

BMJ Open Application of the multiphase optimisation strategy to develop, optimise and evaluate the effectiveness of a multicomponent initiative package to increase 2-to-5-year-old children's vegetable intake in long day care centres: a study protocol

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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

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 randomised controlled trial 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.

centres and childcare organisations; and to researchers via peer-reviewed journals and conferences.

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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 5 years of life (ie, 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 2 and 6 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 (ECEC), most commonly long day care (LDC),^{13,14} where children spend on average 3 days (~30 hours) per week.¹⁵

LDC centres in Australia provide both full-time and part-time care to children aged 6 weeks to 6 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 meal-time 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 19 g) to 67 g (approximately 0.89 serves, with one serve=75 g based on Australian recommendations).^{32–34} In comparison, school-based interventions with older children achieved increases of 0.07 servings of vegetables (approximately 6 g),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 (ie, educators, children), target vegetables (ie, rather than healthy eating) and are of sufficient intensity and duration (at least 6 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 approach 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. Using 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 second, 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.

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 LDC centres. The training will take approximately 45–55 min 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 (one serve=75 g vegetables or cooked legumes/beans, 1 cup of leafy greens), at least 2–3 different types of vegetables per day and at least five different types per week.⁴⁶ Cooks will have 4 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 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

Table 1 Description and alignment with best practice guidelines of initiatives to increase 2-to-5-year-old children's vegetable intake in long day care (LDC)

Initiative	LDC staff	Description	Initiative goals and objectives	Best practice guidelines for vegetable intake in LDC ^{32 41}
Food provision	Cooks	Online cook's training module supported by online menu assessment tool to increase vegetable provision in meals and snacks.	<p>Goal: To support cooks to increase the provision of vegetables on the menu to align with guidelines and across all mealtimes</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase cook's knowledge and skills to provide a menu in line with menu planning guidelines 2. Reduce barriers to the provision of vegetables on the menu 3. Support cooks to plan and monitor their provision of vegetables on the menu 	<ol style="list-style-type: none"> 1. Make vegetables the hero—have simple vegetable specific messages with a clear focus 2. Coordinate sustained effort across multiple players—coordinate long-term action among key players involved in promoting and proving vegetables 3. Grow knowledge and skills to support change—identify and act on gaps in knowledge and skills 4. Minimise barriers to increase success—
Mealtime environment	Educator (mealtimes)	Online educator training module supported to encourage children to taste and enjoy vegetables at mealtimes.	<p>Goal: To increase the use of mealtime practices which will promote children's vegetable acceptance and intake</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. To increase educator's knowledge and skills to use supportive feeding practices at mealtimes to increase children's vegetable acceptance and intake 	<ol style="list-style-type: none"> 5. Understand and identify ways to address barriers 5. Plan for and commit to success—set clear and measurable vegetable-specific goals 6. Create an environment that supports children to eat vegetables—make vegetables the easy choice, promote vegetable familiarisation 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, sensory education and experiential learning	<p>Goal: To create an environment which supports children to enjoy, try and consume vegetables</p> <p>Objectives:</p> <ol style="list-style-type: none"> 1. Increase children's ability to describe their sensory perceptions when eating vegetables 2. Increase exposure to a variety of familiar and unfamiliar vegetables 3. Support children to enjoy vegetables and be able to taste any vegetable 	<ol style="list-style-type: none"> 7. Monitor and provide feedback on progress—monitor progress against goals at regular intervals

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 LDC sector and a service delivery partner who delivers training and resources to the LDC sector. Educators will complete an interactive online training module (~45–55 min) 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 LDC 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 8 weeks of the implementation period (as described below).

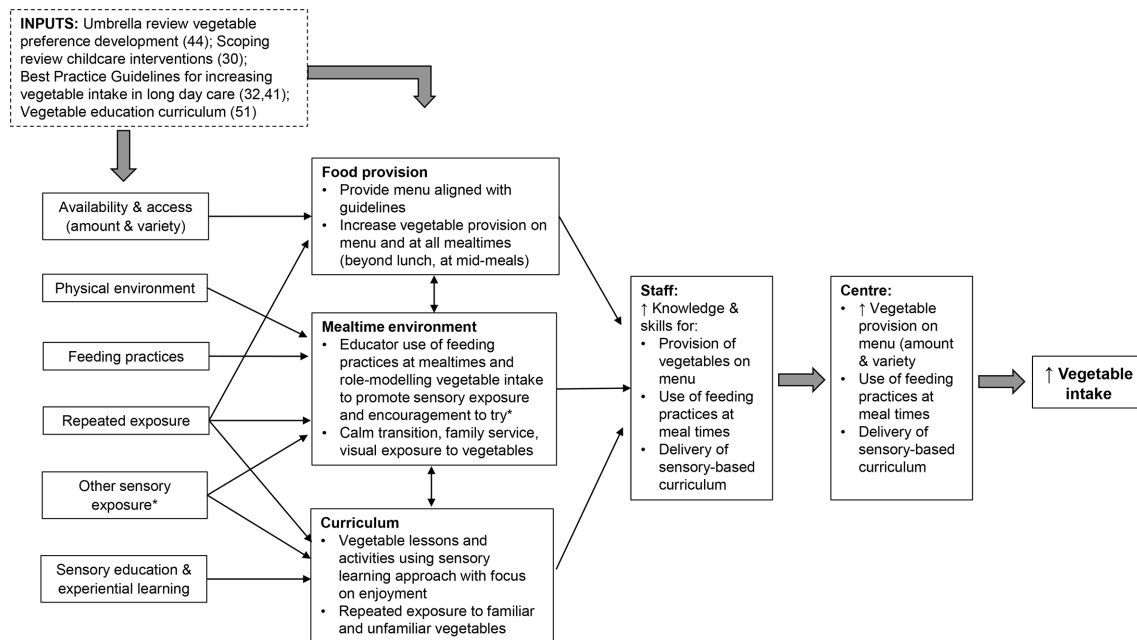


Figure 1 Logic model for development of initiative package for use in long day care to increase children's vegetable intake
*Other sensory exposure—sensory-based explorative behaviours through the five senses (sight, smell, touch, hearing, taste) to promote familiarisation with vegetables.

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, verbalisation skills, acceptance, and willingness to try vegetables.⁵³ The curriculum will consist of the following elements:

- ▶ A series of 16 short (~10–20 min) 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 (eg, 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 programme over the 8-week implementation period. The development process will engage early education experts, including researchers, early education teachers

and dietitians with expertise in LDC, to ensure that the curriculum is appropriate and aligns with usual teaching practice and everyday routines in LDC.

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 vs 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

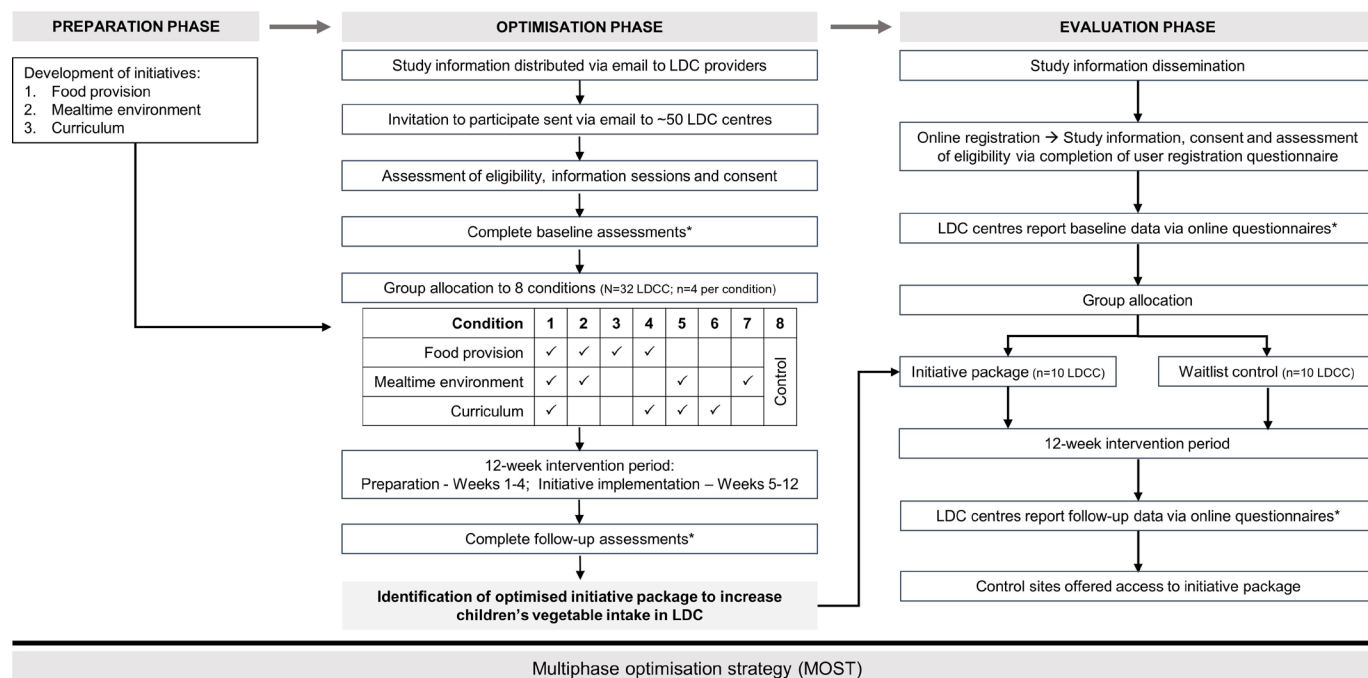


Figure 2 – Study design for development and evaluation of initiative package for use in long day care to increase children's vegetable intake

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

Figure 2 Study design for development and evaluation of initiative package for use in LDC to increase children's vegetable intake *See table 2 for outcome measures and instruments at all time points. LDC long day care; LDCC, long day care centres.

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 8 hours per weekday (Monday to Friday), prepare food onsite, serve lunch and two between-meal snacks each day and enrol children aged 2–5 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 socioeconomic 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 (ie, 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 SEIFA⁵⁶ and size of LDC centre. Research staff and participating centres will be blinded to intervention group allocation at baseline only.

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 2 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 1 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 short message service (SMS) text 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.

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 assess 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 (eg, 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 (eg, 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 V.10 (Xyris Software, 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 (eg, agreement with statement *I am aware of the goals of the*

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-to-5-year-old children's vegetable intake in LDC

Outcome measures	Optimisation phase			Evaluation phase		
	Time point	Instrument	Time point	Instrument	Time point	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, 12 w	Centre data	✓	BL, 12 w SFS-ECEC
Adoption	Characteristics and representativeness of centres (type of provider, centre size, SES, location, cook and 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, 12 w	Plate waste	✓	BL, 12 w SFS-ECEC
	Child intake of other food groups—fruit, grains, dairy, meat and alternatives, extras (serves/day)	✓				
Efficacy/ Effectiveness—Impact	Knowledge (educators and cooks)	✓	BL, 12 w	TDFQ—cook, educator, teacher (curriculum)	✓	BL, 12 w TDFQ—cook, educator, teacher (curriculum)
	Skills (self-report educators and cooks)	✓			✓	
	Menu compliance with guidelines	✓	BL, 12 w	Menu assessment	✓	BL, 12 w Website metrics
Implementation—Fidelity and dose	Initiatives delivery (fidelity):					
	Initiative completion (cook's training, menu assessment completion, educator training)	✓	12 w	Website metrics	✓	12 w Website metrics
	Reasons for non-completion	✓	12 w	Follow-up questionnaire		
	Initiative implementation at centre (dose):					
	Menu implementation	✓	12 w	Cook self-report in follow-up questionnaire	✓	12 w Cook self-report in follow-up questionnaire
	Use of feeding practices at mealtimes	✓	BL, 12 w	Educator TDFQ (skills domain)	✓	BL, 12 w Educator TDFQ (skills domain)
	Curriculum delivery	✓	12 w	Curriculum checklist	✓	12 w Curriculum checklist
	Reasons for non-implementation	✓	12 w	Follow-up questionnaire		
	Other:					
	Contamination and cointervention	✓	12 w	Follow-up questionnaire	✓	12 w Follow-up questionnaire
Completion rate	✓	12 w	Study records	✓	– Study records	
Reasons for withdrawal	✓	–	Study records			

Continued

Table 2 Continued

Outcome measures		Optimisation phase			Evaluation phase		
		Time point		Instrument	Time point		Instrument
Implementation— Process	Acceptability (training and resources)	✓	12 w	TDFQ—cook, educator, teacher (curriculum)	✓	12 w	TDFQ – cook, educator, teacher (curriculum)
	Contextual factors influencing implementation (barriers and facilitators, beliefs about benefits and disadvantages, social influences)	✓	12 w				
	Self-efficacy (educators and cooks)	✓	12 w				
	Feasibility	✓	–	Interpretation of implementation and maintenance	✓	–	Interpretation of implementation and maintenance
Maintenance (sustainability)	Compatibility with practice (part of regular practice, professional role to implement, intention to implement)	✓	12 w	TDFQ—cook, educator, teacher (curriculum)	✓	12 w	TDFQ—cook, educator, teacher (curriculum)

ACECQA, Australian Children's Education & Care Quality Authority; ATSI, Aboriginal and Torres Strait Islander; BL, baseline; LDC, Long Day Care; m, month; RE-AIM, Reach, effectiveness, adoption, implementation and maintenance framework; SA, South Australia; SFS-ECEC, Short Food Survey – Early Care and Education; TDFQ, Theoretical Domains Framework Questionnaire; VIC, Victoria; w, week.

menu planning guidelines). The skills scale will evaluate the training and skills gained for each of the initiatives (eg, 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, reusability 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 TDF. The TDF is an implementation framework that synthesises and evaluates behavioural 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 *et al*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 vs 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 Australian Children's Education & Care Quality Authority data for LDC centres in Adelaide.⁵⁵

Contamination

Contamination and cointervention 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 programmes and teaching resources. At follow-up, centres will also report use of other nutrition policies or programmes during the study. Staff characteristics will be collected via director and staff questionnaires, including number of staff employed and their role (ie, cook, educator, kitchen assistant), hours worked per week, age, gender, years in current position as well as years employed in the 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 child-care 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 measures analysis of variance models will test the effects of the three initiatives on the primary outcome. Initial models will test whether each initiative (provided vs 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 time point. 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,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 postintervention 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 SD 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, LDC providers participating and organisations within the LDC 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 programmes used. This study will be conducted in private LDC 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 LDC centres and professional childcare bodies and researchers. Results will also be disseminated to researchers via peer-reviewed journals and conferences.

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