed and weight
34
35 322 recorded. Any additional servings provided to the children will also be weighed and recorded. At the
36
37 323 end of the meal all plates with remaining food will be weighed. Food dropped from the child's plate
38
39 324 will be collected and added to the plate at the end of the meal for weighing. The amount of food
40
41 325 consumed will be measured by subtracting the mass of the food waste left over from the initial mass.
42
43 326 This will be done for each food group, including vegetables, and converted from grams to Australian
44
45 327 Guide to Healthy Eating standard serves.⁵⁵
46
47

48 328 **Secondary outcome measures**

49
50
51 329 *Menu compliance with guidelines*

52
53
54 330 Compliance of the centre menu with menu guidelines at baseline and follow-up will be assessed by
55
56 331 menu audit completed using an online menu assessment tool. Centres will provide their current menu,
57
58 332 recipes, purchase receipts and number of children catered for, which will be entered by research staff
59
60

1
2
3 333 into the online menu assessment tool. The outcome measures will be the proportion of centres
4
5 334 complying with guidelines at both time points.
6

7
8 335 *Knowledge and skills*
9

10 336 For each initiative, staff knowledge and skills will be evaluated using the knowledge and skills scales
11 337 of the Theoretical Domains Framework Questionnaire (TDFQ) for cooks developed by Seward.⁵⁶ As
12
13 338 described below, the questions for use with cooks will be adapted to be suitable for use with educators
14
15 339 to evaluate the mealtime and curriculum initiatives. The knowledge scale will evaluate awareness and
16
17 340 familiarity with each of the initiatives. The skills scale will evaluate the training and skills gained for
18
19 341 each of the initiatives. Additional purpose-designed items will be added to the skills scale for the
20
21 342 educator's mealtime environment initiative questionnaires to evaluate use of feeding practices at
22
23 343 mealtimes.
24
25
26
27

28 344 *Acceptability*
29

30
31 345 The usability and acceptability of the cook's training and menu assessment tool, educator's training
32
33 346 and curriculum will be evaluated using the content quality, motivation, presentation design, re-
34
35 347 usability and learning goal dimensions of the LORI framework for evaluating the quality of
36
37 348 multimedia learning resources.⁵⁷ Questions will be added to evaluate suitability of the duration/length
38
39 349 of the initiatives. A questionnaire using the LORI framework which was completed by primary school
40
41 350 teachers in the evaluation of Taste & Learn curriculum will be adapted for use in this study.⁵⁸
42
43

44 351 *Contextual and behavioural factors*
45

46
47 352 Contextual and behavioural factors that can influence initiative implementation will be evaluated,
48
49 353 guided by the Theoretical Domains Framework (TDF). The TDF is an implementation framework that
50
51 354 synthesizes and evaluates behaviour change constructs that may affect the implementation of
52
53 355 evidenced based practices and guidelines.⁵⁹ The following TDF domains will be evaluated:
54
55 356 environmental context (barriers and facilitators), beliefs about consequences, social influences, beliefs
56
57 357 about capability (self-efficacy) and three domains that evaluate compatibility with practice (part of
58
59 358 regular practice, professional role to implement and intention to implement). The selection of domains
60

1
2
3 359 was guided by recommendations for a minimum data set of implementation determinants⁶⁰, expert
4
5 360 consultation and previous studies evaluating implementation of interventions in the childcare setting.⁴⁶
6
7 361 ⁶¹ To evaluate implementation of the food provision initiative, the specified domains from the TDFQ
8
9 362 for cooks developed by Seward⁵⁶ will be used, which has been evaluated with Australian LDC cooks
10
11 363 and has good discriminant validity and reliability.⁵⁶ The TDFQ for cooks will be adapted to evaluate
12
13 364 the implementation of the curriculum and mealtime environment initiatives. The questionnaire will be
14
15 365 piloted with LDC content experts and educators to determine acceptability and usability. Data
16
17 366 collected will be used to assess the reliability (Cronbach's alpha) and construct validity using factor
18
19 367 analysis.
20
21
22

23 368 *Maintenance*

24
25 369 Three scales of the TDFQ evaluating compatibility with practice (part of regular practice, professional
26
27 370 role to implement, intention to implement) will provide proxy measures for maintenance in the
28
29 371 optimisation phase as it is not possible to collect longer term follow-up data in this study.
30
31

32 372 *Fidelity and dose*

33
34
35 373 The extent to which the initiatives were delivered as planned to educators and cooks (fidelity) and
36
37 374 implemented by staff at the centre (dose) will be evaluated. The outcome measures will be the
38
39 375 proportion of participating cooks and educators that completed the training modules, menu assessment
40
41 376 and delivered the curriculum and proportion of initiative components that were delivered to children.
42
43 377 Initiative delivery will be determined using website metrics for training modules and menu
44
45 378 assessment tool. Fidelity and dose of the curriculum initiative will be determined using an educator-
46
47 379 completed checklist of lessons and activities delivered. A question will be included in the cook's
48
49 380 follow-up questionnaire asking whether cooks implemented the revised menu. Use of feeding
50
51 381 practices at mealtimes will be evaluated via addition of items to the skills scales of the TDFQ for
52
53 382 educators, as described above. Open-ended questions will be included in the follow-up questionnaire
54
55 383 to determine reasons for non-completion of initiatives.
56
57
58

59 384 *Reach and adoption*

1
2
3 385 Reach, that is the proportion of the intended audience who participated in the study, will be evaluated
4
5 386 based on the response rate and profile of attending children (age, gender, ethnicity, Aboriginal or
6
7 387 Torres Strait Islander). Adoption will be evaluated as the characteristics and representativeness of
8
9 388 participating centres in terms of type of provider (chain versus independent), centre size,
10
11 389 socioeconomic status, location and characteristics of participating staff at centres including
12
13 390 qualifications, experience in sector and previous training. Representativeness will be evaluated by
14
15 391 comparison with ACECQA data for LDC centres in Adelaide.⁵³

18 392 **Contamination**

21 393 Contamination and co-intervention will be evaluated by inclusion of a question in the follow-up
22
23 394 questionnaire asking cooks and educators to report any other menu planning tools, nutrition-related
24
25 395 training and resources used during the study period.

28 396 **Covariates**

31 397 At baseline, centre operational characteristics will be collected for postcode, operating days and
32
33 398 hours, enrolments, attendance, number of Aboriginal or Torres Strait Islander children enrolled, meal
34
35 399 provision, centre nutrition policy, menu cycle length and use of menu guidelines, nutrition-related
36
37 400 programs and teaching resources At follow-up, centres will also report use of other nutrition policies
38
39 401 or programs during the study. Staff characteristics will include number of staff employed and their
40
41 402 role (i.e. cook, educator, kitchen assistant), hours worked per week, age, gender, years in current
42
43 403 position as well as years employed in ECEC sector, and qualifications relevant to role. The age and
44
45 404 gender of children participating in data collection will be collected at baseline and follow-up.

48 405 **Sample size**

51 406 Sample size estimates for factorial experiments are based on the power required to detect the smallest
52
53 407 effect.⁶² From prior research we assume an intraclass correlation coefficient of 0.1 for clustered data.⁴⁶
54
55 408 Based on these assumptions, with 80% power and a two-sided α of 0.05, 576-690 children, or 72-86
56
57 409 participants for each of the eight experimental conditions, will allow detection of a small-moderate
58
59 410 effect ($d=0.31$) on children's vegetable intake.⁶³ Recruitment of 32 centres, with 4 centres per

1
2
3 411 condition, will provide the required sample size. We will assume a 75% response rate based on past
4
5 412 interventions in Australian childcare centres^{56 64} and therefore will expect to approach approximately
6
7 413 45-50 LDC centres to recruit 32 centres.
8
9

10 414 **Statistical analysis**

11
12
13 415 Descriptive statistics will be used to describe centre characteristics and demographics at baseline and
14
15 416 chi-square and t-test statistics will be used to check for differences between groups. A factorial
16
17 417 experiment using repeated measure ANOVA models will test the effects of the three initiatives on the
18
19 418 primary outcome. Initial models will test whether each initiative (provided versus not provided) had a
20
21 419 significant effect on vegetable intake across the 12-week intervention period (pre-post intervention
22
23 420 effect). Subsequent models will test two and three-way interactions between initiative components to
24
25 421 identify the effects of interactions between initiatives on outcomes. Analyses will control for
26
27 422 covariates including child gender, age, and number of children at each timepoint. For secondary
28
29 423 outcomes of impact, logistic regression and linear regression models will assess treatment effects. The
30
31 424 mean change (continuous variables) or difference in proportions (dichotomous variables) in outcome
32
33 425 from baseline to follow-up will be compared between groups. Between-group differences in scores for
34
35 426 TDF domains will be evaluated using t-tests to assess the impact of contextual factors on intervention
36
37 427 effectiveness.
38
39
40

41 428 **Evaluation phase**

42 43 44 429 **Study design**

45
46
47 430 This study will evaluate the reach, adoption, impact and effectiveness of the optimised initiative
48
49 431 package for increasing children's vegetable intake, using a waitlist randomised controlled trial
50
51 432 conducted in target states, including but not limited to South Australia and Victoria. Centres in the
52
53 433 intervention group will use the optimised package following completion of baseline measures. The
54
55 434 waitlist control group will be asked not to change their current practice for the intervention period and
56
57 435 will be provided access to the initiative package following completion of follow-up assessments. We
58
59 436 hypothesise that the optimized initiative package will include all three initiatives and we plan to
60

1
2
3 437 collect evaluation data accordingly. If fewer initiatives are included in the initiative package,
4
5 438 evaluation data will only be collected for included initiatives.
6
7

8 439 **Recruitment and participants**

9

10 440 The recruitment approach will disseminate information about the optimised package widely across the
11 LDC setting as well as directly to management of childcare providers, with an aim to achieve broad
12 reach of the package in target states. Information will be disseminated through the Vegetable Intake
13 Strategic Alliance (VISA),⁶⁵ social media promotion and newsletters to stakeholders. Inclusion and
14 exclusion criteria for LDC centres will be as per the optimization phase. Centres that participated in
15 the optimization phase will be excluded. No exclusion criteria will be applied for children.
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23 446 **Randomisation and blinding**

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25
26 447 Centres will be randomised to intervention or waitlist control group using stratified randomisation
27 based on centre location (state) and socioeconomic status (using postcode to determine SEIFA index).
28
29 448 Due to the nature of the study, blinding of the researchers or participating centres will not be possible
30
31
32
33

34 450 **Study procedures**

35

36 451 This study will be delivered and evaluated online, with all measures self-completed by participating
37 centres using online data collection instruments. This approach will support centres to monitor their
38 own progress towards increasing children's vegetable intake, which will align the initiative package
39 with Best Practice Guidelines.³²⁻⁴⁰ Data will be collected at baseline and 12-weeks. Centres will
40 register for the study using an online user registration form. At the first step of registration, the
41 purpose of the study will be explained, and centres will be asked to read the detailed information sheet
42 and sign a consent form. Centres will distribute information about the study to parents and opt-out
43 consent from parents will be collected using the process described for the Optimisation Phase. The
44 user registration form will collect information about the centre which will be used as covariates and to
45 evaluate reach and adoption (Table 2). Educators and cooks who will be using the initiatives will
46 complete a baseline questionnaire providing information about staff characteristics, knowledge and
47 skills, as per the optimisation phase. Centres will then collect data about children's current vegetable
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3 463 intake and enter this into the online survey platform. At completion of baseline, centres will be
4
5 464 allocated to the intervention or control group. At conclusion of the 12-week intervention period
6
7 465 participating educators and cooks will complete evaluation questionnaires and centres will collect
8
9 466 vegetable intake data as per baseline. Centres in the control group will receive access to the online
10
11 467 package post-intervention and the intervention group will be encouraged to keep using the initiatives.

14 468 **Primary outcome measure**

17 469 The primary outcome measure will be usual serves of vegetables per day at LDC. Individual child
18
19 470 vegetable intake over the past month in care will be measured using the vegetable questions from the
20
21 471 Short Food Survey for Early Care and Education (SFS-ECEC).⁶⁶ The SFS-ECEC is a 47-item
22
23 472 educator-completed questionnaire measuring children's intake in care. Six questions measure the
24
25 473 frequency and usual portion size of starchy, salad and cooked vegetables. The questionnaire is
26
27 474 acceptable to educators and has appropriate validity for estimating intake at the group level.⁶⁶
28
29 475 Instructions and supporting resources for the SFS-ECEC will be provided as downloadable
30
31 476 instructions. Each educator will complete the vegetable intake questions online for a randomly
32
33 477 selected sample of at least 50% of children in their care, which equates to approximately 5-6 children
34
35 478 per educator and approximately a thirty minute time commitment based on educator to child ratios
36
37 479 defined under the National Quality Framework.⁶⁷

41 480 **Secondary outcome measures**

44 481 An online questionnaire in combination with website metrics will assess reach, adoption, impact, and
45
46 482 fidelity as described for the optimisation phase and summarised in Table 2. The follow-up
47
48 483 questionnaire will collect data for key implementation measures of acceptability, barriers and
49
50 484 facilitators, compatibility with practice and intention to implement initiatives, which with adoption
51
52 485 and fidelity data will enable evaluation of feasibility.

55 486 **Sample size**

58 487 Sample size was determined based on the a-priori hypothesis of an increase of 0.5 serves of
59
60 488 vegetables per day achieved by the optimised initiative package (estimated effect size of $d=0.65$ using

1
2
3 489 standard deviation from prior research.⁴⁶ At this effect size, with power at 0.8, $p < 0.05$ and $ICC = 0.1$, a
4
5 490 sample 284 children is needed. Based on 15% attrition in prior studies and estimating data from
6
7 491 approximately 20 children will be provided per centre, 20 LDC centres will need to be recruited.
8
9

10 492 **Statistical analysis**

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12
13 493 Analyses will be conducted at the group level and conclusions about effectiveness will be based on
14
15 494 group effect. Descriptive statistics will be generated for baseline measures. For the primary outcome,
16
17 495 linear mixed modelling will assess between group differences in vegetable intake at 12-weeks. The
18
19 496 primary outcome will be analysed using intention-to-treat principles. Models will control for baseline
20
21 497 intake and potential confounding factors (i.e. baseline differences between groups). For secondary
22
23 498 outcomes of impact, logistic regression and linear regression models will assess treatment effects.
24
25 499 Mean follow up values (continuous variables) or difference in proportions (dichotomous variables) in
26
27 500 outcome from baseline to follow-up will be compared between groups.
28
29

30 501 **Patient and Public Involvement Statement**

31
32
33 502 The initiative package was developed by researchers, dietitians, educators and sensory scientists with
34
35 503 experience in education sectors and food provision in childcare settings. The curriculum development
36
37 504 team included experts in LDC curriculum and LDC educators; and the curriculum was reviewed by
38
39 505 educators for suitability during the development process. The educator module was developed in
40
41 506 collaboration with an adoption partner who has experience delivering training to the LDC sector. LDC
42
43 507 content experts were consulted during the development of evaluation instruments to ensure that all
44
45 508 relevant process outcomes, in particular barriers and facilitators, were measured and language used
46
47 509 was suitable. Final questionnaires were reviewed for suitability and usability by cooks and educators.
48
49 510 The acceptability and feasibility of the initiatives in terms of time investment, barriers, compatibility
50
51 511 with practice and participant burden will be assessed as part of the process evaluation. A summary of
52
53 512 study results will be disseminated to participating centres, long day care providers participating and
54
55 513 organisations within the long day care sector via email distribution.
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59 514
60

515 **DISCUSSION**

516 This study will use the MOST framework to develop, optimise and evaluate a multi-
517 component initiative package to increase children's vegetable intake in childcare. The initiative
518 package will support cooks and educators to increase their knowledge and skills for providing
519 vegetables on the menu, using supportive feeding practices at mealtimes, and delivering a sensory and
520 experiential vegetable-focused curriculum. A strength of this study is use of the MOST framework.
521 MOST differs from the classic resource intensive intervention evaluation process that uses sequential
522 pilot and RCT studies, by using factorial experiments to optimise the intervention components before
523 proceeding to evaluation using an RCT.⁴¹ This provides a more rapid and economical approach for
524 producing effective, efficient and scalable multicomponent interventions.⁴¹ The initiatives will equip
525 cooks and educators with the knowledge and skills to implement the intervention to ensure
526 sustainability outside of the research setting and will be developed with an adoption partner who
527 works within the sector to provide a pathway to roll-out. Growing use of internet technology enables
528 online delivery of the initiatives which will provide the potential for increased reach and adoption by
529 staff and centres for whom time and distance may prohibit participation in face to face training.⁶⁸

530 Some limitations to the study need to be acknowledged. The study design requires that
531 participating LDC centres make organisational changes, therefore it is not possible to conceal group
532 allocation which introduces a risk of bias. However, assessors and centres will be blinded at baseline
533 data collection. In most Australian states, including South Australia, the majority of child care centres
534 are managed by large providers,⁵³ therefore there is a risk of intervention contamination across centres
535 of the same provider who are enrolled in different conditions. Centres participating in both trials will
536 be advised not to use any other training or initiatives during the study and data will be collected about
537 any other programs used.

538 In conclusion, this paper describes the design, delivery, and evaluation of a multi-component
539 initiative package which aims to increase children's vegetable intake in LDC. The initiative package
540 applies evidence for vegetable preference development⁴⁴ and Best Practice Guidelines for increasing
541 vegetable intake in LDC settings.^{32,40} The optimised initiative package will be rolled out online for use

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2
3 542 by LDC centres and has future potential to be adapted for use in other settings including family day
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5 543 care, out of school hours care and schools.
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10 545 **ETHICS APPROVAL AND DISSEMINATION**

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12
13 546 This study has received ethics approval from the Flinders University Research Ethics Committee
14
15 547 (Project No: 1873) for the Optimisation Phase. Approval for the evaluation phase will be obtained as
16
17 548 amendment to current approval at completion of Optimisation Phase, which will identify the final
18
19 549 optimised initiative package for evaluation in the final phase. Findings will be disseminated to
20
21 550 stakeholders in childcare sectors, in particular long day care centres and professional childcare bodies
22
23 551 and researchers. Results will also be disseminated to researchers via peer-reviewed journals and
24
25 552 conferences.
26
27
28

29 553
30

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32
33
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35
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37
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39
40 558 and development corporation for Australian Horticulture. The project is being delivered by a
41
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43
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45
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47
48 562 Excellence Award.
49
50

51 563 **AUTHORS' CONTRIBUTIONS**

52
53
54 564 RKG is a Principal Investigator of this study. The study was conceived, and funding obtained by
55
56 565 RKG, DNC and AAMP. DZ and RKG led the design of the study with all authors contributing to
57
58 566 study design through regular discussion. AAMP, MOCB and JCA with contribution from DZ and
59
60

1
2
3 567 RKG designed and developed the curriculum initiative. RKG, DZ and JCA with contribution from SK
4
5 568 designed and developed the food provision and meal environment initiatives. DZ drafted the
6
7 569 manuscript and wrote the research protocol for the Flinders University Social Behavioural Research
8
9 570 Committee with support from all authors. All authors have read and approved the final manuscript.
10
11

12 571

15 572 **COMPETING INTERESTS**

17
18 573 The authors declare that they have no competing interests. The funding body, Hort Innovation, has a
19
20 574 vested interest in increasing vegetable intake. Hort Innovation had no input into the design of the
21
22 575 study or preparation of this manuscript. Hort Innovation approved the manuscript for publication.
23
24

25 576

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31
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33
34 580 for providing the cooks training module and the menu assessment tool (FoodChecker) for use in the
35
36 581 study and collaboration in the development of the mealtime environment training module for
37
38 582 educators. We would like to acknowledge the contribution of Janet Elliot, Amy Wakem and Ros
39
40 583 Sambell in providing their expertise in the development of the curriculum initiative.
41
42

43 584

46 585 **AVAILABILITY OF DATA AND MATERIALS**

48
49 586 The datasets which will be used and/or analysed during the current study will be available from the
50
51 587 corresponding author on reasonable request.
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3 763 **FIGURES**
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7 765 **Figure 1** – Logic model for development of initiative package for use in long day care to increase
8 766 children’s vegetable intake

9 767 **Other sensory exposure - sensory-based explorative behaviours through the five senses (sight, smell,*
10 768 *touch, hearing, taste) to promote familiarization with vegetables*

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14 770 **Figure 2** – Study design for development and evaluation of initiative package for use in long day care
15 771 to increase children’s vegetable intake

16 772 **See Table 2 for outcome measures and instruments at all timepoints.* Abbreviations: LDC = long day
17 773 care; LDCC = long day care centres

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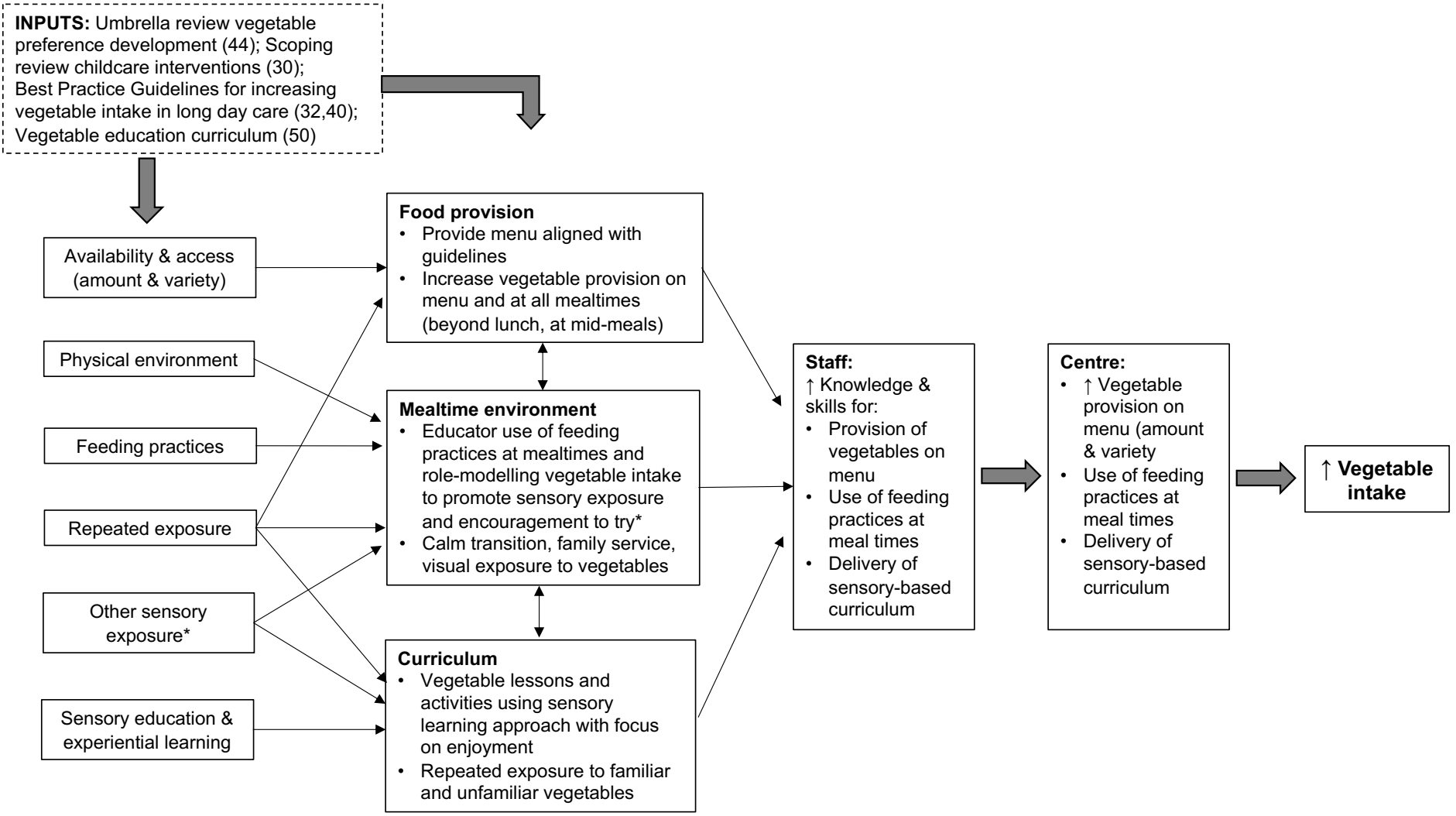


Figure 1 – Logic model for development of initiative package for use in long day care to increase children’s vegetable intake

*Other sensory exposure - sensory-based explorative behaviours through the five senses (sight, smell, touch, hearing, taste) to promote familiarization with vegetables

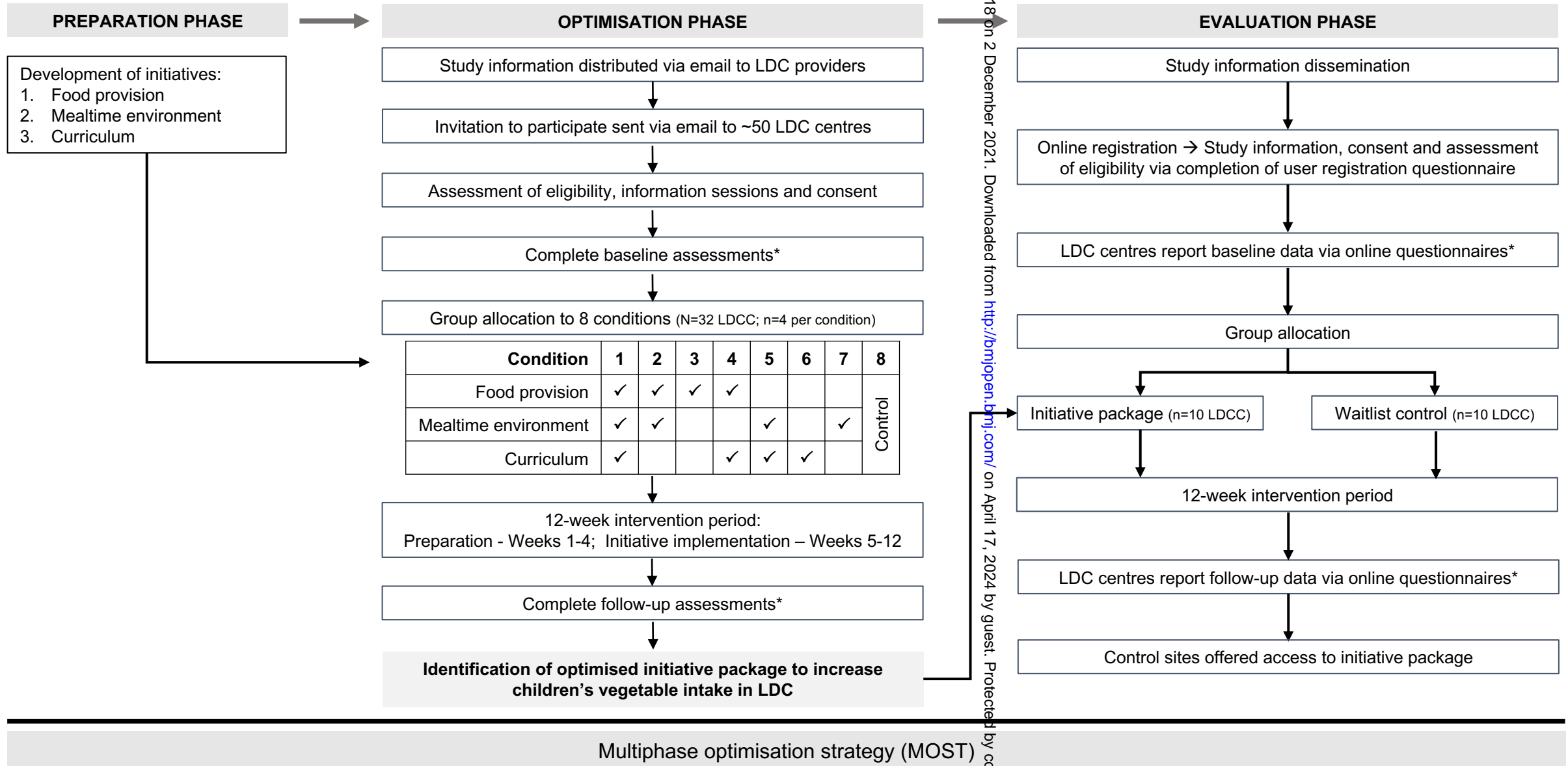


Figure 2 – Study design for development and evaluation of initiative package for use in long day care to increase children's vegetable intake

*See Table 2 for outcome measures and instruments at all timepoints. Abbreviations: LDC = long day care; LDCC = long day care centres

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

Section/item	Item No	Description	Addressed on page number:
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	Trial registration through ANZCTR – as per p.3
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	26
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 27
	5b	Name and contact information for the trial sponsor	26
	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	27

	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	3-6
	6b	Explanation for choice of comparators	3-6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6,7, 12,21
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	4,12,22
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)	12,22
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-11 Figure 1, Table 1
	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

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4		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16,17,19-20
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7		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
8				
9	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	17-20,23 Table 2
10				
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14	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 2)	16,22-23 Figure 2, Table 2
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17	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	20,24
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22	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13,22
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24	Methods: Assignment of interventions (for controlled trials)			
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26	Allocation:			
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28	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	13,22
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34	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	13,22
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4	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13,22
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7	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13,22
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10		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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13	Methods: Data collection, management, and analysis			
14				
15	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	16-20,22-23
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22		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	16-17
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25	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	16
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30	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	21, 24
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33		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21, 24
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35		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)	21, 24
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Methods: Monitoring

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4	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	N/A – DMC is not needed due to the nature of the intervention and minimal risk
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11		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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14	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	N/A
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17	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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21	Ethics and dissemination			
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23	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	26
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26	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)	N/A
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30	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 22
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34		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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37	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
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4	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
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7	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	27
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9				
10	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
11				
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13	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	26
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18		31b	Authorship eligibility guidelines and any intended use of professional writers	26
19				
20		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
21				
22				
23	Appendices			
24				
25	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not attached as Appendices – can be provided upon request
26				
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30				
31	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
32				
33				

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BMJ Open

Application of the Multiphase Optimisation Strategy to develop, optimise and evaluate the effectiveness of a multicomponent initiative package to increase 2-to-5-year-old children's vegetable intake in long day care centres: A study protocol

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7 2 **Application of the Multiphase Optimisation Strategy to develop, optimise**
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11 4 **increase 2-to-5-year-old children's vegetable intake in long day care**
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15 5 **centres: A study protocol**
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27 ABSTRACT

28 **Introduction:** Globally, children do not eat enough core foods, with vegetable intakes persistently
29 low. Early life is critical for establishing vegetable acceptance and intake. Increased usage of formal
30 childcare has led to the importance of childcare settings shaping children's food intake. This study
31 will use the multiphase optimisation strategy to develop, optimise and evaluate the effectiveness of a
32 multicomponent initiative package to increase 2-to-5-year-old children's vegetable intake in long day
33 care centres.

34 **Methods and analysis:** The *Preparation Phase* will use existing literature and best practice
35 guidelines to develop three initiatives aiming to: (1) increase vegetable provision at mealtimes, (2)
36 deliver a vegetable-focused sensory curriculum, and (3) use supportive mealtime practices
37 encouraging children's tasting of vegetables. The *Optimisation Phase* (N=32 centres) will use a 12-
38 week, eight-condition factorial experiment to test main and synergistic effects of the initiatives. The
39 optimum combination of initiatives producing the largest increase in vegetable intake will be
40 identified. The *Evaluation Phase* (N=20 centres) will test the effectiveness of the optimised package
41 using a 12-week waitlist randomised controlled trial. Primary outcomes are children's vegetable
42 intake and food group intake at long day care. Secondary outcomes are menu guideline compliance,
43 cook and educator knowledge and skills, and reach. Process evaluation will include fidelity,
44 acceptability, barriers and facilitators, and compatibility with practice. Repeated measures ANOVA
45 with interaction effects (Optimisation Phase) and linear mixed modelling (Evaluation Phase) will test
46 effects of the initiatives on vegetable intake.

47 **Ethics and dissemination:** This study has received ethics approval from the Flinders University
48 Research Ethics Committee (Project No: 1873) for the Optimisation Phase. Approval for the
49 Evaluation Phase will be obtained following completion of Optimisation Phase. Findings will be
50 disseminated to stakeholders, including long day care centres and childcare organisations; and to
51 researchers via peer-reviewed journals and conferences.

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3 52 **Trial Registration Number:** Optimisation Phase - ACTRN12620001301954; Evaluation Phase -
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5 53 ACTRN12620001323910p.
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8 54 **Keywords:** Multiphase optimisation strategy, Early Care and Education, childcare, nutrition,
9
10 55 vegetable intake, early childhood, menu provision, feeding practices, sensory education, vegetable
11
12 56 acceptance
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17 58 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 20 59 • This study will use the multiphase optimisation strategy (MOST) framework to develop, optimise
21
22
23 60 and evaluate a best-practice multicomponent initiative package which aims to increase children's
24
25 61 vegetable intake in long day care.
- 26
27 62 • The MOST framework is a novel approach for producing effective, efficient and scalable
28
29 63 multicomponent interventions, which is a more rapid and less resource intensive than classical
30
31 64 approaches using sequential pilot and RCT studies.
- 32
33 65 • The initiatives will equip cooks and educators with the knowledge and skills to implement the
34
35 66 intervention to ensure sustainability outside of the research setting and will be developed with an
36
37 67 adoption partner who works within the sector to provide a pathway to roll-out.
- 38
39 68 • Notable limitations include the inability to conceal group allocation as participating centres are
40
41 69 required to make organisational changes and possibility of contamination across centres from the
42
43 70 same childcare provider which are enrolled in different conditions.
44
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47 71

49 72 **INTRODUCTION**

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51
52
53 73 Globally, children do not eat enough foods from the five food groups and overconsume
54
55 74 nutrient-poor foods and drinks.¹ In particular, intake of vegetables is persistently low. Only 6.3% of
56
57 75 Australian children eat the recommended amount of vegetables,² with similar low intake in other
58
59 76 countries.³⁻⁵ The first five years of life (i.e. early childhood) is a critical period when adequate
60

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3 77 nutrition is fundamental for growth and development, influencing a child's lifelong health trajectory.⁶
4
5 78 ⁷ Early childhood is also an important period for establishing vegetable liking and acceptance, which
6
7 79 are associated with vegetable intake.⁸⁻¹⁰ Humans are born with an innate liking for sweet taste and a
8
9 80 predisposition to reject foods with bitter flavours, such as vegetables.^{8,9} However, food preferences
10
11 81 are most malleable in early childhood when young children can learn to like a range of foods,
12
13 82 including vegetables, through a variety of mechanisms including early and repeated exposure.^{8,10,11}
14
15 83 Repeated exposure can overcome low willingness to try new foods and food rejection that occur as
16
17 84 part of child development between ages two and six years, leading to increased vegetable intake.^{8,11}
18
19 85 Parents are a key influence on children's food intake in the early years, but many young children also
20
21 86 spend considerable time in non-parental formal and informal care arrangements where food is
22
23 87 provided to them.^{12,13} Over half of 2-to-5 year old children in Australia attend formal centre-based
24
25 88 early childhood education and care, most commonly long day care (LDC),^{13,14} where children spend
26
27 89 on average three days (~30 hours) per week.¹⁵

30
31 90 LDC centres in Australia provide both full-time and part-time care to children aged six weeks
32
33 91 to six years, for up to 12 hours a day.^{13,14} LDC generally includes an education element to prepare
34
35 92 children for school and approximately 70% (variable by state and territory) of centres provide food
36
37 93 that is prepared onsite for morning snack, lunch and afternoon snack, accounting for 40-60% of
38
39 94 children's daily food intake in care.^{16,17} Many also provide breakfast and a late snack.¹⁷ Australian
40
41 95 LDC services must comply with a National Quality Framework which outlines standards for the
42
43 96 sector, including those for healthy eating.¹⁸ Menu planning guidelines that guide the provision of
44
45 97 foods according to dietary guidelines are also common.¹⁹ Despite these standards, children's food
46
47 98 intake while in childcare is not consistent with dietary guidelines²⁰⁻²² and menus at most LDC centres
48
49 99 do not comply with menu guidelines.^{23,24} For example, 0- 55% of centres comply with guidelines for
50
51 100 vegetable provision.^{23,25,26} Barriers reported by cooks to improving menu compliance with guidelines
52
53 101 include perceptions about children's likes and dislikes, increased cost and food wastage.²⁷ Further,
54
55 102 although educators report that promoting healthy eating is an important part of their role, use of
56
57 103 feeding practices that create a supportive mealtime environment for tasting new foods and enjoying
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3 104 vegetables have not been consistently observed in practice.^{28 29} Given the pivotal role that early care
4
5 105 settings can play in shaping children's dietary intake and the importance of the early years for
6
7 106 establishing vegetable acceptance, there is a need to better support LDC centres to provide supportive
8
9 107 environments for promoting vegetable intake.

11
12 108 Childcare-based nutrition promotion strategies can be effective for improving children's food
13
14 109 intake in care.^{30 31} Interventions targeting improvements in vegetable intake in childcare settings have
15
16 110 achieved small-moderate increases in intake ranging from one-quarter of a serve (approximately 19g)
17
18 111 to 67g (approximately 0.89 serves, with 1 serve = 75g based on Australian recommendations).³²⁻³⁴ In
19
20 112 comparison, school-based interventions with older children achieved increases of 0.07 servings of
21
22 113 vegetables (approximately 6g),³⁵ suggesting that intervening at an earlier age when vegetable
23
24 114 preferences are being formed can produce superior results. Multilevel (targeting individuals and
25
26 115 environments) and multicomponent nutrition promotion approaches in childcare have been most
27
28 116 successful.^{30 32} Interventions which improved children's healthy eating behaviours in care have
29
30 117 targeted a combination of nutrition policies and food provision,^{31 36} director and educator training,^{36 37}
31
32 118 educators' nutrition knowledge and feeding practices,^{38 39} delivery of curricula and sensory
33
34 119 education,^{31 36 38} role-modelling and observational learning.⁴⁰ Further, providing training and
35
36 120 embedding interventions into everyday routines of the childcare centre is likely to improve the
37
38 121 sustainability of interventions.³⁰ Best practice guidelines for designing interventions to increase
39
40 122 children's vegetable intake emphasise the need for multilevel and multicomponent interventions,
41
42 123 which target both individuals and the environment, have more than one target audience (i.e. educators,
43
44 124 children), target vegetables (i.e. rather than healthy eating) and are of sufficient intensity and duration
45
46 125 (at least six weeks duration, with weekly participant contact).^{32 41} Accordingly, a multicomponent
47
48 126 intervention with a strong vegetable focus, which combines strategies that target children, such as
49
50 127 education and hands-on sensory experiences, with strategies targeting educators, cooks and the centre
51
52 128 environment to support regular and repeated exposure to vegetables, is needed to produce optimum
53
54 129 results for increasing vegetable intake in young children.³⁰

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3 130 Delivery and evaluation of multicomponent interventions within community settings presents
4
5 131 many challenges. Traditional approaches using randomised controlled trials (RCT) to evaluate the
6
7 132 performance of several intervention components are resource intensive, requiring multiple trials or
8
9 133 multiple parallel conditions with high cost and large sample sizes. Although the RCT is the gold
10
11 134 standard for evaluating the effectiveness of interventions, evaluation of multicomponent interventions
12
13 135 solely via RCT does not provide information about the independent, relative and synergistic effects of
14
15 136 intervention components. To overcome these limitations, the multiphase optimisation strategy
16
17 137 (MOST) uses a multiphase experimental design to build effective, efficient and scalable
18
19 138 multicomponent behavioural interventions.⁴² The MOST provides an efficient approach for
20
21 139 identifying the most effective combination of intervention components, by testing main, additive and
22
23 140 interactive effects of multiple interventions.⁴³ Further, MOST embeds within its design evaluation of
24
25 141 compatibility with practice and effectiveness within real-world settings, supporting the development
26
27 142 of interventions that can be more readily translated into policy and practice.⁴²
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29
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31 143 This study will use the MOST framework to develop and evaluate a multicomponent initiative
32
33 144 package for use in LDC centres to increase children's vegetable intake while in care. The initiatives
34
35 145 will use a paradigm that focuses on building acceptance and familiarity with vegetables, as a
36
37 146 sustainable approach to increasing vegetable intake.⁴⁴ This study will use a full factorial design
38
39 147 during the optimisation phase to identify which components individually and in combination, produce
40
41 148 the best initiative package subject to constraints. Utilising this approach will overcome limitations of
42
43 149 studies testing either single intervention components or multicomponent interventions, that are unable
44
45 150 to identify which component(s) or combination of components are most effective. This will support
46
47 151 the development of feasible, efficient and effective initiative package that can be implemented in
48
49 152 practice, without placing burden on LDC centres. The aims of this study are to (1) develop three
50
51 153 initiatives targeting food provision, meal time practices and curriculum which integrate best practice
52
53 154 guidelines for increasing vegetable intake in LDC (*preparation phase*), (2) identify the optimum
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55 155 combination of initiatives for increasing 2-to-5 year old children's vegetable intake in LDC
56
57 156 (*optimisation phase*), and (3) determine the effectiveness of the optimised initiative package for
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3 157 increasing children's vegetable intake in care (*evaluation phase*). We hypothesise that the effects of
4
5 158 the three initiatives for increasing vegetable intake will be synergistic, and secondly, that the
6
7 159 optimised initiative package will increase children's mean vegetable intake while in care by more than
8
9 160 0.5 serves.

12 161 **METHODS AND ANALYSIS**

15 162 **Trial design**

18 163 This project will undertake the three stages of the MOST: the preparation phase will select and
19
20 164 develop the initiatives to be tested; the optimisation phase will assess the independent and synergistic
21
22 165 effects of the initiatives to identify the optimal initiative package; and the evaluation phase will test
23
24 166 the effectiveness of the initiative package.⁴² The RE-AIM model will be used to evaluate the reach,
25
26 167 efficacy/effectiveness, adoption, implementation and maintenance of the initiative package across the
27
28 168 optimisation and evaluation phases.⁴⁵ The optimisation phase will be conducted from December 2020
29
30 169 to August 2021 and the evaluation phase will be conducted from January to August 2022.

33 170

36 171 **INSERT FIGURE 1 HERE**

39 172 **Preparation Phase**

42 173 Three initiatives will be developed which draw on evidence for effective strategies for increasing
43
44 174 vegetable intake and acceptance in the early years^{30 44} and align with best practice guidelines for
45
46 175 increasing vegetable intake in LDC, which recommend multilevel and multicomponent interventions
47
48 176 that combine strategies targeting children and the centre environment.^{32 41} (Table 1). The target
49
50 177 audience of the initiatives will be children, educators, and cooks. The initiatives will aim to increase
51
52 178 educator's and cook's knowledge and skills to create a supportive environment that promotes
53
54 179 children's vegetable familiarisation, acceptance, and consumption (Figure 1). Changes to food
55
56 180 provision via increasing vegetables on the menu, delivery of experiential and sensory curriculum

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3 181 activities and use of supportive feeding practices at mealtimes will increase vegetable availability and
4
5 182 repeated exposure to vegetables.
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8 183 *Food provision initiative*
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10 184 The food provision initiative will support cooks to increase the provision of vegetables across all
11
12 185 eating occasions, in the context of training to plan a menu that aligns with healthy menu guidelines.⁴⁶
13
14 186 Interventions supporting childcare centres to improve compliance with menu guidelines have
15
16 187 increased children's vegetable intake by 0.1-0.4 serves.^{25 47} Cooks will complete an online training
17
18 188 module, use an online menu planning tool to review their menu and implement the revised menu. The
19
20 189 online training and menu assessment tool were developed by dietitians, with feedback from long day
21
22 190 care centres. The training will take approximately 45-55 minutes to complete and covers menu
23
24 191 planning, importance of healthy eating, implementing menu guidelines and overcoming common
25
26 192 barriers. Cooks will use an automated online menu assessment tool to assess compliance of their
27
28 193 menu with guidelines. There are currently no South Australian guidelines, therefore Victorian Menu
29
30 194 Planning Guidelines will be used, which align closely with previous South Australian guidelines.^{19 46}
31
32 195 Cooks will enter their current menu, recipes, and number of children for whom their menu caters and
33
34 196 will receive an overview of compliance of the menu with guidelines for each food group.
35
36 197 Recommendations by food group will be provided, identifying meal occasions (morning snack, lunch,
37
38 198 and afternoon snack) and days where the menu needs to be revised to meet guidelines. According to
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40 199 the guidelines, children should be offered 1-1.5 serves of vegetables and legumes/beans per day (1
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42 200 serve = 75g vegetables or cooked legumes/beans, 1 cup of leafy greens), at least 2-3 different types of
43
44 201 vegetables per day and at least 5 different types per week.⁴⁶ Cooks will have four weeks to complete
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46 202 training, the menu assessment and revise their menu according to the recommendations provided
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48 203 before implementing the revised menu at their next menu change.
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204 **Table 1** – Description and alignment with Best Practice Guidelines of initiatives to increase 2-5-year-old children’s vegetable intake in long day care (LDC)

Initiative	LDC Staff	Description	Initiative goals and objectives	Best practice guidelines for vegetable intake in LDC ^{32 41}
Food provision	Cooks	Online cook’s training module supported by online menu assessment tool to increase vegetable provision in meals and snacks.	<p>Goal: To support cooks to increase the provision of vegetables on the menu to align with guidelines and across all mealtimes</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase cook’s knowledge and skills to provide a menu in line with menu planning guidelines 2. Reduce barriers to the provision of vegetables on the menu 3. Support cooks to plan and monitor their provision of vegetables on the menu 	<p>Make vegetables the hero – have simple vegetable specific messages with a clear focus</p> <p>Coordinate sustained effort across multiple players – coordinate long-term action among key players involved in promoting & proving vegetables</p> <p>Grow knowledge and skills to support change – identify and act on gaps in knowledge and skills</p> <p>Minimise barriers to increase success – understand and identify ways to address barriers</p> <p>Plan for and commit to success – set clear and measurable vegetable-specific goals</p> <p>Create an environment that supports children to eat vegetables – make vegetables the easy choice, promote vegetable familiarisation & intake</p> <p>Monitor and provide feedback on progress – monitor progress</p>
Mealtime environment	Educator (mealtimes)	Online educator training module supported to encourage children to taste and enjoy vegetables at mealtimes.	<p>Goal: To increase the use of mealtime practices which will promote children’s vegetable acceptance and intake</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. To increase educator’s knowledge and skills to use supportive feeding practices at mealtimes to increase children’s vegetable acceptance and intake 	
Curriculum	Educator (teaching)	Lesson plans and teaching resources aligned with The Early Years Learning Framework (51), focusing on increasing vegetable liking and intake via repeated and other sensory exposure,	<p>Goal: To create an environment which supports children to enjoy, try and consume vegetables</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase children’s ability to describe their sensory perceptions when eating vegetables 2. Increase exposure to a variety of familiar and unfamiliar vegetables 	

sensory education and
experiential learning

3. Support children to enjoy vegetables and be
able to taste any vegetable

against goals at regular intervals

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3 207 *Mealtime environment*
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6 208 The mealtime environment initiative will support educators to use mealtime practices that promote
7
8 209 children's vegetable acceptance and intake. The initiative will apply evidence for effective strategies
9
10 210 that support development of vegetable acceptance development in other settings within a childcare
11
12 211 setting.^{44 48} The initiative will aim to increase educator's knowledge and skills to use feeding practices
13
14 212 at mealtimes that will promote vegetable familiarisation via repeated exposure and opportunities to try
15
16 213 vegetables, including the division of responsibility ('educator provides, child decides'),⁴⁹ repeated
17
18 214 encouragement to try, use of neutral language, sensory tasting using the five senses and role
19
20 215 modelling of vegetable intake.^{10 44 48 50} The training will be developed by a team of dietitians and
21
22 216 researchers with knowledge of the long day care sector and a service delivery partner who delivers
23
24 217 training and resources to the long day care sector. Educators will complete an interactive online
25
26 218 training module (~45-55 minutes) which includes topics about the role of the educator in promoting
27
28 219 healthy eating, creating supportive meal time environments, use of feeding practices, overcoming
29
30 220 barriers related to food rejection and planning and implementing a strategy within their centre.
31
32 221 Examples of interactive components include short quiz questions, reflection questions and planning
33
34 222 activities for action within the long day care centre. The training module will promote strategies to
35
36 223 increasing vegetable acceptance and intake within the context of creating a mealtime environment
37
38 224 which promotes healthy eating. Educators and teachers will then apply the knowledge and strategies
39
40 225 learnt in training during mealtimes in the eight weeks of the implementation period (as described
41
42 226 below).
43
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45
46
47 227 *Curriculum*
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49 228 The curriculum initiative will consist of a lesson package for educators that aims to provide
50
51 229 opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a
52
53 230 variety of familiar and unfamiliar vegetables. The curriculum is based on experiential learning,
54
55 231 sensory education, and insights on vegetable preference development in children. The curriculum will
56
57 232 be adapted from the evidence-based Taste & Learn vegetable education curriculum for primary school
58
59 233 children (aged 5-12 years)⁵¹ to be suitable for younger children and align with The Early Years
60

234 Learning Framework.⁵² Taste & Learn is effective for increasing children's vegetable knowledge,
235 verbalization skills, acceptance, and willingness to try vegetables.⁵³ The curriculum will consist of the
236 following elements:

- 237 • A series of 16 short (~10-20min) lessons and hands-on activities delivered during intentional
238 teaching time. Children will discover how to enjoy a variety of vegetables using sensory
239 education and tasting lessons that focus on fun, involvement and experiential learning.
- 240 • A series of 16 snack time occasions where vegetables will be tasted and critical strategies to
241 reinforce children's enjoyment of vegetables can be consolidated.
- 242 • Supporting resources and activities to further familiarise children with vegetables and their
243 senses (e.g. reading corner, songs) and a group reward chart to track progress of vegetables
244 tasted

245 Educators will be provided with written background information and lesson plans to teach and
246 implement the program over the eight-week implementation period. The development process will
247 engage early education experts, including researchers, early education teachers and dietitians with
248 expertise in long day care, to ensure that the curriculum is appropriate and aligns with usual teaching
249 practice and everyday routines in LDC.

250 **INSERT FIGURE 2 HERE**

251 **Optimisation Phase**

252 **Study design**

253 The optimisation phase will use a full factorial design to test the efficacy of the three initiatives for
254 increasing vegetable intake in LDC centres. The objectives will be to (1) evaluate the independent and
255 combined effects of three initiatives to identify the optimised combination of initiatives for increasing
256 children's vegetable intake while in care, and (2) undertake a process evaluation to understand
257 acceptability and factors that influence adoption of the initiatives. LDC centres will be randomly
258 assigned to eight experimental conditions resulting from the crossing of the three initiatives, each of
259 which has two conditions (present versus not present) and reflecting all possible combinations of

1
2
3 260 initiative components (Figure 2). This study design maximises the statistical power to identify the
4
5 261 main effect of each individual initiative, as well as additive and synergistic effects of initiatives to
6
7 262 identify the optimised initiative package that is efficient, scalable and effective for increasing
8
9 263 children's vegetable intake. The optimisation criterion is the initiative or combination of initiatives
10
11 264 that deliver an increase of more than 0.5 serves of vegetables, anticipating that this should also be a
12
13 265 statistically significant increase. The optimisation criterion has been determined based on a
14
15 266 meaningful increase in the key outcome variable of vegetable intake, defined as an initiative effect
16
17 267 greater than those currently seen in the literature.^{32 54} If none of the combinations of initiatives achieve
18
19 268 the optimisation criterion, the package will consist of the intervention elements that show a
20
21 269 statistically significant increase in vegetable intake, taking into consideration findings of the process
22
23 270 evaluation.

27 271 **Eligibility criteria**

28
29
30 272 Private (non-Government) LDC centres will be eligible if they operate for at least eight hours per
31
32 273 weekday (Monday to Friday), prepare food onsite, serve lunch and two between-meal snacks each day
33
34 274 and enrol children aged two to five years. Centres will be excluded if they cater exclusively to
35
36 275 children with special needs. Within participating centres, children aged 2-5 years enrolled in the
37
38 276 centres and present on data collection days will be eligible to participate in data collection. Children
39
40 277 with severe allergies or medical conditions that significantly affect their food intake and prevent them
41
42 278 from consuming the standard centre menu will be excluded.

45 279 **Recruitment**

46
47
48 280 LDC centres in metropolitan Adelaide, South Australia will be recruited. The majority of LDC centres
49
50 281 in South Australia are part of large-chain providers,⁵⁵ therefore private LDC providers will be
51
52 282 approached to provide endorsement for the study. Centres will be randomly sampled from provider
53
54 283 lists, stratified by centre size and socio-economic status using the Socio-Economic Indexes for Areas
55
56 284 (SEIFA).⁵⁶ Randomly sampled centres will be sent information about the study by email to the
57
58 285 Director. Centres will then be contacted by phone to determine interest in study participation. An
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2
3 286 information session about the study will be conducted at the centre to inform all staff of what is
4
5 287 involved and allow the opportunity to ask questions. Centre directors will provide consent for their
6
7 288 centre to participate in the study, and participating cooks and educators within centres will provide
8
9 289 consent to be involved in initiatives and provide data. The standard electronic method of
10
11 290 communication (i.e. communication Apps) within participating centres will be used to distribute
12
13 291 information about the study to parents. These systems allow parents to notify the centre (via the App)
14
15 292 when forms or notices have been opened and read. Parents will indicate that they wish to exclude
16
17 293 children from data collection by electronically signing and returning the opt-out form via the App.
18
19 294 This opt-out strategy has been used successfully in a previous study in South Australian LDC centres
20
21 295 and is approved by the ethics committee.²⁵
22
23
24

25 296 **Randomisation and blinding**

26
27 297 Centres will be randomised to one of the eight experimental conditions at completion of baseline data
28
29 298 collection by a member of the research team who is not directly involved in this study. Random
30
31 299 allocation will be done using computer number sequence generation in Excel, stratified by
32
33 300 socioeconomic status determined from postcodes (zip codes) using SEIFA⁵⁶ and size of LDC centre.
34
35 301 Research staff and participating centres will be blinded to intervention group allocation at baseline
36
37 302 only.
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Table 2 – Summary of evaluation data collected using the RE-AIM framework in the Multiphase Optimisation Strategy study evaluating the effectiveness of an initiative package to increase 2-5-year-old children’s vegetable intake in long day care

	Outcome measures	OPTIMISATION PHASE			EVALUATION PHASE	
		Timepoint	Instrument	Timepoint	Instrument	
REACH	Response rate	✓	-	Study records		
	Proportion of LDC centres in state participating	✓	BL	Study records, ACECQA data	✓	Registration questionnaire, ACECQA data
	Profile of participating children (age, gender, ATSI, ethnicity)	✓	BL, 12w	Centre data	✓	BL, 12w SFS-ECEC
ADOPTION	Characteristics & representativeness of centres (type of provider, centre size, SES, location, cook & educator experience in sector, previous training)	✓	BL	Baseline questionnaire – cook, educator, Director	✓	BL Baseline questionnaire – cook, educator, Director
EFFICACY / EFFECTIVENESS - Primary outcome	Child vegetable intake in care (serves/day)	✓			✓	BL, 12w SFS-ECEC
	Child intake of other food groups – fruit, grains, dairy, meat & alternatives, extras (serves/day)	✓	BL, 12w	Plate waste		
EFFICACY / EFFECTIVENESS - Impact	Knowledge (educators and cooks)	✓	BL, 12w	TDFQ – cook, educator, teacher (curriculum)	✓	BL, 12w TDFQ – cook, educator, teacher (curriculum)
	Skills (self-report educators and cooks)	✓	BL, 12w	Menu assessment	✓	BL, 12w Website metrics
	Menu compliance with guidelines	✓	BL, 12w		✓	BL, 12w Website metrics
IMPLEMENTATION - Fidelity & dose	Initiatives delivery (fidelity):					
	Initiative completion (cook’s training, menu assessment completion, educator training)	✓	12w	Website metrics	✓	12w Website metrics
	Reasons for non-completion	✓	12w	Follow-up questionnaire		
	Initiative implementation at centre (dose):					
	Menu implementation	✓	12w	Cook self-report in follow-up questionnaire	✓	12w Cook self-report in follow-up questionnaire
	Use of feeding practices at mealtimes	✓	BL, 12w	Educator TDFQ (skills domain)	✓	BL, 12w Educator TDFQ (skills domain)
	Curriculum delivery	✓	12w	Curriculum checklist	✓	12w Curriculum checklist
Reasons for non-implementation	✓	12w	Follow-up questionnaire			
Other:						
	Contamination & co-intervention	✓	12w	Follow-up questionnaire	✓	12w Follow-up questionnaire

	Completion rate	✓	12w	Study records	✓	-	Study records
	Reasons for withdrawal	✓	-	Study records			
IMPLEMENTATION - Process	Acceptability (training & resources)	✓	12w		✓	12w	TDFQ – cook, educator, teacher (curriculum)
	Contextual factors influencing implementation (barriers & facilitators, beliefs about benefits & disadvantages, social influences)	✓	12w	TDFQ – cook, educator, teacher (curriculum)			
	Self-efficacy (educators and cooks)	✓	12w				
	<i>Feasibility</i>	✓	-	<i>Interpretation of implementation & maintenance</i>	✓	-	<i>Interpretation of implementation & maintenance</i>
MAINTENANCE (sustainability)	Compatibility with practice (part of regular practice, professional role to implement, intention to implement)	✓	12w	TDFQ – cook, educator, teacher (curriculum)	✓	12w	TDFQ – cook, educator, teacher (curriculum)

Abbreviations: ACECQA = Australian Children’s Education & Care Quality Authority; ATSI = Aboriginal and Torres Strait Islander; BL = baseline; LDC = Long Day Care; m = month; SA = South Australia; SFS-ECEC = Short Food Survey – Early Care and Education; TDFQ – Theoretical Domains Framework Questionnaire; VIC = Victoria; w = week

310 **Study procedures**

311 Data collection will be conducted at baseline and at the conclusion of the 12-week
312 intervention period (Figure 1). The intervention period will comprise a 4-week preparation period
313 (completion of training, menu assessment and curriculum preparation) and 8-week implementation
314 period (initiative delivery to children within centres). Centres allocated to the control condition will
315 continue with their usual practice and will be offered access to intervention at the completion of
316 follow-up data collection. Data collection of primary outcome data (children's vegetable intake) will
317 be conducted by trained research assistants within centres on two days each at baseline and follow-up
318 (end of intervention period). Data collection will be undertaken on the same days of the week at
319 baseline and follow-up within each centre to control as much as possible for differences in attendance
320 patterns. Secondary data will be collected via cook and educator completed questionnaires at baseline
321 and follow-up. The baseline questionnaire (~30-items) will collect data on staff characteristics, usual
322 practices, knowledge, and skills. The follow-up questionnaire (~70-items) will collect data for
323 knowledge, skills, process and impact measures (Table 2). Staff will be able to complete
324 questionnaires online or as paper and pen questionnaires. Questionnaires will be provided on the first
325 data collection day and staff will have a period of one week to complete them. Hard copies of data
326 will be stored in locked filing cabinets in locked offices of the chief investigators at the Flinders
327 University campus and electronic data will be stored on password protected Flinders University
328 server. To protect participant confidentiality throughout the trial, LDC centres and individuals (staff
329 and children) will be assigned ID codes and all data will be identified using this number. Prior to data
330 entry, questionnaires will be coded by the chief investigator and data dictionary developed. Data from
331 questionnaires will be entered by trained research assistants and double data entry will be conducted
332 for 10% of measures.

333 *Strategies to minimise attrition and improve fidelity*

334 To minimise centre attrition and increase fidelity, 8-10 SMS messages will be sent to participating
335 educators and cooks over the 12-week intervention period, with timing of messages varying as
336 relevant to the initiative. Message content will provide a reminder to complete elements of the

1
2
3 337 initiative and reinforce key messages of the initiatives. For example, for the food provision initiative
4
5 338 messages will be sent weekly in the preparation phase when cooks are completing the training and
6
7 339 assessing their menu and then fortnightly in the eight-implementation phase once the menu is
8
9 340 implemented. Educators participating in the curriculum and mealtime environment initiatives will
10
11 341 receive messages fortnightly in the preparation period and weekly in the implementation period when
12
13 342 they are delivering the curriculum and using feeding practices at mealtimes.
14
15

16 343 **INSERT TABLE 2 HERE**

17
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19 344 **Primary outcome measures**

20
21
22 345 *Children's vegetable intake and dietary intake*

23
24
25 346 Children's vegetable intake will be assessed within the context of total food intake while in care,
26
27 347 estimated using the plate wastage method which is considered a gold standard method for assessment
28
29 348 of dietary intake as it uses direct observation and is not subject to recall or memory bias. Plate
30
31 349 wastage methods have been used previously to assess food intake in childcare.^{25 47 57} Standardised data
32
33 350 collection procedures will be followed in all centres. To minimise any potential effects of labelling
34
35 351 plates/cups and the presence of research assistants on children's intake, usual mealtime practices of
36
37 352 the centre will be adhered to (e.g. educators serving, progressive mealtimes), researchers will stand
38
39 353 off to the side, avoid interacting with children at mealtimes and will not provide any encouragement
40
41 354 to children regarding their food intake. Data will be collected from all eligible children present on the
42
43 355 day. Prior to each mealtime (morning tea, lunch, and afternoon tea) bowls/plates and cups will be
44
45 356 labelled with ID stickers and weighed by research staff. As food is served each component of the meal
46
47 357 (e.g. bread, pasta with sauce, milk) will be weighed by research staff and weight recorded. Any
48
49 358 additional servings provided to the children will also be weighed and recorded. At the end of the meal
50
51 359 all plates with remaining food will be weighed. Food dropped from the child's plate will be collected
52
53 360 and added to the plate at the end of the meal for weighing. The amount of food consumed will be
54
55 361 measured by subtracting the mass of the food waste left over from the initial mass. Detailed
56
57 362 information about recipes, including type and brands of foods, will be obtained from the centre cook.
58
59
60

1
2
3 363 For mixed meals, recipes will be entered into FoodWorks Professional version 10 (Xyris Software Pty
4
5 364 Ltd, Queensland, Australia) to determine proportional ingredient weights and used to calculate weight
6
7 365 of intake by food group for each recipe. This will be done for each food group, including vegetables,
8
9 366 and converted from grams to Australian Guide to Healthy Eating standard serves.³⁴
10

11 367 **Secondary outcome measures**

12 368 *Menu compliance with guidelines*

13
14
15 369 Compliance of the centre menu with menu guidelines at baseline and follow-up will be assessed by
16
17 370 menu audit completed using an online menu assessment tool. Centres will provide their current menu,
18
19 371 recipes, purchase receipts and number of children catered for, which will be entered by research staff
20
21 372 into the online menu assessment tool. The outcome measures will be the proportion of centres
22
23 373 complying with guidelines at both time points.
24
25
26
27

28 374 *Knowledge and skills*

29
30
31 375 For each initiative, staff knowledge and skills will be evaluated using the knowledge and skills scales
32
33 376 of the Theoretical Domains Framework Questionnaire (TDFQ) for cooks developed by Seward.⁵⁸ As
34
35 377 described below, the questions for use with cooks will be adapted to be suitable for use with educators
36
37 378 to evaluate the mealtime and curriculum initiatives. The knowledge scale will evaluate awareness and
38
39 379 familiarity with each of the initiatives (For example – agreement with statement ‘*I am aware of the*
40
41 380 *goals of the menu planning guidelines*’). The skills scale will evaluate the training and skills gained
42
43 381 for each of the initiatives (For example – agreement with statement ‘*I have the skills needed to plan a*
44
45 382 *menu according to the menu planning guidelines*’). Additional purpose-designed items will be added
46
47 383 to the skills scale for the educator’s mealtime environment initiative questionnaires to evaluate use of
48
49 384 feeding practices at mealtimes.
50

51 385 *Acceptability*

52
53
54 386 The usability and acceptability of the cook’s training and menu assessment tool, educator’s training
55
56 387 and curriculum will be evaluated using the content quality, motivation, presentation design, re-
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58
59
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1
2
3 388 usability and learning goal dimensions of the LORI framework for evaluating the quality of
4
5 389 multimedia learning resources.⁵⁹ Questions will be added to evaluate suitability of the duration/length
6
7 390 of the initiatives. A questionnaire using the LORI framework which was completed by primary school
8
9 391 teachers in the evaluation of Taste & Learn curriculum will be adapted for use in this study.⁶⁰

12 392 *Contextual and behavioural factors*

15 393 Contextual and behavioural factors that can influence initiative implementation will be evaluated,
16
17 394 guided by the Theoretical Domains Framework (TDF). The TDF is an implementation framework that
18
19 395 synthesizes and evaluates behaviour change constructs that may affect the implementation of
20
21 396 evidenced based practices and guidelines.⁶¹ The following TDF domains will be evaluated:
22
23 397 environmental context (barriers and facilitators), beliefs about consequences, social influences, beliefs
24
25 398 about capability (self-efficacy) and three domains that evaluate compatibility with practice (part of
26
27 399 regular practice, professional role to implement and intention to implement). The selection of domains
28
29 400 was guided by recommendations for a minimum data set of implementation determinants,⁶² expert
30
31 401 consultation and previous studies evaluating implementation of interventions in the childcare setting.⁴⁷
32
33 402 ⁶³ To evaluate implementation of the food provision initiative, the specified domains from the TDFQ
34
35 403 for cooks developed by Seward⁵⁸ will be used, which has been evaluated with Australian LDC cooks
36
37 404 and has good discriminant validity and reliability.⁵⁸ The TDFQ for cooks will be adapted to evaluate
38
39 405 the implementation of the curriculum and mealtime environment initiatives. The questionnaire will be
40
41 406 piloted with LDC content experts and educators to determine acceptability and usability. Data
42
43 407 collected will be used to assess the reliability (Cronbach's alpha) and construct validity using factor
44
45 408 analysis.

49 409 *Maintenance – compatibility with practice*

51
52 410 Three scales of the TDFQ evaluating compatibility with practice (part of regular practice, professional
53
54 411 role to implement, intention to implement) will provide proxy measures for maintenance in the
55
56 412 optimisation phase as it is not possible to collect longer term follow-up data in this study.

59 413 *Fidelity and dose*

1
2
3 414 The extent to which the initiatives were delivered as planned to educators and cooks (fidelity) and
4
5 415 implemented by staff at the centre (dose) will be evaluated. The outcome measures will be the
6
7 416 proportion of participating cooks and educators that completed the training modules, menu assessment
8
9 417 and delivered the curriculum and proportion of initiative components that were delivered to children.
10
11 418 Initiative delivery will be determined using website metrics for training modules and menu
12
13 419 assessment tool. Fidelity and dose of the curriculum initiative will be determined using an educator-
14
15 420 completed checklist of lessons and activities delivered. A question will be included in the cook's
16
17 421 follow-up questionnaire asking whether cooks implemented the revised menu. Use of feeding
18
19 422 practices at mealtimes will be evaluated via addition of items to the skills scales of the TDFQ for
20
21 423 educators, as described above. Open-ended questions will be included in the follow-up questionnaire
22
23 424 to determine reasons for non-completion of initiatives.
24
25

26 27 425 *Reach and adoption*

28
29
30 426 Reach, that is the proportion of the intended audience who participated in the study, will be evaluated
31
32 427 based on the response rate and profile of attending children (age, gender, ethnicity, Aboriginal or
33
34 428 Torres Strait Islander). Adoption will be evaluated as the characteristics and representativeness of
35
36 429 participating centres in terms of type of provider (chain versus independent), centre size,
37
38 430 socioeconomic status, location and characteristics of participating staff at centres including
39
40 431 qualifications, experience in sector and previous training. Representativeness will be evaluated by
41
42 432 comparison with ACECQA data for LDC centres in Adelaide.⁵⁵
43
44

45 433 **Contamination**

46
47
48 434 Contamination and co-intervention will be evaluated by inclusion of a question in the follow-up
49
50 435 questionnaire asking cooks and educators to report any other menu planning tools, nutrition-related
51
52 436 training and resources used during the study period.
53
54

55 437 **Covariates**

56
57
58 438 At baseline, centre operational characteristics will be collected for postcode, operating days and
59
60 439 hours, enrolments, attendance, number of Aboriginal or Torres Strait Islander children enrolled, meal

1
2
3 440 provision, centre nutrition policy, menu cycle length and use of menu guidelines, nutrition-related
4
5 441 programs and teaching resources At follow-up, centres will also report use of other nutrition policies
6
7 442 or programs during the study. Staff characteristics will be collected via director and staff
8
9 443 questionnaires, including number of staff employed and their role (i.e. cook, educator, kitchen
10
11 444 assistant), hours worked per week, age, gender, years in current position as well as years employed in
12
13 445 the early childhood education and care (ECEC) sector, and qualifications relevant to role. The age and
14
15 446 gender of children participating in data collection will be collected at baseline and follow-up.

18 447 **Sample size**

21 448 Sample size estimates for factorial experiments are based on the power required to detect the smallest
22
23 449 effect.⁶⁴ From prior research we assume an intraclass correlation coefficient of 0.1 for clustered data,
24
25 450 with approximately 20 children per centre.⁴⁷ Based on these assumptions, with 80% power and a two-
26
27 451 sided α of 0.05, 576-690 children, or 72-86 participants for each of the eight experimental conditions,
28
29 452 will allow detection of a small-moderate effect ($d=0.31$) on children's vegetable intake.⁶⁵ Recruitment
30
31 453 of 32 centres, with 4 centres per condition, will provide the required sample size. We will assume a
32
33 454 75% response rate based on past interventions in Australian childcare centres^{58 66} and therefore will
34
35 455 expect to approach approximately 45-50 LDC centres to recruit 32 centres.

39 456 **Statistical analysis**

41 457 Descriptive statistics will be used to describe centre characteristics and demographics at baseline and
42
43 458 check for differences between groups. A factorial experiment using repeated measure ANOVA
44
45 459 models will test the effects of the three initiatives on the primary outcome. Initial models will test
46
47 460 whether each initiative (provided versus not provided) had a significant effect on vegetable intake
48
49 461 across the 12-week intervention period (pre-post intervention effect). Subsequent models will test two
50
51 462 and three-way interactions between initiative components to identify the effects of interactions
52
53 463 between initiatives on outcomes. Analyses will control for covariates including child gender, age, and
54
55 464 number of children at each timepoint. For secondary outcomes of impact, logistic regression and
56
57 465 linear regression models will assess treatment effects. The mean change (continuous variables) or
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2
3 466 difference in proportions (dichotomous variables) in outcome from baseline to follow-up will be
4
5 467 compared between groups. Between-group differences in scores for TDF domains will be evaluated
6
7 468 using t-tests to assess the impact of contextual factors on intervention effectiveness.
8
9

10 469 **Evaluation phase**

11 12 13 470 **Study design**

14
15
16 471 This study will evaluate the reach, adoption, impact and effectiveness of the optimised initiative
17
18 472 package for increasing children's vegetable intake, using a waitlist randomised controlled trial
19
20 473 conducted in target states, including but not limited to South Australia and Victoria. Centres in the
21
22 474 intervention group will use the optimised package following completion of baseline measures. The
23
24 475 waitlist control group will be asked not to change their current practice for the intervention period and
25
26 476 will be provided access to the initiative package following completion of follow-up assessments. We
27
28 477 hypothesise that the optimised initiative package will include all three initiatives and we plan to
29
30 478 collect evaluation data accordingly. If fewer initiatives are included in the initiative package,
31
32 479 evaluation data will only be collected for included initiatives.
33
34

35 480 **Recruitment and participants**

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37
38 481 The recruitment approach will disseminate information about the optimised package widely across the
39
40 482 LDC setting as well as directly to management of childcare providers, with an aim to achieve broad
41
42 483 reach of the package in target states. Information will be disseminated through the Vegetable Intake
43
44 484 Strategic Alliance (VISA),⁶⁷ social media promotion and newsletters to stakeholders. Inclusion and
45
46 485 exclusion criteria for LDC centres will be as per the optimisation phase. Centres that participated in
47
48 486 the optimisation phase will be excluded. No exclusion criteria will be applied for children.
49
50

51 487 **Randomisation and blinding**

52
53
54 488 Centres will be randomised to intervention or waitlist control group using stratified randomisation
55
56 489 based on centre location (state) and socioeconomic status (using postcode to determine SEIFA index).
57
58 490 Due to the nature of the study, blinding of the researchers or participating centres will not be possible
59
60

491 **Study procedures**

492 This study will be delivered and evaluated online, with all measures self-completed by participating
493 centres using online data collection instruments. This approach will support centres to monitor their
494 own progress towards increasing children's vegetable intake, which will align the initiative package
495 with Best Practice Guidelines.³²⁻⁴¹ Data will be collected at baseline and 12-weeks. Centres will
496 register for the study using an online user registration form. At the first step of registration, the
497 purpose of the study will be explained, and centres will be asked to read the detailed information sheet
498 and sign a consent form. Centres will distribute information about the study to parents and opt-out
499 consent from parents will be collected using the process described for the Optimisation Phase. The
500 user registration form will collect information about the centre which will be used as covariates and to
501 evaluate reach and adoption (Table 2). Educators and cooks who will be using the initiatives will
502 complete a baseline questionnaire providing information about staff characteristics, knowledge and
503 skills, as per the optimisation phase. Centres will then collect data about children's current vegetable
504 intake and enter this into the online survey platform. At completion of baseline, centres will be
505 allocated to the intervention or control group. At conclusion of the 12-week intervention period
506 participating educators and cooks will complete evaluation questionnaires and centres will collect
507 vegetable intake data as per baseline. Centres in the control group will receive access to the online
508 package post-intervention and the intervention group will be encouraged to keep using the initiatives.

509 **Primary outcome measure**

510 The primary outcome measure will be usual serves of vegetables per day at LDC. Individual child
511 vegetable intake over the past month in care will be measured using the vegetable questions from the
512 Short Food Survey for Early Care and Education (SFS-ECEC).⁶⁸ The SFS-ECEC is a 47-item
513 educator-completed questionnaire measuring children's intake in care. Six questions measure the
514 frequency and usual portion size of starchy, salad and cooked vegetables. The questionnaire is
515 acceptable to educators and has appropriate validity for estimating intake at the group level.⁶⁸
516 Instructions and supporting resources for the SFS-ECEC will be provided as downloadable
517 instructions. Each educator will complete the vegetable intake questions online for a randomly

1
2
3 518 selected sample of at least 50% of children in their care, which equates to approximately 5-6 children
4
5 519 per educator and approximately a thirty minute time commitment based on educator to child ratios
6
7 520 defined under the National Quality Framework.⁶⁹
8
9

10 521 **Secondary outcome measures**

11
12
13 522 An online questionnaire in combination with website metrics will assess reach, adoption, impact, and
14
15 523 fidelity as described for the optimisation phase and summarised in Table 2. The follow-up
16
17 524 questionnaire will collect data for key implementation measures of acceptability, knowledge and skills
18
19 525 of educators and cooks and compatibility with practice, which with adoption and fidelity data will
20
21 526 enable evaluation of feasibility.
22
23

24 527 **Sample size**

25
26
27 528 The sample size calculation was determined based on the hypothesised effect of an increase of 0.5
28
29 529 serves of vegetables from the optimised initiative package identified in the optimisation phase. An
30
31 530 effect size of $d=0.65$ was calculated based on this hypothesised effect on vegetable intake and using
32
33 531 standard deviation from prior research in Australian childcare centres.⁴⁷ At this effect size, with power
34
35 532 at 0.8, $p<0.05$ and $ICC=0.1$, a sample of 284 children is needed. Based on 15% attrition in prior
36
37 533 studies and estimating data from approximately 20 children will be provided per centre, 20 LDC
38
39 534 centres will need to be recruited. The sample size calculation will be confirmed at completion of the
40
41 535 optimisation phase, when the effect size of the optimised initiative package is determined.
42
43

44 536 **Statistical analysis**

45
46
47 537 Analyses will be conducted at the group level and conclusions about effectiveness will be based on
48
49 538 group effect. Descriptive statistics will be generated for baseline measures. For the primary outcome,
50
51 539 linear mixed modelling will assess between group differences in vegetable intake at 12-weeks,
52
53 540 controlling for baseline intake and potential confounding factors including any identified baseline
54
55 541 differences between groups. The primary outcome will be analysed using intention-to-treat principles.
56
57 542 For secondary outcomes of impact, logistic regression and linear regression models will assess
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3 543 treatment effects. Mean follow up values (continuous variables) or difference in proportions
4
5 544 (dichotomous variables) in outcome from baseline to follow-up will be compared between groups.
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7

8 545 **Patient and Public Involvement Statement**

9

10 546 The initiative package was developed by researchers, dietitians, educators and sensory scientists with
11 547 experience in education sectors and food provision in childcare settings. The curriculum development
12
13 548 team included experts in LDC curriculum and LDC educators; and the curriculum was reviewed by
14
15 549 educators for suitability during the development process. The educator module was developed in
16
17 550 collaboration with an adoption partner who has experience delivering training to the LDC sector. LDC
18
19 551 content experts were consulted during the development of evaluation instruments to ensure that all
20
21 552 relevant process outcomes, in particular barriers and facilitators, were measured and language used
22
23 553 was suitable. Final questionnaires were reviewed for suitability and usability by cooks and educators.
24
25 554 The acceptability and feasibility of the initiatives in terms of time investment, barriers, compatibility
26
27 555 with practice and participant burden will be assessed as part of the process evaluation. A summary of
28
29 556 study results will be disseminated to participating centres, long day care providers participating and
30
31 557 organisations within the long day care sector via email distribution.
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39 559 **DISCUSSION**

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42 560 This study will use the MOST framework to develop, optimise and evaluate a
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44 561 multicomponent initiative package to increase children's vegetable intake in childcare. The initiative
45
46 562 package will support cooks and educators to increase their knowledge and skills for providing
47
48 563 vegetables on the menu, using supportive feeding practices at mealtimes, and delivering a sensory and
49
50 564 experiential vegetable-focused curriculum. A strength of this study is use of the MOST framework.
51
52 565 MOST differs from the classic resource intensive intervention evaluation process that uses sequential
53
54 566 pilot and RCT studies, by using factorial experiments to optimise the intervention components before
55
56 567 proceeding to evaluation using an RCT.⁴² This provides a more rapid and economical approach for
57
58 568 producing effective, efficient and scalable multicomponent interventions.⁴² The initiatives will equip
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2
3 569 cooks and educators with the knowledge and skills to implement the intervention to ensure
4
5 570 sustainability outside of the research setting and will be developed with an adoption partner who
6
7 571 works within the sector to provide a pathway to roll-out. Growing use of internet technology enables
8
9 572 online delivery of the initiatives which will provide the potential for increased reach and adoption by
10
11 573 staff and centres for whom time and distance may prohibit participation in face to face training.⁷⁰
12
13 574 While face-to-face delivery of training can be valuable for sharing of experiences between educators,
14
15 575 it is more resource intensive and requires moderation without necessarily adding value above online
16
17 576 training.⁶⁰ The cost of face-to-face training can also have implications on limiting the potential for
18
19 577 scalability and sustainability. Therefore, as our aim was to deliver an initiative package that would be
20
21 578 sustainable and scalable outside of the research setting, online delivery was used. The optimised
22
23 579 initiative package will be rolled out online for use by LDC centres and has future potential to be
24
25 580 adapted for use in other settings including family day care, out of school hours care and schools.
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29 581 Some limitations to the study need to be acknowledged. The study design requires that
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31 582 participating LDC centres make organisational changes, therefore it is not possible to conceal group
32
33 583 allocation which introduces a risk of bias. However, assessors and centres will be blinded at baseline
34
35 584 data collection. In most Australian states, including South Australia, the majority of childcare centres
36
37 585 are managed by large providers,⁵⁵ therefore there is a risk of intervention contamination across centres
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39 586 of the same provider who are enrolled in different conditions. Centres participating in both trials will
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41 587 be advised not to use any other training or initiatives during the study and data will be collected about
42
43 588 any other programs used. This study will be conducted in private long day care centres in two
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45 589 jurisdictions in Australia, limiting the generalisability of the findings outside of these jurisdictions.
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52 53 54 592 **ETHICS APPROVAL AND DISSEMINATION**

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57 593 This study has received ethics approval from the Flinders University Research Ethics Committee
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59 594 (Project No: 1873) for the Optimisation Phase. Approval for the Evaluation Phase will be obtained as
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3 595 amendment to current approval at completion of Optimisation Phase, which will identify the final
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5 596 optimised initiative package for evaluation in the final phase. Findings will be disseminated to
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7 597 stakeholders in childcare sectors, in particular long day care centres and professional childcare bodies
8
9 598 and researchers. Results will also be disseminated to researchers via peer-reviewed journals and
10
11 599 conferences.

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14 600

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18
19
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21
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23
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25
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27
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29
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31
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33
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40 611 **AUTHORS' CONTRIBUTIONS**

41
42
43 612 RKG is a Principal Investigator of this study. The study was conceived, and funding obtained by
44
45 613 RKG, DNC and AAMP. DZ and RKG led the design of the study with all authors contributing to
46
47 614 study design through regular discussion. AAMP, MOCB with contribution from JCA, DZ and RKG
48
49 615 designed and developed the curriculum initiative. RKG, DZ and JCA with contribution from SK
50
51 616 designed and developed the food provision and meal environment initiatives. DZ drafted the
52
53 617 manuscript and wrote the research protocol for the Flinders University Social Behavioural Research
54
55 618 Committee with support from all authors. All authors have read and approved the final manuscript.

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3 620 **COMPETING INTERESTS**
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6 621 The authors declare that they have no competing interests. The funding body, Hort Innovation, has a
7
8 622 vested interest in increasing vegetable intake. Hort Innovation had no input into the design of the
9
10 623 study or preparation of this manuscript. Hort Innovation approved the manuscript for publication.
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17

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34 633 **AVAILABILITY OF DATA AND MATERIALS**
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37 634 The datasets which will be used and/or analysed during the current study will be available from the
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39 635 corresponding author on reasonable request.
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3 828 **FIGURES**
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7 830 **Figure 1** – Logic model for development of initiative package for use in long day care to increase
8 831 children’s vegetable intake

9 832 **Other sensory exposure - sensory-based explorative behaviours through the five senses (sight, smell,*
10 833 *touch, hearing, taste) to promote familiarization with vegetables*

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14 835 **Figure 2** – Study design for development and evaluation of initiative package for use in long day care
15 836 to increase children’s vegetable intake

16 837 **See Table 2 for outcome measures and instruments at all timepoints.* Abbreviations: LDC = long day
17 838 care; LDCC = long day care centres

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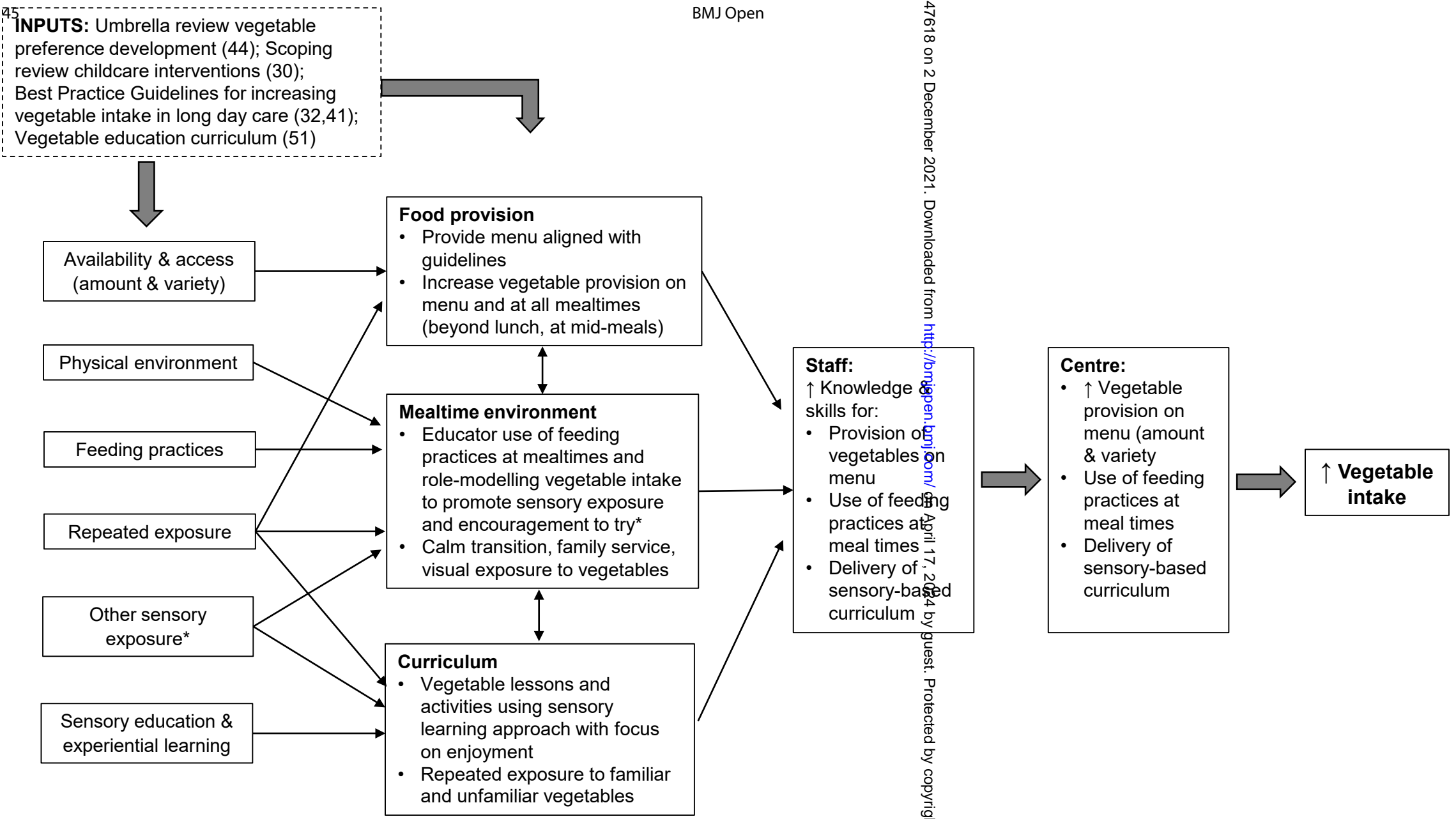


Figure 1 – Logic model for development of initiative package for use in long day care to increase children’s vegetable intake

*Other sensory exposure - sensory-based explorative behaviours through the five senses (sight, smell, touch, hearing, taste) to promote familiarization with vegetables

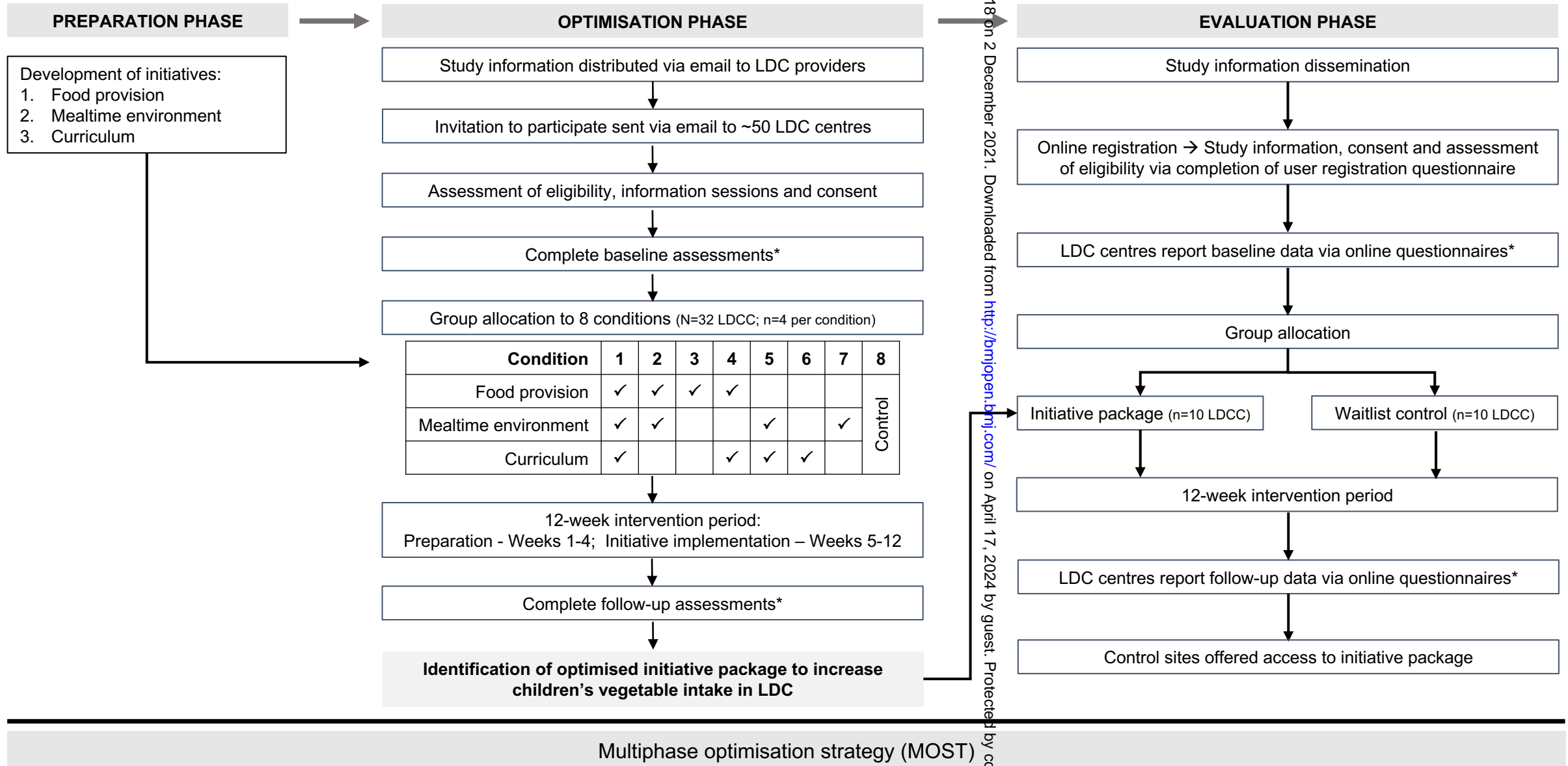


Figure 2 – Study design for development and evaluation of initiative package for use in long day care to increase children's vegetable intake

*See Table 2 for outcome measures and instruments at all timepoints. Abbreviations: LDC = long day care; LDCC = long day care centres

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

Section/item	Item No	Description	Addressed on page number:
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	Trial registration through ANZCTR – as per p.3
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	26
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 27
	5b	Name and contact information for the trial sponsor	26
	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	27

	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	3-6
	6b	Explanation for choice of comparators	3-6
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6,7, 12,21
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	4,12,22
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)	12,22
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-11 Figure 1, Table 1
	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

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4		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16,17,19-20
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7		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
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9	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	17-20,23 Table 2
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14	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 2)	16,22-23 Figure 2, Table 2
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17	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	20,24
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22	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13,22
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24	Methods: Assignment of interventions (for controlled trials)			
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26	Allocation:			
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28	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	13,22
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34	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	13,22
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4	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13,22
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7	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13,22
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10		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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13	Methods: Data collection, management, and analysis			
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15	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	16-20,22-23
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22		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	16-17
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25	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	16
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30	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	21, 24
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33		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21, 24
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35		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)	21, 24
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Methods: Monitoring

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4	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	N/A – DMC is not needed due to the nature of the intervention and minimal risk
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11		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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14	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	N/A
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17	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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21	Ethics and dissemination			
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23	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	26
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26	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)	N/A
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29				
30	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 22
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34		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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36	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
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4	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
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7	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	27
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10	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
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13	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	26
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18		31b	Authorship eligibility guidelines and any intended use of professional writers	26
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20		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
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23	Appendices			
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25	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not attached as Appendices – can be provided upon request
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31	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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