BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-047618
Article Type:	Protocol
Date Submitted by the Author:	03-Dec-2020
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Keywords:	Community child health < PAEDIATRICS, NUTRITION & DIETETICS, PUBLIC HEALTH

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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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Word Count: 5964 words

3rd December 2020, Version 1

ABSTRACT

Introduction: Globally, children do not eat enough foods from the five food groups, with vegetable intake being persistently low. Early life is a crucial period for establishing vegetable acceptance and intake. Increased reliance by families on formal childcare has led to childcare settings playing an important role in shaping young children's food intake. This study will use 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.

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

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

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

Keywords: Multiphase Optimisation Strategy, Early Care and Education, childcare, nutrition, vegetable intake, early childhood, menu provision, feeding practices, sensory education, vegetable acceptance

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will use the Multiphase Optimisation Strategy (MOST) framework to develop, optimise and evaluate a best-practice multicomponent initiative package which aims to increase children's vegetable intake in long day care.
- The MOST framework is a novel approach for producing effective, efficient and scalable multicomponent interventions, which is a more rapid and less resource intensive than classical approaches using sequential pilot and RCT studies.
- The initiatives will equip cooks and educators with the knowledge and skills to implement the intervention to ensure sustainability outside of the research setting and will be developed with an adoption partner who works within the sector to provide a pathway to roll-out.
- Notable limitations include the inability to conceal group allocation as participating centres are required to make organisational changes and possibility of contamination across centres from the same childcare provider which are enrolled in different conditions.

INTRODUCTION

Globally, children do not eat enough foods from the five food groups and overconsume nutrient-poor foods and drinks.[1] In particular, intake of vegetables is persistently low. Only 6.3% of Australian children eat the recommended amount of vegetables,[2] with similar low intake in other countries.[3-5] The first five years of life (i.e. early childhood) is a critical period when adequate nutrition is fundamental for growth and development, influencing a child's lifelong health trajectory.[6] [7] Early childhood is also an important period for establishing vegetable liking and acceptance, which

are associated with vegetable intake.[8-10] Humans are born with an innate liking for sweet taste and a predisposition to reject foods with bitter flavours, such as vegetables.[8 9] However, food preferences are most malleable in early childhood when young children can learn to like a range of foods, including vegetables, through a variety of mechanisms including early and repeated exposure.[8 10 11] Repeated exposure can overcome low willingness to try new foods and food rejection that occur as part of child development between ages two and six years, leading to increased vegetable intake.[8 11] Parents are a key influence on children's food intake in the early years, but many young children also spend considerable time in non-parental formal and informal care arrangements where food is provided to them.[12 13] Over half of 2-to-5 year old children in Australia attend formal centre-based early childhood education and care, most commonly long day care (LDC),[13 14] where children spend on average three days (~30 hours) per week.[15]

LDC centres in Australia provide both full-time and part-time care to children aged six weeks to six years, for up to 12 hours a day.[13 14] LDC generally includes an education element to prepare children for school and approximately 70% (variable by state and territory) of centres provide food that is prepared onsite for morning snack, lunch and afternoon snack, accounting for 40-60% of children's daily food intake in care.[16 17] Many also provide breakfast and a late snack.[17] Australian LDC services must comply with a National Quality Framework which outlines standards for the sector, including for healthy eating.[18] Menu planning guidelines that guide the provision of foods according to dietary guidelines are also common.[19] Despite these standards, children's food intake while in child care is not consistent with dietary guidelines [20-22] and menus at most LDC centres do not comply with menu guidelines.[23 24] For example, 0- 55% of centres comply with guidelines for vegetable provision.[23 25 26] Barriers reported by cooks to improving menu compliance with guidelines include perceptions about children's likes and dislikes, increased cost and food wastage.[27] Further, although educators report that promoting healthy eating is an important part of their role, use of feeding practices that create a supportive mealtime environment for tasting new foods and enjoying vegetables have not been consistently observed in practice.[28 29] Given the pivotal role that early care settings can play in shaping children's dietary intake and the importance of the early years for

establishing vegetable acceptance, there is a need to better support LDC centres to provide supportive environments for promoting vegetable intake.

Childcare-based nutrition promotion strategies can be effective for improving children's food intake in care.[30 31] Interventions targeting improvements in vegetable intake in childcare settings have achieved small-moderate increases in intake ranging from one-quarter of a serve to 67g (1 serve = 75g).[32 33] In comparison, school-based interventions with older children achieved increases of 0.07 servings of vegetables,[34] suggesting that intervening at an earlier age when vegetable preferences are being formed can produce superior results. Multi-level (targeting individuals and environments) and multi-component nutrition promotion approaches in child care have been most successful.[30 32] Interventions which improved children's healthy eating behaviours in care have targeted a combination of nutrition policies and food provision,[31 35] staff training,[35 36] educators' nutrition knowledge and feeding practices,[37 38] delivery of curricula and sensory education,[31 35 37] role-modelling and observational learning.[39] Further, providing training and embedding interventions into everyday routines of the child care centre is likely to improve the sustainability of interventions.[30] Best practice guidelines for intervention design to increase young children's vegetable intake also emphasise the need for multilevel and multicomponent approaches, which target both individuals and the environment, have more than one target audience (i.e. educators, children), focus on vegetables and making frequent contact with participants over at least six weeks.[32 40] Accordingly, a multicomponent intervention with a strong vegetable focus, which combines strategies that target children, such as education and hands-on sensory experiences, with strategies targeting educators, cooks and the centre environment to support regular and repeated exposure to vegetables, is needed to produce optimum results for increasing vegetable intake in young children.[30]

Delivery and evaluation of multicomponent interventions within community settings presents many challenges. Traditional approaches using randomised controlled trials (RCT) to evaluate the performance of several intervention components are resource intensive, requiring multiple trials or many experimental conditions with high cost and large sample sizes. Conversely, evaluation of a multi-component intervention 'package' via RCT does not provide information about the relative

effectiveness of individual intervention components or the synergy between components. To overcome these limitations, the Multiphase Optimisation Strategy (MOST) uses a multi-phase experimental design to develop multi-component behavioural interventions.[41] The MOST provides an efficient approach for identifying the most effective combination of intervention components, by testing main, additive and interactive effects of multiple interventions [42]. Further, MOST embeds within its design evaluation of compatibility with practice and effectiveness within real-world settings, supporting the development of interventions that can be more readily translated into policy and practice.[41]

This study will use the MOST experimental design to develop and evaluate a multicomponent initiative package for use in LDC centres to increase children's vegetable intake while in care. The aims of this study are to 1) develop three initiatives targeting food provision, meal time practices and curriculum which integrate best practice guidelines for increasing vegetable intake in LDC (*preparation phase*), (2) identify the optimum combination of initiatives for increasing 2-to-5 year old children's vegetable intake in LDC (*optimisation phase*), and (3) determine the effectiveness of the optimised initiative package for increasing children's vegetable intake in care (*evaluation phase*). We hypothesise that the effects of the three initiatives for increasing vegetable intake will be synergistic, and secondly, that the optimised initiative package will increase children's mean vegetable intake while in care by more than 0.5 serves.

METHODS

Trial design

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

INSERT FIGURE 1 HERE

Preparation Phase

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

Food provision initiative

The food provision initiative will support cooks to increase the provision of vegetables across all eating occasions, in the context of training to plan a menu that aligns with healthy menu guidelines.[45] Interventions supporting childcare centres to improve compliance with menu guidelines have increased children's vegetable intake by 0.1-0.4 serves.[25 46] Cooks will complete an online training 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.	**Goal**: To support cooks to increase the provision of vegetables on the menu to align with guidelines and across all mealtimes **Objectives**: 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	**Make vegetables the hero** – have simple vegetable specific messages with a clear focus **Coordinate sustained effort across multiple players** – coordinate long-term action among key players involved in promoting & proving vegetables **Grow knowledge and skills to support change** – identify and act on gaps in knowledge and skills **Minimise barriers to increase success** – understand and identify ways to address barriers **Plan for and commit to success** – set clear and measurable vegetable-specific goals **Create an environment that supports children to eat vegetables** – make vegetables the easy choice, promote vegetable familiarisation & intake **Monitor and provide feedback on progress** – monitor progress
Mealtime environment	Educator (mealtimes)	Online educator training module supported to encourage children to taste and enjoy vegetables at mealtimes.	**Goal**: To increase the use of mealtime practices which will promote children's vegetable acceptance and intake **Objectives**: 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,	**Goal**: To create an environment which supports children to enjoy, try and consume vegetables **Objectives**: 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

revised menu. The training will take approximately 45-55 minutes to complete and covers menu planning, importance of healthy eating, implementing menu guidelines and overcoming common barriers. Cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines. There are currently no South Australian guidelines, therefore Victorian Menu Planning Guidelines will be used, which align closely with previous South Australian guidelines.[19 45] Cooks will enter their current menu, recipes, and number of children for whom their menu caters and will receive an overview of compliance of the menu with guidelines for each food group. Recommendations by food group will be provided, identifying meal occasions (morning snack, lunch, and afternoon snack) and days where the menu needs to be revised to meet guidelines. According to the guidelines, children should be offered 1-1.5 serves of vegetables and legumes/beans per day (1 serve = 75g vegetables or cooked beans, 1 cup of leafy greens), at least 2-3 different types of vegetables per day and at least 5 different types per week.[45] Cooks will have four weeks to complete training, the menu assessment and revise their menu according to the recommendations provided before implementing the revised menu at their next menu change.

Mealtime environment

The mealtime environment initiative will support educators to use mealtime practices that promote children's vegetable acceptance and intake. The initiative will apply evidence for effective strategies that support development of vegetable acceptance development in other settings within a childcare setting.[44 47] The initiative will aim to increase educator's knowledge and skills to use feeding practices at mealtimes that will promote vegetable familiarisation via repeated exposure and opportunities to try vegetables, including the division of responsibility ('educator provides, child decides'),[48] repeated encouragement to try, use of neutral language, sensory tasting using the five senses and role modelling of vegetable intake.[10 44 47 49] Educators will complete an interactive online training module (~45-55 minutes) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and planning and implementing a strategy within their centre. The training module will

promote strategies to increasing vegetable acceptance and intake within the context of creating a mealtime environment which promotes healthy eating. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the eight weeks of the implementation period (as described below).

Curriculum

The curriculum initiative will consist of a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables. The curriculum is based on experiential learning, sensory education, and insights on vegetable preference development in children. The curriculum will be adapted from the evidence-based Taste & Learn vegetable education curriculum for primary school children (aged 5-12 years)[50] to be suitable for younger children and align with The Early Years Learning Framework.[51] Taste & Learn is effective for increasing children's vegetable knowledge, verbalization skills, acceptance, and willingness to try vegetables.[52] The curriculum will consist of the following elements:

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

Educators will be provided with written background information and lesson plans to teach and implement the program over the eight-week implementation period. The development process will engage early education experts to ensure that the curriculum is appropriate and aligns with usual teaching practice and everyday routines in LDC.

INSERT FIGURE 2 HERE

Optimisation Phase

Study design

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

Eligibility criteria

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

Recruitment

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

approached to provide endorsement for the study. Centres will be randomly sampled from provider lists, stratified by centre size and socio-economic status using the Socio-Economic Indexes for Areas (SEIFA).[54] Randomly sampled centres will be sent information about the study by email to the Director. Centres will then be contacted by phone to determine interest in study participation. An information session about the study will be conducted at the centre to inform all staff of what is involved and allow the opportunity to ask questions. Centre directors will provide consent for their centre to participate in the study, and participating cooks and educators within centres will provide consent to be involved in initiatives and provide data. The standard electronic method of communication (i.e. communication Apps) within participating centres will be used to distribute information about the study to parents. These systems allow parents to notify the centre (via the App) when forms or notices have been opened and read. Parents will indicate that they wish to exclude children from data collection by electronically signing and returning the opt-out form via the App. This opt-out strategy has been used successfully in a previous study in South Australian LDC centres and is approved by the ethics committee.[25]

Randomisation and blinding

Centres will be randomised to one of the eight experimental conditions at completion of baseline data collection by a member of the research team who is not directly involved in this study. Random allocation will be done using computer number sequence generation in Excel, stratified by socioeconomic status determined from postcodes (zip codes) using SEIFA[54] and size of long day care centre. Research staff and participating centres will be blinded to intervention group allocation at baseline only.

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	Plate waste	✓	BL, 12w	SFS-ECEC
	Child intake of other food groups – fruit, grains, dairy, meat & alternatives, extras (serves/day)	✓					
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)	✓			✓		
	Menu compliance with guidelines	✓	BL, 12w	Menu assessment	✓	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				
	Feasibility	✓	-	*Interpretation of implementation & maintenance*	✓	-	*Interpretation of implementation & maintenance*
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

Study procedures

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

Strategies to minimise attrition and improve fidelity

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

initiative and reinforce key messages of the initiatives. For example, for the food provision initiative messages will be sent weekly in the preparation phase when cooks are completing the training and assessing their menu and then fortnightly in the eight-implementation phase once the menu is implemented. Educators participating in the curriculum and mealtime environment initiatives will receive messages fortnightly in the preparation period and weekly in the implementation period when they are delivering the curriculum and using feeding practices at mealtimes.

INSERT TABLE 2 HERE

Primary outcome measures

Dietary intake

Children's vegetable intake will be assessed within the context of total food intake while in care, estimated using the plate wastage method which is a standard method for assessment of food intake in child care [25]. Data will be collected from all eligible children present on the day. Prior to each mealtime (morning tea, lunch, and afternoon tea) bowls/plates and cups will be labelled with ID stickers and weighed. As food is served each component of the meal will be weighed and weight recorded. Any additional servings provided to the children will also be weighed and recorded. At the end of the meal all plates with remaining food will be weighed. Food dropped from the child's plate will be collected and added to the plate at the end of the meal for weighing. The amount of food consumed will be measured by subtracting the mass of the food waste left over from the initial mass. This will be done for each food group, including vegetables, and converted from grams to Australian Guide to Healthy Eating standard serves.[55]

Secondary outcome measures

Menu compliance with guidelines

Compliance of the centre menu with menu guidelines at baseline and follow-up will be assessed by menu audit completed using an online menu assessment tool. Centres will provide their current menu, recipes, purchase receipts and number of children catered for, which will be entered by research staff

into the online menu assessment tool. The outcome measures will be the proportion of centres complying with guidelines at both time points.

Knowledge and skills

For each initiative, staff knowledge and skills will be evaluated using the knowledge and skills scales of the Theoretical Domains Framework Questionnaire (TDFQ) for cooks developed by Seward.[56] As described below, the questions for use with cooks will be adapted to be suitable for use with educators to evaluate the mealtime and curriculum initiatives. The knowledge scale will evaluate awareness and familiarity with each of the initiatives. The skills scale will evaluate the training and skills gained for each of the initiatives. Additional purpose-designed items will be added to the skills scale for the educator's mealtime environment initiative questionnaires to evaluate use of feeding practices at mealtimes.

Acceptability

The usability and acceptability of the cook's training and menu assessment tool, educator's training and curriculum will be evaluated using the content quality, motivation, presentation design, re-usability and learning goal dimensions of the LORI framework for evaluating the quality of multimedia learning resources.[57] Questions will be added to evaluate suitability of the duration/length of the initiatives. A questionnaire using the LORI framework which was completed by primary school teachers in the evaluation of Taste & Learn curriculum will be adapted for use in this study.[58]

Contextual and behavioural factors

Contextual and behavioural factors that can influence initiative implementation will be evaluated, guided by the Theoretical Domains Framework (TDF). The TDF is an implementation framework that synthesizes and evaluates behaviour change constructs that may affect the implementation of evidenced based practices and guidelines.[59] The following TDF domains will be evaluated: environmental context (barriers and facilitators), beliefs about consequences, social influences, beliefs about capability (self-efficacy) and three domains that evaluate compatibility with practice (part of regular practice, professional role to implement and intention to implement). The selection of domains

was guided by recommendations for a minimum data set of implementation determinants [60], expert consultation and previous studies evaluating implementation of interventions in the childcare setting.[46 61] To evaluate implementation of the food provision initiative, the specified domains from the TDFQ for cooks developed by Seward[56] will be used, which has been evaluated with Australian LDC cooks and has good discriminant validity and reliability.[56] The TDFQ for cooks will be adapted to evaluate the implementation of the curriculum and mealtime environment initiatives. The questionnaire will be piloted with LDC content experts and educators to determine acceptability and usability. Data collected will be used to assess the reliability (Cronbach's alpha) and construct validity using factor analysis.

Maintenance

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

Fidelity and dose

The extent to which the initiatives were delivered as planned to educators and cooks (fidelity) and implemented by staff at the centre (dose) will be evaluated. The outcome measures will be the proportion of participating cooks and educators that completed the training modules, menu assessment and delivered the curriculum and proportion of initiative components that were delivered to children. Initiative delivery will be determined using website metrics for training modules and menu assessment tool. Fidelity and dose of the curriculum initiative will be determined using an educator-completed checklist of lessons and activities delivered. A question will be included in the cook's follow-up questionnaire asking whether cooks implemented the revised menu. Use of feeding practices at mealtimes will be evaluated via addition of items to the skills scales of the TDFQ for educators, as described above. Open-ended questions will be included in the follow-up questionnaire to determine reasons for non-completion of initiatives.

Reach and adoption

Reach, that is the proportion of the intended audience who participated in the study, will be evaluated based on the response rate and profile of attending children (age, gender, ethnicity, Aboriginal or Torres Strait Islander). Adoption will be evaluated as the characteristics and representativeness of participating centres in terms of type of provider (chain versus independent), centre size, socioeconomic status, location and characteristics of participating staff at centres including qualifications, experience in sector and previous training. Representativeness will be evaluated by comparison with ACECQA data for LDC centres in Adelaide.[53]

Contamination

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

Covariates

At baseline, centre operational characteristics will be collected for postcode, operating days and hours, enrolments, attendance, number of Aboriginal or Torres Strait Islander children enrolled, meal provision, centre nutrition policy, menu cycle length and use of menu guidelines, nutrition-related programs and teaching resources At follow-up, centres will also report use of other nutrition policies or programs during the study. Staff characteristics will include number of staff employed and their role (i.e. cook, educator, kitchen assistant), hours worked per week, age, gender, years in current position as well as years employed in ECEC sector, and qualifications relevant to role. The age and gender of children participating in data collection will be collected at baseline and follow-up.

Sample size

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

condition, will provide the required sample size. We will assume a 75% response rate based on past interventions in Australian childcare centres[56 64] and therefore will expect to approach approximately 45-50 LDC centres to recruit 32 centres.

Statistical analysis

Descriptive statistics will be used to describe centre characteristics and demographics at baseline and chi-square and t-test statistics will be used to check for differences between groups. A factorial experiment using repeated measure ANOVA models will test the effects of the three initiatives on the primary outcome. Initial models will test whether each initiative (provided versus not provided) had a significant effect on vegetable intake across the 12-week intervention period (pre-post intervention effect). Subsequent models will test two and three-way interactions between initiative components to identify the effects of interactions between initiatives on outcomes. Analyses will control for covariates including child gender, age, and number of children at each timepoint. For secondary outcomes of impact, logistic regression and linear regression models will assess treatment effects. The mean change (continuous variables) or difference in proportions (dichotomous variables) in outcome from baseline to follow-up will be compared between groups. Between-group differences in scores for TDF domains will be evaluated using t-tests to assess the impact of contextual factors on intervention effectiveness.

Evaluation phase

Study design

This study will evaluate the reach, adoption, impact and effectiveness of the optimised initiative package for increasing children's vegetable intake, using a waitlist randomised controlled trial conducted in target states, including but not limited to South Australia and Victoria. Centres in the intervention group will use the optimised package following completion of baseline measures. The waitlist control group will be asked not to change their current practice for the intervention period and will be provided access to the initiative package following completion of follow-up assessments. We hypothesise that the optimized initiative package will include all three initiatives and we plan to

collect evaluation data accordingly. If fewer initiatives are included in the initiative package, evaluation data will only be collected for included initiatives.

Recruitment and participants

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

Randomisation and blinding

Centres will be randomised to intervention or waitlist control group using stratified randomisation based on centre location (state) and socioeconomic status (using postcode to determine SEIFA index). Due to the nature of the study, blinding of the researchers or participating centres will not be possible

Study procedures

This study will be delivered and evaluated online, with all measures self-completed by participating centres using online data collection instruments. This approach will support centres to monitor their own progress towards increasing children's vegetable intake, which will align the initiative package with Best Practice Guidelines.[32 40] Data will be collected at baseline and 12-weeks. Centres will register for the study using an online user registration form. At the first step of registration, the purpose of the study will be explained, and centres will be asked to read the detailed information sheet and sign a consent form. Centres will distribute information about the study to parents and opt-out consent from parents will be collected using the process described for the Optimisation Phase. The user registration form will collect information about the centre which will be used as covariates and to evaluate reach and adoption (Table 2). Educators and cooks who will be using the initiatives will complete a baseline questionnaire providing information about staff characteristics, knowledge and skills, as per the optimisation phase. Centres will then collect data about children's current vegetable

intake and enter this into the online survey platform. At completion of baseline, centres will be allocated to the intervention or control group. At conclusion of the 12-week intervention period participating educators and cooks will complete evaluation questionnaires and centres will collect vegetable intake data as per baseline. Centres in the control group will receive access to the online package post-intervention and the intervention group will be encouraged to keep using the initiatives.

Primary outcome measure

The primary outcome measure will be usual serves of vegetables per day at LDC. Individual child vegetable intake over the past month in care will be measured using the vegetable questions from the Short Food Survey for Early Care and Education (SFS-ECEC).[66] The SFS-ECEC is a 47-item educator-completed questionnaire measuring children's intake in care. Six questions measure the frequency and usual portion size of starchy, salad and cooked vegetables. The questionnaire is acceptable to educators and has appropriate validity for estimating intake at the group level.[66] Instructions and supporting resources for the SFS-ECEC will be provided as downloadable instructions. Each educator will complete the vegetable intake questions online for a randomly selected sample of at least 50% of children in their care, which equates to approximately 5-6 children per educator and approximately a thirty minute time commitment based on educator to child ratios defined under the National Quality Framework.[67]

Secondary outcome measures

An online questionnaire in combination with website metrics will assess reach, adoption, impact, and fidelity as described for the optimisation phase and summarised in Table 2. The follow-up questionnaire will collect data for key implementation measures of acceptability, barriers and facilitators, compatibility with practice and intention to implement initiatives, which with adoption and fidelity data will enable evaluation of feasibility.

Sample size

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

standard deviation from prior research.[46] At this effect size, with power at 0.8, $p<0.05$ and ICC=0.1, a sample 284 children is needed. Based on 15% attrition in prior studies and estimating data from approximately 20 children will be provided per centre, 20 LDC centres will need to be recruited.

Statistical analysis

Analyses will be conducted at the group level and conclusions about effectiveness will be based on group effect. Descriptive statistics will be generated for baseline measures. For the primary outcome, linear mixed modelling will assess between group differences in vegetable intake at 12-weeks. The primary outcome will be analysed using intention-to-treat principles. Models will control for baseline intake and potential confounding factors (i.e. baseline differences between groups). For secondary outcomes of impact, logistic regression and linear regression models will assess treatment effects. Mean follow up values (continuous variables) or difference in proportions (dichotomous variables) in outcome from baseline to follow-up will be compared between groups.

Patient and Public Involvement Statement

The initiative package was developed by researchers, dietitians, educators and sensory scientists with experience in education sectors and food provision in childcare settings. The curriculum development team included experts in LDC curriculum and LDC educators; and the curriculum was reviewed by educators for suitability during the development process. The educator module was developed in collaboration with an adoption partner who has experience delivering training to the LDC sector. LDC content experts were consulted during the development of evaluation instruments to ensure that all relevant process outcomes, in particular barriers and facilitators, were measured and language used was suitable. Final questionnaires were reviewed for suitability and usability by cooks and educators. The acceptability and feasibility of the initiatives in terms of time investment, barriers, compatibility with practice and participant burden will be assessed as part of the process evaluation. A summary of study results will be disseminated to participating centres, long day care providers participating and organisations within the long day care sector via email distribution.

DISCUSSION

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

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

In conclusion, this paper describes the design, delivery, and evaluation of a multi-component initiative package which aims to increase children's vegetable intake in LDC. The initiative package applies evidence for vegetable preference development[44] and Best Practice Guidelines for increasing vegetable intake in LDC settings.[32 40] The optimised initiative package will be rolled out online for use

by LDC centres and has future potential to be adapted for use in other settings including family day care, out of school hours care and schools.

ETHICS APPROVAL AND DISSEMINATION

This study has received ethics approval from the Flinders University Research Ethics Committee (Project No: 1873) for the Optimisation Phase. Approval for the evaluation phase will be obtained as amendment to current approval at completion of Optimisation Phase, which will identify the final optimised initiative package for evaluation in the final phase. Findings will be disseminated to stakeholders in childcare sectors, in particular long day care centres and professional childcare bodies and researchers. Results will also be disseminated to researchers via peer-reviewed journals and conferences.

FUNDING

This project is being conducted as part of VegKIT (www.vegkit.com.au). VegKIT is funded by Hort Innovation, using the vegetable research and development levy and contributions from the Australian Government (grant number VG16064). Hort Innovation is the grower-owned, not-for-profit research and development corporation for Australian Horticulture. The project is being delivered by a collaboration between CSIRO, Flinders University and Nutrition Australia. DZ is supported by the Early Prevention of Obesity in Childhood Centre of Research Excellence (EPOCH CRE). SK is supported by Flinders University Research Scholarship and Healthy Development Adelaide PhD Excellence Award.

AUTHORS' CONTRIBUTIONS

RKG is a Principal Investigator of this study. The study was conceived, and funding obtained by RKG, DNC and AAMP. DZ and RKG led the design of the study with all authors contributing to study design through regular discussion. AAMP, MOCB and JCA with contribution from DZ and

RKG designed and developed the curriculum initiative. RKG, DZ and JCA with contribution from SK designed and developed the food provision and meal environment initiatives. DZ drafted the manuscript and wrote the research protocol for the Flinders University Social Behavioural Research Committee with support from all authors. All authors have read and approved the final manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests. The funding body, Hort Innovation, has a vested interest in increasing vegetable intake. Hort Innovation had no input into the design of the study or preparation of this manuscript. Hort Innovation approved the manuscript for publication.

ACKNOWLEDGEMENTS

We would like to acknowledge the support of the Healthy Eating Advisory Service, funded by the Victorian Department of Health and Human Services and delivered by Nutrition Australia (Victoria) for providing the cooks training module and the menu assessment tool (FoodChecker) for use in the study and collaboration in the development of the mealtime environment training module for educators. We would like to acknowledge the contribution of Janet Elliot, Amy Wakem and Ros Sambell in providing their expertise in the development of the curriculum initiative.

AVAILABILITY OF DATA AND MATERIALS

The datasets which will be used and/or analysed during the current study will be available from the corresponding author on reasonable request.

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FIGURES

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

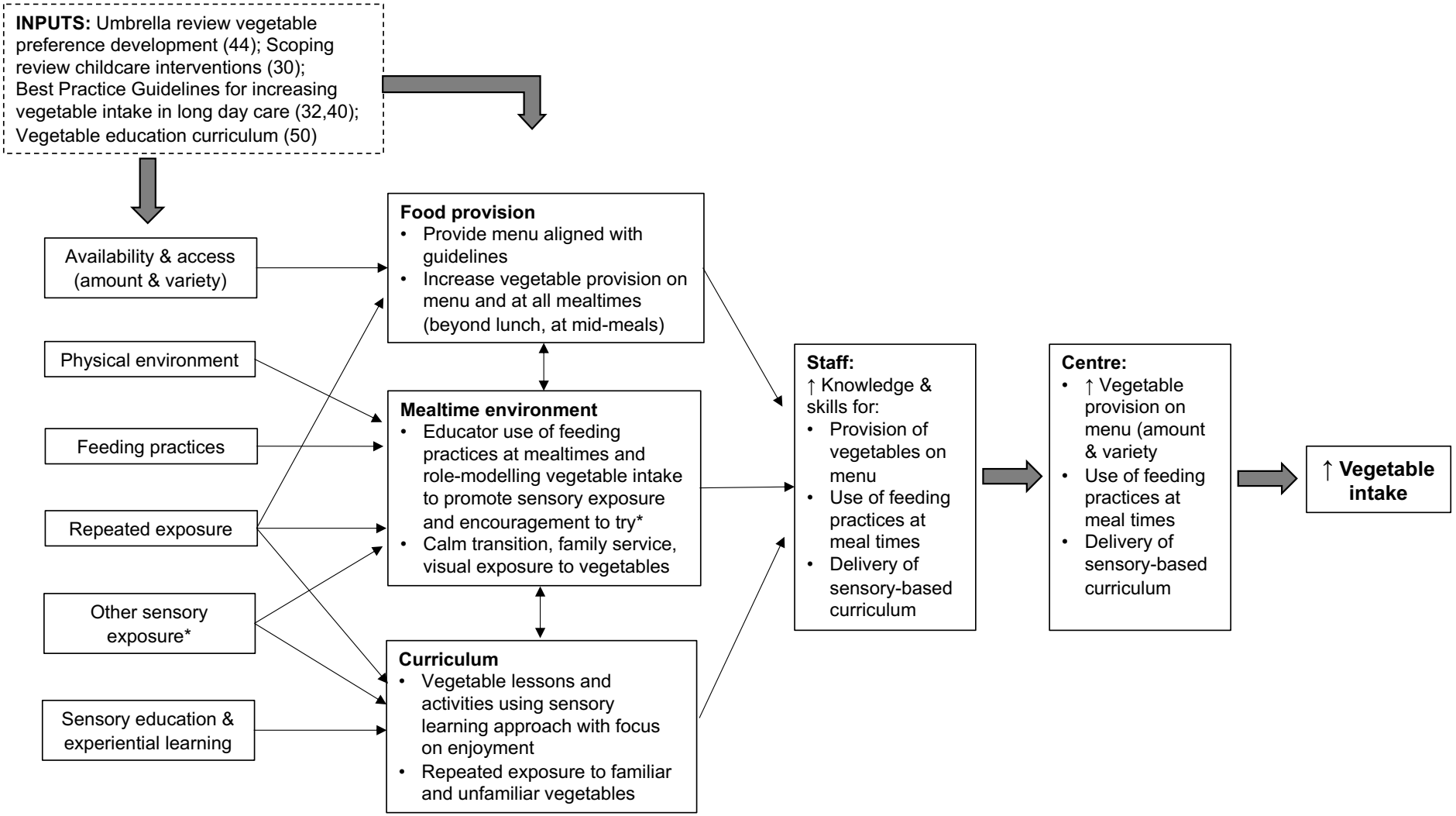

Figure 1 – Logic model for development of initiative package for use in long day care to increase children's vegetable intake

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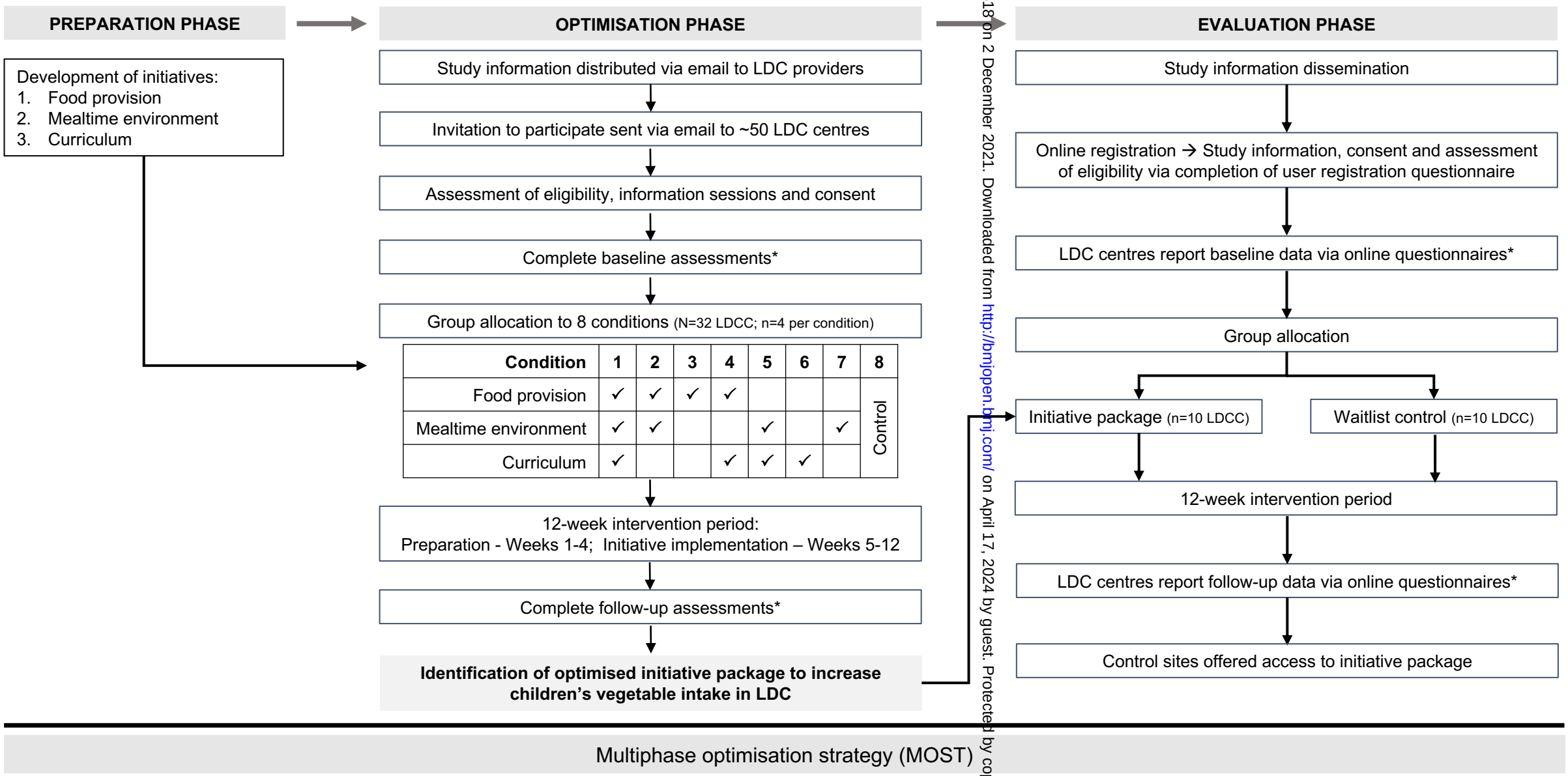

Figure 2 – Study design for development and evaluation of initiative package for use in long day care to increase children's vegetable intake

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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

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16,17,19-20
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
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
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)	16,22-23 Figure 2, Table 2
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13,22
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13,22
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

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13,22
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13,22
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-20,22-23
	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
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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21, 24
	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
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A – DMC is not needed due to the nature of the intervention and minimal risk
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
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
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	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
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
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
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
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
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
	31b	Authorship eligibility guidelines and any intended use of professional writers	26
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
Appendices			
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
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

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

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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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-047618.R1
Article Type:	Protocol
Date Submitted by the Author:	13-Aug-2021
Complete List of Authors:	Zarnowiecki, Dorota; Flinders University, Caring Futures Institute, College of Nursing and Health Sciences Kashef, Shabnam; Flinders University, Caring Futures Institute, College of Nursing and Health Sciences Poelman, Astrid; Commonwealth Scientific and Industrial Research Organisation (CSIRO), Health & Biosecurity Cochet-Broch, Maeva; Commonwealth Scientific and Industrial Research Organisation (CSIRO), Agriculture and Food Arguelles, Jennifer; Nutrition Australia (Victoria) Cox, David; Commonwealth Scientific and Industrial Research Organisation (CSIRO), Health & Biosecurity Golley, Rebecca; Flinders University, Caring Futures Institute, College of Nursing and Health Sciences
Primary Subject Heading:	Public health
Secondary Subject Heading:	Nutrition and metabolism, Paediatrics
Keywords:	Community child health < PAEDIATRICS, NUTRITION & DIETETICS, PUBLIC HEALTH

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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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Word Count: 7165 words

5th August 2021, Version 2

ABSTRACT

Introduction: Globally, children do not eat enough core foods, with vegetable intakes persistently low. Early life is critical for establishing vegetable acceptance and intake. Increased usage of formal childcare has led to the importance of childcare settings shaping children's food intake. This study will use 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.

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

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

Trial Registration Number: Optimisation Phase - ACTRN12620001301954; Evaluation Phase - ACTRN12620001323910p.

Keywords: Multiphase optimisation strategy, Early Care and Education, childcare, nutrition, vegetable intake, early childhood, menu provision, feeding practices, sensory education, vegetable acceptance

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will use the multiphase optimisation strategy (MOST) framework to develop, optimise and evaluate a best-practice multicomponent initiative package which aims to increase children's vegetable intake in long day care.
- The MOST framework is a novel approach for producing effective, efficient and scalable multicomponent interventions, which is a more rapid and less resource intensive than classical approaches using sequential pilot and RCT studies.
- The initiatives will equip cooks and educators with the knowledge and skills to implement the intervention to ensure sustainability outside of the research setting and will be developed with an adoption partner who works within the sector to provide a pathway to roll-out.
- Notable limitations include the inability to conceal group allocation as participating centres are required to make organisational changes and possibility of contamination across centres from the same childcare provider which are enrolled in different conditions.

INTRODUCTION

Globally, children do not eat enough foods from the five food groups and overconsume nutrient-poor foods and drinks.[1] In particular, intake of vegetables is persistently low. Only 6.3% of Australian children eat the recommended amount of vegetables,[2] with similar low intake in other countries.[3-5] The first five years of life (i.e. early childhood) is a critical period when adequate

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

LDC centres in Australia provide both full-time and part-time care to children aged six weeks to six years, for up to 12 hours a day.[13 14] LDC generally includes an education element to prepare children for school and approximately 70% (variable by state and territory) of centres provide food that is prepared onsite for morning snack, lunch and afternoon snack, accounting for 40-60% of children's daily food intake in care.[16 17] Many also provide breakfast and a late snack.[17] Australian LDC services must comply with a National Quality Framework which outlines standards for the sector, including those for healthy eating.[18] Menu planning guidelines that guide the provision of foods according to dietary guidelines are also common.[19] Despite these standards, children's food intake while in childcare is not consistent with dietary guidelines [20-22] and menus at most LDC centres do not comply with menu guidelines.[23 24] For example, 0- 55% of centres comply with guidelines for vegetable provision.[23 25 26] Barriers reported by cooks to improving menu compliance with guidelines include perceptions about children's likes and dislikes, increased cost and food wastage.[27] Further, although educators report that promoting healthy eating is an important part of their role, use of feeding practices that create a supportive mealtime environment for tasting new foods and enjoying

vegetables have not been consistently observed in practice.[28 29] Given the pivotal role that early care settings can play in shaping children's dietary intake and the importance of the early years for establishing vegetable acceptance, there is a need to better support LDC centres to provide supportive environments for promoting vegetable intake.

Childcare-based nutrition promotion strategies can be effective for improving children's food intake in care.[30 31] Interventions targeting improvements in vegetable intake in childcare settings have achieved small-moderate increases in intake ranging from one-quarter of a serve (approximately 19g) to 67g (approximately 0.89 serves, with 1 serve = 75g based on Australian recommendations).[32-34] In comparison, school-based interventions with older children achieved increases of 0.07 servings of vegetables (approximately 6g),[35] suggesting that intervening at an earlier age when vegetable preferences are being formed can produce superior results. Multilevel (targeting individuals and environments) and multicomponent nutrition promotion approaches in childcare have been most successful.[30 32] Interventions which improved children's healthy eating behaviours in care have targeted a combination of nutrition policies and food provision,[31 36] director and educator training,[36 37] educators' nutrition knowledge and feeding practices,[38 39] delivery of curricula and sensory education,[31 36 38] role-modelling and observational learning.[40] Further, providing training and embedding interventions into everyday routines of the childcare centre is likely to improve the sustainability of interventions.[30] Best practice guidelines for designing interventions to increase children's vegetable intake emphasise the need for multilevel and multicomponent interventions, which target both individuals and the environment, have more than one target audience (i.e. educators, children), target vegetables (i.e. rather than healthy eating) and are of sufficient intensity and duration (at least six weeks duration, with weekly participant contact).[32 41] Accordingly, a multicomponent intervention with a strong vegetable focus, which combines strategies that target children, such as education and hands-on sensory experiences, with strategies targeting educators, cooks and the centre environment to support regular and repeated exposure to vegetables, is needed to produce optimum results for increasing vegetable intake in young children.[30]

Delivery and evaluation of multicomponent interventions within community settings presents many challenges. Traditional approaches using randomised controlled trials (RCT) to evaluate the performance of several intervention components are resource intensive, requiring multiple trials or multiple parallel conditions with high cost and large sample sizes. Although the RCT is the gold standard for evaluating the effectiveness of interventions, evaluation of multicomponent interventions solely via RCT does not provide information about the independent, relative and synergistic effects of intervention components. To overcome these limitations, the multiphase optimisation strategy (MOST) uses a multiphase experimental design to build effective, efficient and scalable multicomponent behavioural interventions.[42] The MOST provides an efficient approach for identifying the most effective combination of intervention components, by testing main, additive and interactive effects of multiple interventions.[43] Further, MOST embeds within its design evaluation of compatibility with practice and effectiveness within real-world settings, supporting the development of interventions that can be more readily translated into policy and practice.[42]

This study will use the MOST framework to develop and evaluate a multicomponent initiative package for use in LDC centres to increase children's vegetable intake while in care. The initiatives will use a paradigm that focuses on building acceptance and familiarity with vegetables, as a sustainable approached to increasing vegetable intake.[44]. This study will use a full factorial design during the optimisation phase to identify which components individually and in combination, produce the best initiative package subject to constraints. Utilising this approach will overcome limitations of studies testing either single intervention components or multicomponent interventions, that are unable to identify which component(s) or combination of components are most effective. This will support the development of feasible, efficient and effective initiative package that can be implemented in practice, without placing burden on LDC centres. The aims of this study are to (1) develop three initiatives targeting food provision, meal time practices and curriculum which integrate best practice guidelines for increasing vegetable intake in LDC (*preparation phase*), (2) identify the optimum combination of initiatives for increasing 2-to-5 year old children's vegetable intake in LDC (*optimisation phase*), and (3) determine the effectiveness of the optimised initiative package for

increasing children's vegetable intake in care (*evaluation phase*). We hypothesise that the effects of the three initiatives for increasing vegetable intake will be synergistic, and secondly, that the optimised initiative package will increase children's mean vegetable intake while in care by more than 0.5 serves.

METHODS AND ANALYSIS

Trial design

This project will undertake the three stages of the MOST: the preparation phase will select and develop the initiatives to be tested; the optimisation phase will assess the independent and synergistic effects of the initiatives to identify the optimal initiative package; and the evaluation phase will test the effectiveness of the initiative package.[42] The RE-AIM model will be used to evaluate the reach, efficacy/effectiveness, adoption, implementation and maintenance of the initiative package across the optimisation and evaluation phases.[45] The optimisation phase will be conducted from December 2020 to August 2021 and the evaluation phase will be conducted from January to August 2022.

INSERT FIGURE 1 HERE

Preparation Phase

Three initiatives will be developed which draw on evidence for effective strategies for increasing vegetable intake and acceptance in the early years[30 44] and align with best practice guidelines for increasing vegetable intake in LDC, which recommend multilevel and multicomponent interventions that combine strategies targeting children and the centre environment. [32 41] (Table 1). The target audience of the initiatives will be children, educators, and cooks. The initiatives will aim to increase educator's and cook's knowledge and skills to create a supportive environment that promotes children's vegetable familiarisation, acceptance, and consumption (Figure 1). Changes to food provision via increasing vegetables on the menu, delivery of experiential and sensory curriculum

activities and use of supportive feeding practices at mealtimes will increase vegetable availability and repeated exposure to vegetables.

Food provision initiative

The food provision initiative will support cooks to increase the provision of vegetables across all eating occasions, in the context of training to plan a menu that aligns with healthy menu guidelines.[46] Interventions supporting childcare centres to improve compliance with menu guidelines have increased children's vegetable intake by 0.1-0.4 serves.[25 47] Cooks will complete an online training module, use an online menu planning tool to review their menu and implement the revised menu. The online training and menu assessment tool were developed by dietitians, with feedback from long day care centres. The training will take approximately 45-55 minutes to complete and covers menu planning, importance of healthy eating, implementing menu guidelines and overcoming common barriers. Cooks will use an automated online menu assessment tool to assess compliance of their menu with guidelines. There are currently no South Australian guidelines, therefore Victorian Menu Planning Guidelines will be used, which align closely with previous South Australian guidelines.[19 46] Cooks will enter their current menu, recipes, and number of children for whom their menu caters and will receive an overview of compliance of the menu with guidelines for each food group. Recommendations by food group will be provided, identifying meal occasions (morning snack, lunch, and afternoon snack) and days where the menu needs to be revised to meet guidelines. According to the guidelines, children should be offered 1-1.5 serves of vegetables and legumes/beans per day (1 serve = 75g vegetables or cooked legumes/beans, 1 cup of leafy greens), at least 2-3 different types of vegetables per day and at least 5 different types per week.[46] Cooks will have four weeks to complete training, the menu assessment and revise their menu according to the recommendations provided before implementing the revised menu at their next menu change.

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.	**Goal**: To support cooks to increase the provision of vegetables on the menu to align with guidelines and across all mealtimes **Objectives**: 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	**Make vegetables the hero** – have simple vegetable specific messages with a clear focus **Coordinate sustained effort across multiple players** – coordinate long-term action among key players involved in promoting & proving vegetables **Grow knowledge and skills to support change** – identify and act on gaps in knowledge and skills **Minimise barriers to increase success** – understand and identify ways to address barriers **Plan for and commit to success** – set clear and measurable vegetable-specific goals **Create an environment that supports children to eat vegetables** – make vegetables the easy choice, promote vegetable familiarisation & intake **Monitor and provide feedback on progress** – monitor progress
Mealtime environment	Educator (mealtimes)	Online educator training module supported to encourage children to taste and enjoy vegetables at mealtimes.	**Goal**: To increase the use of mealtime practices which will promote children's vegetable acceptance and intake **Objectives**: 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,	**Goal**: To create an environment which supports children to enjoy, try and consume vegetables **Objectives**: 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

Mealtime environment

The mealtime environment initiative will support educators to use mealtime practices that promote children's vegetable acceptance and intake. The initiative will apply evidence for effective strategies that support development of vegetable acceptance development in other settings within a childcare setting.[44 48] The initiative will aim to increase educator's knowledge and skills to use feeding practices at mealtimes that will promote vegetable familiarisation via repeated exposure and opportunities to try vegetables, including the division of responsibility ('educator provides, child decides'),[49] repeated encouragement to try, use of neutral language, sensory tasting using the five senses and role modelling of vegetable intake.[10 44 48 50] The training will be developed by a team of dietitians and researchers with knowledge of the long day care sector and a service delivery partner who delivers training and resources to the long day care sector. Educators will complete an interactive online training module (~45-55 minutes) which includes topics about the role of the educator in promoting healthy eating, creating supportive meal time environments, use of feeding practices, overcoming barriers related to food rejection and planning and implementing a strategy within their centre. Examples of interactive components include short quiz questions, reflection questions and planning activities for action within the long day care centre. The training module will promote strategies to increasing vegetable acceptance and intake within the context of creating a mealtime environment which promotes healthy eating. Educators and teachers will then apply the knowledge and strategies learnt in training during mealtimes in the eight weeks of the implementation period (as described below).

Curriculum

The curriculum initiative will consist of a lesson package for educators that aims to provide opportunities for children to learn about, try and enjoy vegetables by increasing their exposure to a variety of familiar and unfamiliar vegetables. The curriculum is based on experiential learning, sensory education, and insights on vegetable preference development in children. The curriculum will be adapted from the evidence-based Taste & Learn vegetable education curriculum for primary school children (aged 5-12 years)[51] to be suitable for younger children and align with The Early Years

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

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

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

INSERT FIGURE 2 HERE

Optimisation Phase

Study design

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

initiative components (Figure 2). This study design maximises the statistical power to identify the main effect of each individual initiative, as well as additive and synergistic effects of initiatives to identify the optimised initiative package that is efficient, scalable and effective for increasing children's vegetable intake. The optimisation criterion is the initiative or combination of initiatives that deliver an increase of more than 0.5 serves of vegetables, anticipating that this should also be a statistically significant increase. The optimisation criterion has been determined based on a meaningful increase in the key outcome variable of vegetable intake, defined as an initiative effect greater than those currently seen in the literature.[32 54] If none of the combinations of initiatives achieve the optimisation criterion, the package will consist of the intervention elements that show a statistically significant increase in vegetable intake, taking into consideration findings of the process evaluation.

Eligibility criteria

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

Recruitment

LDC centres in metropolitan Adelaide, South Australia will be recruited. The majority of LDC centres in South Australia are part of large-chain providers,[55] therefore private LDC providers will be approached to provide endorsement for the study. Centres will be randomly sampled from provider lists, stratified by centre size and socio-economic status using the Socio-Economic Indexes for Areas (SEIFA).[56] Randomly sampled centres will be sent information about the study by email to the Director. Centres will then be contacted by phone to determine interest in study participation. An

information session about the study will be conducted at the centre to inform all staff of what is involved and allow the opportunity to ask questions. Centre directors will provide consent for their centre to participate in the study, and participating cooks and educators within centres will provide consent to be involved in initiatives and provide data. The standard electronic method of communication (i.e. communication Apps) within participating centres will be used to distribute information about the study to parents. These systems allow parents to notify the centre (via the App) when forms or notices have been opened and read. Parents will indicate that they wish to exclude children from data collection by electronically signing and returning the opt-out form via the App. This opt-out strategy has been used successfully in a previous study in South Australian LDC centres and is approved by the ethics committee.[25]

Randomisation and blinding

Centres will be randomised to one of the eight experimental conditions at completion of baseline data collection by a member of the research team who is not directly involved in this study. Random allocation will be done using computer number sequence generation in Excel, stratified by socioeconomic status determined from postcodes (zip codes) using SEIFA[56] and size of LDC centre. Research staff and participating centres will be blinded to intervention group allocation at baseline only.

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	Plate waste	✓	BL, 12w	SFS-ECEC
	Child intake of other food groups – fruit, grains, dairy, meat & alternatives, extras (serves/day)	✓					
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)	✓			✓		
	Menu compliance with guidelines	✓	BL, 12w	Menu assessment	✓	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				
	Feasibility	✓	-	*Interpretation of implementation & maintenance*	✓	-	*Interpretation of implementation & maintenance*
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

Study procedures

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

Strategies to minimise attrition and improve fidelity

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

initiative and reinforce key messages of the initiatives. For example, for the food provision initiative messages will be sent weekly in the preparation phase when cooks are completing the training and assessing their menu and then fortnightly in the eight-implementation phase once the menu is implemented. Educators participating in the curriculum and mealtime environment initiatives will receive messages fortnightly in the preparation period and weekly in the implementation period when they are delivering the curriculum and using feeding practices at mealtimes.

INSERT TABLE 2 HERE

Primary outcome measures

Children's vegetable intake and dietary intake

Children's vegetable intake will be assessed within the context of total food intake while in care, estimated using the plate wastage method which is considered a gold standard method for assessment of dietary intake as it uses direct observation and is not subject to recall or memory bias. Plate wastage methods have been used previously to asses food intake in childcare.[25 47 57] Standardised data collection procedures will be followed in all centres. To minimise any potential effects of labelling plates/cups and the presence of research assistants on children's intake, usual mealtime practices of the centre will be adhered to (e.g. educators serving, progressive mealtimes), researchers will stand off to the side, avoid interacting with children at mealtimes and will not provide any encouragement to children regarding their food intake. Data will be collected from all eligible children present on the day. Prior to each mealtime (morning tea, lunch, and afternoon tea) bowls/plates and cups will be labelled with ID stickers and weighed by research staff. As food is served each component of the meal (e.g. bread, pasta with sauce, milk) will be weighed by research staff and weight recorded. Any additional servings provided to the children will also be weighed and recorded. At the end of the meal all plates with remaining food will be weighed. Food dropped from the child's plate will be collected and added to the plate at the end of the meal for weighing. The amount of food consumed will be measured by subtracting the mass of the food waste left over from the initial mass. Detailed information about recipes, including type and brands of foods, will be obtained from the centre cook.

For mixed meals, recipes will be entered into FoodWorks Professional version 10 (Xyris Software Pty Ltd, Queensland, Australia) to determine proportional ingredient weights and used to calculate weight of intake by food group for each recipe. This will be done for each food group, including vegetables, and converted from grams to Australian Guide to Healthy Eating standard serves.[34]

Secondary outcome measures

Menu compliance with guidelines

Compliance of the centre menu with menu guidelines at baseline and follow-up will be assessed by menu audit completed using an online menu assessment tool. Centres will provide their current menu, recipes, purchase receipts and number of children catered for, which will be entered by research staff into the online menu assessment tool. The outcome measures will be the proportion of centres complying with guidelines at both time points.

Knowledge and skills

For each initiative, staff knowledge and skills will be evaluated using the knowledge and skills scales of the Theoretical Domains Framework Questionnaire (TDFQ) for cooks developed by Seward.[58] As described below, the questions for use with cooks will be adapted to be suitable for use with educators to evaluate the mealtime and curriculum initiatives. The knowledge scale will evaluate awareness and familiarity with each of the initiatives (For example – agreement with statement *'I am aware of the goals of the menu planning guidelines'*). The skills scale will evaluate the training and skills gained for each of the initiatives (For example – agreement with statement *'I have the skills needed to plan a menu according to the menu planning guidelines'*). Additional purpose-designed items will be added to the skills scale for the educator's mealtime environment initiative questionnaires to evaluate use of feeding practices at mealtimes.

Acceptability

The usability and acceptability of the cook's training and menu assessment tool, educator's training and curriculum will be evaluated using the content quality, motivation, presentation design, re-

usability and learning goal dimensions of the LORI framework for evaluating the quality of multimedia learning resources.[59] Questions will be added to evaluate suitability of the duration/length of the initiatives. A questionnaire using the LORI framework which was completed by primary school teachers in the evaluation of Taste & Learn curriculum will be adapted for use in this study.[60]

Contextual and behavioural factors

Contextual and behavioural factors that can influence initiative implementation will be evaluated, guided by the Theoretical Domains Framework (TDF). The TDF is an implementation framework that synthesizes and evaluates behaviour change constructs that may affect the implementation of evidenced based practices and guidelines.[61] The following TDF domains will be evaluated: environmental context (barriers and facilitators), beliefs about consequences, social influences, beliefs about capability (self-efficacy) and three domains that evaluate compatibility with practice (part of regular practice, professional role to implement and intention to implement). The selection of domains was guided by recommendations for a minimum data set of implementation determinants,[62] expert consultation and previous studies evaluating implementation of interventions in the childcare setting.[47] [63] To evaluate implementation of the food provision initiative, the specified domains from the TDFQ for cooks developed by Seward[58] will be used, which has been evaluated with Australian LDC cooks and has good discriminant validity and reliability.[58] The TDFQ for cooks will be adapted to evaluate the implementation of the curriculum and mealtime environment initiatives. The questionnaire will be piloted with LDC content experts and educators to determine acceptability and usability. Data collected will be used to assess the reliability (Cronbach's alpha) and construct validity using factor analysis.

Maintenance – compatibility with practice

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

Fidelity and dose

The extent to which the initiatives were delivered as planned to educators and cooks (fidelity) and implemented by staff at the centre (dose) will be evaluated. The outcome measures will be the proportion of participating cooks and educators that completed the training modules, menu assessment and delivered the curriculum and proportion of initiative components that were delivered to children. Initiative delivery will be determined using website metrics for training modules and menu assessment tool. Fidelity and dose of the curriculum initiative will be determined using an educator-completed checklist of lessons and activities delivered. A question will be included in the cook's follow-up questionnaire asking whether cooks implemented the revised menu. Use of feeding practices at mealtimes will be evaluated via addition of items to the skills scales of the TDFQ for educators, as described above. Open-ended questions will be included in the follow-up questionnaire to determine reasons for non-completion of initiatives.

Reach and adoption

Reach, that is the proportion of the intended audience who participated in the study, will be evaluated based on the response rate and profile of attending children (age, gender, ethnicity, Aboriginal or Torres Strait Islander). Adoption will be evaluated as the characteristics and representativeness of participating centres in terms of type of provider (chain versus independent), centre size, socioeconomic status, location and characteristics of participating staff at centres including qualifications, experience in sector and previous training. Representativeness will be evaluated by comparison with ACECQA data for LDC centres in Adelaide.[55]

Contamination

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

Covariates

At baseline, centre operational characteristics will be collected for postcode, operating days and hours, enrolments, attendance, number of Aboriginal or Torres Strait Islander children enrolled, meal

provision, centre nutrition policy, menu cycle length and use of menu guidelines, nutrition-related programs and teaching resources At follow-up, centres will also report use of other nutrition policies or programs during the study. Staff characteristics will be collected via director and staff questionnaires, including number of staff employed and their role (i.e. cook, educator, kitchen assistant), hours worked per week, age, gender, years in current position as well as years employed in the early childhood education and care (ECEC) sector, and qualifications relevant to role. The age and gender of children participating in data collection will be collected at baseline and follow-up.

Sample size

Sample size estimates for factorial experiments are based on the power required to detect the smallest effect.[64] From prior research we assume an intraclass correlation coefficient of 0.1 for clustered data, with approximately 20 children per centre.[47] Based on these assumptions, with 80% power and a two-sided α of 0.05, 576-690 children, or 72-86 participants for each of the eight experimental conditions, will allow detection of a small-moderate effect (d=0.31) on children's vegetable intake.[65] Recruitment of 32 centres, with 4 centres per condition, will provide the required sample size. We will assume a 75% response rate based on past interventions in Australian childcare centres[58 66] and therefore will expect to approach approximately 45-50 LDC centres to recruit 32 centres.

Statistical analysis

Descriptive statistics will be used to describe centre characteristics and demographics at baseline and check for differences between groups. A factorial experiment using repeated measure ANOVA models will test the effects of the three initiatives on the primary outcome. Initial models will test whether each initiative (provided versus not provided) had a significant effect on vegetable intake across the 12-week intervention period (pre-post intervention effect). Subsequent models will test two and three-way interactions between initiative components to identify the effects of interactions between initiatives on outcomes. Analyses will control for covariates including child gender, age, and number of children at each timepoint. For secondary outcomes of impact, logistic regression and linear regression models will assess treatment effects. The mean change (continuous variables) or

difference in proportions (dichotomous variables) in outcome from baseline to follow-up will be compared between groups. Between-group differences in scores for TDF domains will be evaluated using t-tests to assess the impact of contextual factors on intervention effectiveness.

Evaluation phase

Study design

This study will evaluate the reach, adoption, impact and effectiveness of the optimised initiative package for increasing children's vegetable intake, using a waitlist randomised controlled trial conducted in target states, including but not limited to South Australia and Victoria. Centres in the intervention group will use the optimised package following completion of baseline measures. The waitlist control group will be asked not to change their current practice for the intervention period and will be provided access to the initiative package following completion of follow-up assessments. We hypothesise that the optimised initiative package will include all three initiatives and we plan to collect evaluation data accordingly. If fewer initiatives are included in the initiative package, evaluation data will only be collected for included initiatives.

Recruitment and participants

The recruitment approach will disseminate information about the optimised package widely across the LDC setting as well as directly to management of childcare providers, with an aim to achieve broad reach of the package in target states. Information will be disseminated through the Vegetable Intake Strategic Alliance (VISA),[67] social media promotion and newsletters to stakeholders. Inclusion and exclusion criteria for LDC centres will be as per the optimisation phase. Centres that participated in the optimisation phase will be excluded. No exclusion criteria will be applied for children.

Randomisation and blinding

Centres will be randomised to intervention or waitlist control group using stratified randomisation based on centre location (state) and socioeconomic status (using postcode to determine SEIFA index). Due to the nature of the study, blinding of the researchers or participating centres will not be possible

Study procedures

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

Primary outcome measure

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

selected sample of at least 50% of children in their care, which equates to approximately 5-6 children per educator and approximately a thirty minute time commitment based on educator to child ratios defined under the National Quality Framework.[69]

Secondary outcome measures

An online questionnaire in combination with website metrics will assess reach, adoption, impact, and fidelity as described for the optimisation phase and summarised in Table 2. The follow-up questionnaire will collect data for key implementation measures of acceptability, knowledge and skills of educators and cooks and compatibility with practice, which with adoption and fidelity data will enable evaluation of feasibility.

Sample size

The sample size calculation was determined based on the hypothesised effect of an increase of 0.5 serves of vegetables from the optimised initiative package identified in the optimisation phase. An effect size of d=0.65 was calculated based on this hypothesised effect on vegetable intake and using standard deviation from prior research in Australian childcare centres.[47] At this effect size, with power at 0.8, $p<0.05$ and ICC=0.1, a sample of 284 children is needed. Based on 15% attrition in prior studies and estimating data from approximately 20 children will be provided per centre, 20 LDC centres will need to be recruited. The sample size calculation will be confirmed at completion of the optimisation phase, when the effect size of the optimised initiative package is determined.

Statistical analysis

Analyses will be conducted at the group level and conclusions about effectiveness will be based on group effect. Descriptive statistics will be generated for baseline measures. For the primary outcome, linear mixed modelling will assess between group differences in vegetable intake at 12-weeks, controlling for baseline intake and potential confounding factors including any identified baseline differences between groups. The primary outcome will be analysed using intention-to-treat principles. For secondary outcomes of impact, logistic regression and linear regression models will assess

treatment effects. Mean follow up values (continuous variables) or difference in proportions (dichotomous variables) in outcome from baseline to follow-up will be compared between groups.

Patient and Public Involvement Statement

The initiative package was developed by researchers, dietitians, educators and sensory scientists with experience in education sectors and food provision in childcare settings. The curriculum development team included experts in LDC curriculum and LDC educators; and the curriculum was reviewed by educators for suitability during the development process. The educator module was developed in collaboration with an adoption partner who has experience delivering training to the LDC sector. LDC content experts were consulted during the development of evaluation instruments to ensure that all relevant process outcomes, in particular barriers and facilitators, were measured and language used was suitable. Final questionnaires were reviewed for suitability and usability by cooks and educators. The acceptability and feasibility of the initiatives in terms of time investment, barriers, compatibility with practice and participant burden will be assessed as part of the process evaluation. A summary of study results will be disseminated to participating centres, long day care providers participating and organisations within the long day care sector via email distribution.

DISCUSSION

This study will use the MOST framework to develop, optimise and evaluate a multicomponent initiative package to increase children's vegetable intake in childcare. The initiative package will support cooks and educators to increase their knowledge and skills for providing vegetables on the menu, using supportive feeding practices at mealtimes, and delivering a sensory and experiential vegetable-focused curriculum. A strength of this study is use of the MOST framework. MOST differs from the classic resource intensive intervention evaluation process that uses sequential pilot and RCT studies, by using factorial experiments to optimise the intervention components before proceeding to evaluation using an RCT.[42] This provides a more rapid and economical approach for producing effective, efficient and scalable multicomponent interventions.[42] The initiatives will equip

cooks and educators with the knowledge and skills to implement the intervention to ensure sustainability outside of the research setting and will be developed with an adoption partner who works within the sector to provide a pathway to roll-out. Growing use of internet technology enables online delivery of the initiatives which will provide the potential for increased reach and adoption by staff and centres for whom time and distance may prohibit participation in face to face training.[70] While face-to-face delivery of training can be valuable for sharing of experiences between educators, it is more resource intensive and requires moderation without necessarily adding value above online training.[60] The cost of face-to-face training can also have implications on limiting the potential for scalability and sustainability. Therefore, as our aim was to deliver an initiative package that would be sustainable and scalable outside of the research setting, online delivery was used. The optimised initiative package will be rolled out online for use by LDC centres and has future potential to be adapted for use in other settings including family day care, out of school hours care and schools.

Some limitations to the study need to be acknowledged. The study design requires that participating LDC centres make organisational changes, therefore it is not possible to conceal group allocation which introduces a risk of bias. However, assessors and centres will be blinded at baseline data collection. In most Australian states, including South Australia, the majority of childcare centres are managed by large providers,[55] therefore there is a risk of intervention contamination across centres of the same provider who are enrolled in different conditions. Centres participating in both trials will be advised not to use any other training or initiatives during the study and data will be collected about any other programs used. This study will be conducted in private long day care centres in two jurisdictions in Australia, limiting the generalisability of the findings outside of these jurisdictions.

ETHICS APPROVAL AND DISSEMINATION

This study has received ethics approval from the Flinders University Research Ethics Committee (Project No: 1873) for the Optimisation Phase. Approval for the Evaluation Phase will be obtained as

amendment to current approval at completion of Optimisation Phase, which will identify the final optimised initiative package for evaluation in the final phase. Findings will be disseminated to stakeholders in childcare sectors, in particular long day care centres and professional childcare bodies and researchers. Results will also be disseminated to researchers via peer-reviewed journals and conferences.

FUNDING

This project is being conducted as part of VegKIT (www.vegkit.com.au). VegKIT is funded by Hort Innovation, using the vegetable research and development levy and contributions from the Australian Government (grant number VG16064). Hort Innovation is the grower-owned, not-for-profit research and development corporation for Australian Horticulture. The project is being delivered by a collaboration between CSIRO, Flinders University and Nutrition Australia. DZ is supported by the Early Prevention of Obesity in Childhood Centre of Research Excellence (EPOCH CRE). SK is supported by Flinders University Research Scholarship and Healthy Development Adelaide PhD Excellence Award.

AUTHORS' CONTRIBUTIONS

RKG is a Principal Investigator of this study. The study was conceived, and funding obtained by RKG, DNC and AAMP. DZ and RKG led the design of the study with all authors contributing to study design through regular discussion. AAMP, MOCB with contribution from JCA, DZ and RKG designed and developed the curriculum initiative. RKG, DZ and JCA with contribution from SK designed and developed the food provision and meal environment initiatives. DZ drafted the manuscript and wrote the research protocol for the Flinders University Social Behavioural Research Committee with support from all authors. All authors have read and approved the final manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests. The funding body, Hort Innovation, has a vested interest in increasing vegetable intake. Hort Innovation had no input into the design of the study or preparation of this manuscript. Hort Innovation approved the manuscript for publication.

ACKNOWLEDGEMENTS

We would like to acknowledge the Healthy Eating Advisory Service, funded by the Victorian Department of Health and Human Services and delivered by Nutrition Australia (Victoria) for providing the cooks training module and the menu assessment tool (FoodChecker) for use in the study and collaboration in the development of the mealtime environment training module for educators. We would like to acknowledge the contribution of Janet Elliot, Amy Wakem and Ros Sambell in providing their expertise in the development of the curriculum initiative.

AVAILABILITY OF DATA AND MATERIALS

The datasets which will be used and/or analysed during the current study will be available from the corresponding author on reasonable request.

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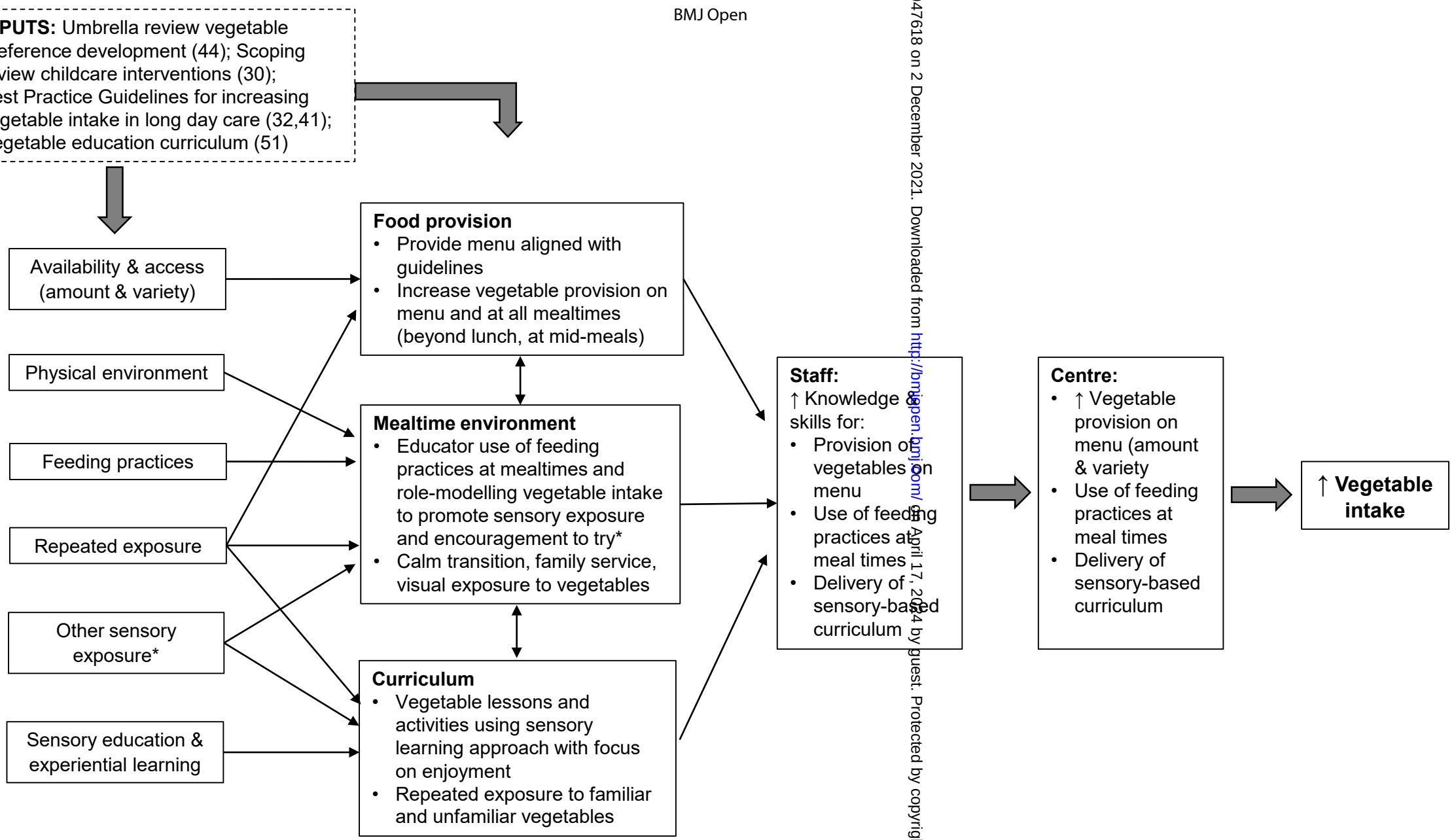
FIGURES

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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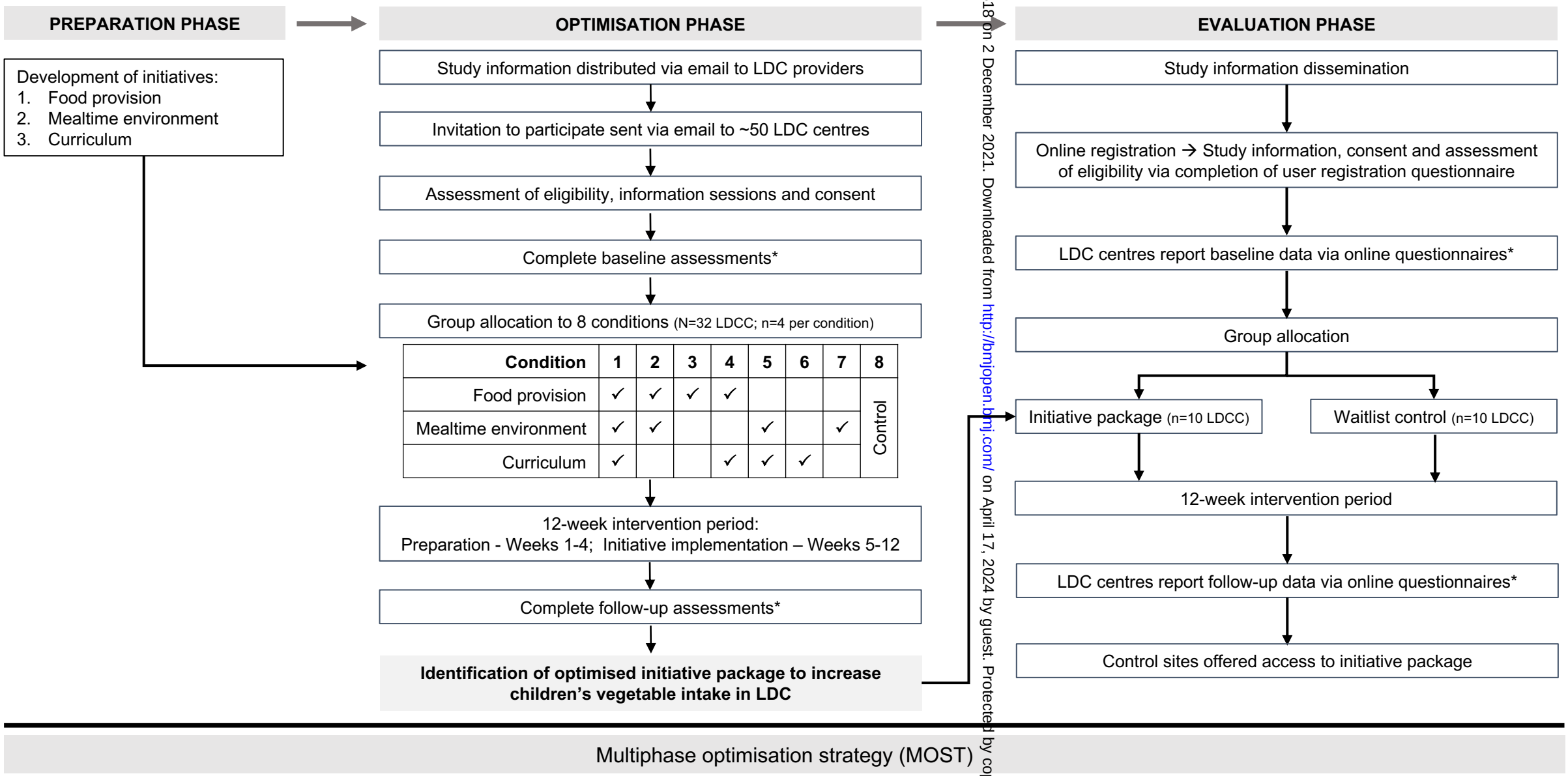

Figure 2 – Study design for development and evaluation of initiative package for use in long day care to increase children's vegetable intake

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

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

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16,17,19-20
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	20
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
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)	16,22-23 Figure 2, Table 2
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
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12-13,22
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13,22
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

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13,22
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13,22
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-20,22-23
	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
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
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
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21, 24
	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
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A – DMC is not needed due to the nature of the intervention and minimal risk
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
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
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	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
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
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
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
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
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
	31b	Authorship eligibility guidelines and any intended use of professional writers	26
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
Appendices			
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
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

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