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Unpacking the behavioural components and delivery features of early childhood obesity prevention interventions in the TOPCHILD Collaboration: a systematic review and intervention coding protocol

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TITLE

Unpacking the behavioural components and delivery features of early childhood obesity prevention interventions in the TOPCHILD Collaboration: a systematic review and intervention coding protocol

ABSTRACT

Introduction: Little is known about how early (e.g., commencing antenatally or in the first 12 months after birth) obesity prevention interventions seek to change behaviour and which components are or are not effective. This study aims to 1) characterise early obesity prevention interventions in terms of target behaviours, delivery features, and behaviour change techniques (BCTs), 2) explore similarities and differences in BCTs used to target behaviours, and 3) explore effectiveness of intervention components in preventing childhood obesity.

Methods and analysis: Annual comprehensive systematic searches will be performed in Epub Ahead of Print/MEDLINE, Embase, Cochrane (CENTRAL), CINAHL, PsycINFO, as well as clinical trial registries. Eligible randomised controlled trials of behavioural interventions to prevent childhood obesity commencing antenatally or in the first year after birth will be invited to join the TOPCHILD Collaboration. Standard ontologies will be used to code target behaviours, delivery features and BCTs in both published and unpublished intervention materials provided by trialists. Narrative syntheses will be performed to summarise intervention components and compare applied BCTs by types of target behaviours. Exploratory analyses will be undertaken to assess effectiveness of intervention components.

Ethics and dissemination: The study has been approved by The University of Sydney Human Research Ethics Committee (project no. 2020/273) and Flinders University Social and Behavioural Research Ethics Committee (project no. HREC CIA2133-1). The study's findings will be disseminated through peer-reviewed publications, conference presentations, and targeted communication with key stakeholders.

Discussion: Our study will provide an in depth understanding of behavioural components and delivery features used in obesity prevention interventions starting antenatally or in the first 12 months after birth. Understanding common intervention approaches in a systematic way will provide much needed insight to advance the design of early obesity prevention interventions and provide the opportunity to undertake future quantitative predictive modelling.

Registration PROSPERO registration no. CRD42020177408

KEYWORDS

Early childhood obesity, behaviour change techniques, intervention components, infants

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study provides an understanding of behaviours targeted, behaviour change techniques and delivery features used in early childhood obesity prevention trials identified in a systematic review as being eligible for inclusion in the Transforming Obesity Prevention in CHILDren (TOPCHILD) Collaboration.
- Extends previous methods by coding behaviour change techniques in published and unpublished intervention materials and performing cross validation with trialists through the TOPCHILD Collaboration.
- Using standardised coding taxonomies will allow for comparisons across studies, and we will pilot test new ontologies from the Human Behaviour Change Project.
- Explores the complex area of targeting parent and caregivers' behaviours to impact child outcomes across four key obesity prevention behavioural domains (relating to infant feeding practices, food provision and parent feeding practices, movement practices, sleep health practices).
- This study will provide preliminary results regarding the examination of intervention components' effectiveness based on exploratory analysis. Yet, the internationally unique database this project creates will further our understanding of effective intervention components in future research.
- To date we already have 38 out of 65 eligible trials agreeing to share data, since not all trials may provide unpublished material we may perform sensitivity analyses comparing trials that have shared data to trials that have not shared materials.

INTRODUCTION

Childhood overweight and obesity are a global concern, with 2019 estimates indicating that 38 million children under the age of five years are affected.[1] Increasing rates of overweight and obesity have been observed in young children in low- and middle-income countries, highlighting this widespread issue and the overlap of undernutrition and obesity as a double burden for public health systems.[2 3] The causes of childhood obesity are multifaceted, including genetic, epigenetic,

environmental, social and behavioural factors.[4] Many suggest that obesity prevention should start early in life, if not prenatally or prior to conception, to establish healthy behavioural patterns in young children and avoid metabolic programming that will continue across the life course.[5 6]

Parents and caregivers play a key role in shaping children's developmental environment and behaviours, particularly in the first year after birth when children are dependent on their parents' and caregivers' guidance.[7 8] While infant behavioural outcomes are the focus for early obesity prevention, parents and caregivers are the key agents of change.[8] Parents and caregivers should be supported to obtain the knowledge and acquired behaviour to act in ways that provide infants with home environments to develop optimal energy-balance related behaviours, resulting in favourable infant feeding, dietary intake, physical activity, sedentary behaviour, and sleep.

Trials commencing antenatally or in the first 12 months after birth are from here on referred to as early obesity prevention interventions. Many of the first of such complex trials began in 2006-2009 (e.g. [9-15]). These trials aimed to modify several parent behaviours known to be associated with infant obesity risk. Since the first trials, the number of early obesity prevention interventions has grown substantially, providing an extensive evidence base to inform how we seek to prevent the global issue of childhood obesity. This evidence base continues to grow as more early obesity prevention interventions are developed and tested.[16] Interventions published to date, vary in their effectiveness to reduce childhood obesity and energy-balance related behaviours.[7 16-18] A potential source of variation in intervention effectiveness may be the components of the interventions.

Intervention components can differ, such as behaviours targeted, delivery features (e.g. mode, setting) and behaviour change techniques (BCTs). Little is known about which components are included in early obesity prevention interventions seeking to change behaviour, and which of those included specific components are and are not effective.[19] Interventions designed to modify the trajectory of a young child's growth trajectory are hypothesized to exert their effect by changing parental behaviours that influence children's energy balance. Traditionally, the different components of behaviour change interventions are under-specified in published reports contributing to a poor understanding of the ways in which effective interventions have their impact (i.e. the 'black box' problem).[19] This limits the ability of researchers and practitioners to optimise, implement and scale up effective interventions that are needed to prevent childhood obesity.[19 20] Exploring the extent to which the target behaviours, delivery features and BCTs differ between interventions may help to understand why some interventions work better than others.

Deconstructing interventions into their components can provide important information about the parental behaviours that were targeted for change, how an intervention was delivered (i.e. delivery features), and the behaviour change techniques (BCTs; i.e. the smallest, measurable and reproducible behaviour change components)[21] used to change parents' behaviour. Deconstructing interventions in this way is possible through the use of ontologies to systematically categorise various intervention components.[21-23] While there are several reporting checklists, taxonomies and ontologies available to describe behaviour change interventions, the BCT Taxonomy v1 (BCTTv1) to specify BCTs is one of the most commonly used, including examination of obesity-related interventions among adults.[24-26]

Researchers have explored BCTs in parent-focused interventions targeting child obesity-related behaviours, including infant feeding practices, dietary behaviours and physical activity patterns.[27-31] The proposed work builds on prior work by Martin and colleagues[30] and Matvienko-Sikar and colleagues[29] that identified components of interventions targeting obesity, focused on physical activity and eating, and infant feeding interventions (in 2 to 18 year old children and infants, respectively). The current project advances previous reviews by examining interventions commencing antenatally or within one year of birth, covering all obesity-relevant behaviours (relating to infant feeding, dietary intake, physical activity, sedentary behaviour, sleep), drawing on unpublished material describing interventions and using the most comprehensive BCT taxonomy (i.e. BCTTv1).[29 30 32] To date, no review has comprehensively explored the intervention components of early obesity prevention interventions across multiple behaviours or utilised unpublished intervention materials.

Members of our research team have previously applied a comprehensive approach to better understand factors contributing to the effectiveness of four early obesity prevention interventions undertaken in Australia and New Zealand.[33] The approach included analysing the content of interventions using descriptions of interventions in both published peer reviewed articles and unpublished materials (e.g. participant manuals, telephone scripts, videos). The number of BCTs identified from published materials only (1 to 11 BCTs per trial)[29] was much smaller than when including unpublished materials (13 to 25 BCTs per trial),[33] reinforcing the importance of analysing unpublished intervention materials to obtain a more accurate understanding of such interventions.[34] This prior work was limited to four trials in one geographical region and results may not be generalisable on a global level. Furthermore, small sample sizes hindered exploration of BCTs by the

types of behaviours targeted. We propose extending this innovative approach to include all ongoing and completed trials in this field and analysing BCTs to address all relevant target behaviours in both published and unpublished intervention materials.

The current study will answer the following questions:

1) What are the targeted behaviours, delivery features and behaviour change techniques used in early obesity prevention interventions?
2) What are the similarities and differences in behaviour change techniques used to target different behaviours?
3) Are particular intervention components more effective at reducing obesity risk among children aged around 24 months (i.e. body mass index z-score) than others?

To address these questions, we will code intervention content and evaluate the effectiveness of components to prevent obesity.

METHODS AND ANALYSIS

This study has been prospectively registered on PROSPERO International prospective register of systematic reviews (CRD42020177408). The current project will complement our individual participant data meta-analysis assessing the effectiveness of early child obesity prevention interventions (Hunter et al. unpublished). A systematic search has been used to identify trials eligible to join the Transforming Obesity in CHILDren (TOPCHILD) Collaboration (www.topchildcollaboration.org), and all eligible trials will be able to contribute to both the current review and the individual participant data meta-analysis. This protocol follows the Preferred Reporting Items for Systematic review and Meta-Analysis protocols (PRISMA) checklist (Supplementary File 1).[35]

Eligibility criteria

Trials will be included if they 1) are a randomised controlled trial for which randomisation can occur at the individual level or by cluster, including stepped-wedge designs; 2) involve parents/caregivers (including pregnant women) and their infant(s) aged 0 to 12 months at baseline; 3) are evaluating an intervention which continues beyond pregnancy, is child obesity prevention focused and includes at least one behavioural component related to parent feeding practices, early feeding, diet quality, activity/sedentary behaviour or sleep; 4) include a usual care control arm, no intervention or attentional control; 5) include at least one measure of child adiposity measured at the end of intervention (e.g. BMI z-score, prevalence of overweight/obesity, skinfold thickness). Trials will be

excluded if they focus solely on obesity in pregnancy, or include non-behavioural interventions (e.g. supplements). See our companion paper for further details (Hunter et al. unpublished).

Information sources and search strategy

Systematic searches will be conducted annually to identify eligible trials for the duration of the TOPCHILD Collaboration (currently funded until the end of 2023). An initial systematic search was performed on the 18th of March 2020 in the following databases: Medline (Ovid), Embase (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL (EBSCO), PsycINFO. No limits were placed on publication date or language. A search strategy for Medline is presented in Supplementary File 2.

We also searched ClinicalTrials.gov (24th March 2020) and other trial registries via the World Health Organization's International Clinical Trials Registry Platform (13th May 2020) search portal to identify planned and ongoing trials. Additional trials will be identified by collaborators and contacts notifying the research team of any planned, ongoing or completed trials of which they are aware and will be screened for eligibility.

Selection process

Two reviewers will independently screen title/abstracts and full text articles against the eligibility criteria, in Covidence systematic review software (Veritas Health Innovation, Melbourne Australia). Agreement between reviewers will be calculated as percent agreement for title/abstract and full text screening. Any disagreements will be resolved by discussion or consulting a third reviewer.

Data extraction and risk of bias

Eligible trials will be invited by email to nominate a representative/s to join the TOPCHILD Collaboration. Trial representatives (i.e. trialists) will be contacted via email to share unpublished intervention materials for this current review, in English language where possible. Primary analyses will only include trials that have provided both published and unpublished intervention materials, allowing comprehensive intervention coding to be performed. If required, sensitivity analyses will be undertaken to compare intervention components using intervention descriptions reported in published materials of trials that have not shared intervention materials to address potential selection bias. Two reviewers will independently extract general trial characteristics (e.g. author, publication date, intervention name, method of sequence generation and allocation concealment, geographical location, participants) and outcome measures, and record them in FileMaker (FileMaker Pro 18 Advanced; Claris International Inc., Santa Clara, CA, USA). Risk of bias will be

assessed for the complementary review examining intervention effectiveness; however, is not required for the current study focused on describing the content of interventions.

Coding of target behaviours, delivery features and behaviour change techniques

Outcomes for which data will be sought are the discrete intervention components that will be coded by the study team, namely target behaviours, delivery features and BCTs. A standardised procedure will be followed to code intervention materials with a brief training session held to ensure all coders are familiar with the processes to assist consistency in coding target behaviours, delivery features and BCTs. All coders will have completed at minimum the University College London online training for the Behaviour Change Technique Taxonomy v1 (BCTTv1; http://www.bct-taxonomy.com/) and, where possible, have experience in coding BCTs in past projects. All material will be coded by two independent coders, when possible, exceptions may include when unpublished materials are only available in languages other than English. Agreement between coders will be calculated. Any discrepancies in coding will be resolved through discussion; or if no consensus is reached, a third coder will be consulted to reach consensus. The standardised procedure will be used whenever possible, however where unpublished materials are provided in languages other than English a modified procedure will be followed, such as using one coder fluent in the required language resulting in a subset of unpublished materials from a trial being coded once. If necessary, translation services will be sought to ensure the intervention components can be appropriately coded.

Target behaviours will be coded to capture the parental behaviour(s) addressed in each intervention. **Table 1** provides examples of behaviours that may be targeted in early obesity prevention interventions. Additional behaviours extracted from trials will be iteratively added to this pre-specified list. Behaviours will be grouped into clusters of behavioural topics, and these may include infant feeding practices, food provision and parent feeding practices, movement practices and sleep health practices (**Table 1**). While eligible interventions can commence antenatally, this study is focused on understanding the behavioural content relating to parental behaviours directed towards infants in the first 12 to 24 months after birth, rather than focusing on parents own health behaviours.

Table 1: Examples of specific parental behaviours grouped into clusters of behavioural topics

Target parental behaviour cluster	Example of specific parental behaviours
Infant feeding practices	Promoting and/or sustaining breastfeeding, including exclusive breastfeeding to 6 months of age

	Feeding formula appropriately, if necessary (e.g. making formula per package instructions, feeding in response to the infant's hunger/satiety cues, feeling with suitable types of formula) Avoiding unnecessary overfeeding with breastmilk and supplementing with formula Delaying introduction of solid foods (complementary feeding) until 6 months of age
Food provision and parent feeding practices	*Behaviours related to dietary intake* Providing appropriate types of foods (e.g. vegetables, meat and alternatives, fruits, whole grains, dairy) Providing age-appropriate portions of each food group (i.e. portion sizes; incl. limiting portions of milk) Limiting provision of certain foods and drinks (e.g. energy-dense, nutrient poor foods, sugar-sweetened beverages) *Behaviours related to feeding practices* Offering foods repeatedly that have previously been rejected Offering foods and drinks in response to infants' hunger/satiety cues (e.g. letting the infant decide how much they eat, not pressuring to eat) Avoiding use of food to control (or reward) the infant's emotions, behaviour or consumption of other foods Providing regular meal routines (incl. eating together, limiting distractions)
Movement practices	*Behaviours related to physical activity* Placing infant on their stomach for prone play ('tummy time') Promoting age appropriate physical activity such as active play, outdoor play, activities relating to fundamental movement skills Providing toys that promote movement such as balls and toys on wheels *Behaviours related to sedentary behaviour* Limiting the amount of time the infant is restrained (e.g. prams/strollers, high chairs, strapped on a caregivers back) Limiting the amount of time the infant is exposed to screens (e.g. television, mobile devices) Providing alternatives to screen time
Sleep health practices	Promoting regular sleep routine (e.g. calm, quiet, soothing) Letting the infant settle back to sleep when stirring/crying during sleep cycle (e.g. leaving the room, only picking up infant when awake) Promoting a positive sleep environment (e.g. quiet, darkened, warm) Placing infant in cot/bassinet while awake and letting infant learn to fall asleep (e.g. following infant's signs of tiredness) Avoiding bed-sharing / co-sleeping (i.e. sleeping with the infant in the same bed) Maximising day-night differences (e.g. lights on and play in the day, lights off and sleep at night)

Delivery features refer to a broad number of intervention characteristics that relate to how an intervention is delivered. Delivery features will include items in the Template for Intervention Description and Replication (TIDieR) reporting checklist,[36] such as who conducted the intervention, how (mode of delivery), where (setting), when and how much (intensity), how well the intervention was delivered (fidelity), and if there were modifications made at the intervention level (**Table 2**). Draft ontologies from the Human Behaviour Change Project[22] will be used to code the intervention

setting (Intervention Setting Ontology), mode of delivery (Mode of Delivery Ontology) and source delivering the intervention (Intervention Source Ontology). Such ontologies provide a common language to describe and compare several delivery features across interventions. Delivery features that cannot be classified using existing checklists/ontologies will be added as additional categories.

Table 2: Delivery features and corresponding Human Behaviour Change Project ontologies and project-developed categories based on the TIDieR framework

Delivery features[1]	**Example categories**
Why – theory: Rational, theory or goal	*Theory name and / or factors identified as needing to change reported in intervention*
What – materials: Physical or informational materials, including provided to participants	DVD / video Written materials Newsletters PowerPoint slides Website Mobile application
What – procedures: Procedures, activities, processed used in the intervention	Didactic sessions Group discussion Peer support
Who provided – intervention delivered by: Expertise, background and any specific training (for each intervention provider)	*Intervention Source Ontology* e.g. Nursing professional Community health worker Dietician and Nutritionist
How – delivery mode: (includes delivery to individuals or groups)	*Mode of Delivery Ontology* e.g. Face to face Letter Mobile digital device
Where – intervention setting: Location	*Intervention Setting Ontology* e.g. Household residence Community healthcare facility
When and how much – intervention dose:	Total number of contacts Frequency of contact: < weekly, weekly to <monthly; monthly or greater Duration of contact: brief, moderate, extended
Tailoring: If the intervention was planned to be personalised, titrated or adapted at the participant level	Yes – there was an element of tailoring in the intervention No Not described
Modifications: If the intervention was modified during the study at the intervention level	Yes – the intervention was modified No Not described
Fidelity: Planned and Actual	*Fidelity of the intervention extracted as reported in the intervention*

TIDieR: Template for Intervention Description and Replication

[1] Adapted from Hoffmann et al.[36]

Behaviour Change Techniques will be coded using the BCTTv1.[21] This taxonomy was developed through a consensus process with experts from a range of disciplines from several countries, and selected for the current study as a multidisciplinary standardised language to categorise intervention content.[21] Standard coding procedures will be followed, for example the whole intervention description will be read before coding.[2] Behaviour Change Techniques that are clearly present in the intervention from the description provided will be coded as 'Yes', and BCTs that are likely present but with insufficient evidence will be coded as 'Maybe'.[37 38] To be coded as 'Yes' the BCTs are required to target parents (i.e. target population) and a parental behaviour related to the target behavioural clusters as described in Table 1. Due to the complex number of different target behaviours across eligible trials and the scope of this project, BCTs will be coded to the target behaviour cluster rather than each individual target behaviour. Each BCT identified will be coded to the relevant target behaviour cluster/s when there is sufficient detail to separate content in this way. When this is not possible BCTs will be coded to 'unspecified behavioural cluster'. Intervention content will be coded from both published (e.g. protocols, main results, and follow-up publications) and unpublished intervention materials (e.g. participant manuals, telephone scripts, videos). Access to unpublished materials is important to understand details of an intervention and allow coding of additional BCTs not reported in published descriptions.[19 34] Control arms will also be coded for the presence of BCTs relevant to the target population and behaviours, and only BCTs unique to the intervention arm will be used in the results synthesis.[20] Two trained coders will perform and record coding in Microsoft Excel. Agreement of initial coding between coders will be calculated by kappa and prevalence-adjusted bias-adjusted kappa (PABAK) statistics to assess strength of agreement.[39]

Following agreement between coders, a validation process will be undertaken. Coded BCTs for each target behaviour cluster from published and unpublished materials for each trial will be sent to the respective trialists to validate the coding. Where possible, a virtual meeting will be organised for the coder to discuss the coding with the trial representative and to minimize reliance on trialists knowledge of BCTs. If there are discrepancies between the coder and trial representative, these will be discussed to reach consensus, including referring to the intervention materials as the primary source of evidence.

Synthesis of results

To address the first research question, a structured summary will be prepared to describe the targeted behavioural clusters, delivery features and BCTs used in early obesity prevention interventions. To address the second research question, narrative comparisons of BCTs used by

target behaviour clusters will be made to explore the similarities and differences in BCTs used to target different behaviours. To address the third research question, exploratory analyses will be undertaken to provide preliminary information about the effectiveness of commonly used intervention components in reducing body mass index (BMI) z-scores at 2 years of age (+/- 6 months). For this purpose, a meta-regression analysis will be performed for each commonly used intervention component (i.e. used in 5 or more interventions), to compare infant BMI z-score for trials including the intervention component compared to trials not including the intervention component. Our proposed approach will take into account small sample sizes and importantly the variability of the observed effect sizes, however, will not be able to determine independent effects of each component.

Patients and public involvement

The TOPCHILD Collaboration involves a broad range of stakeholders including health professionals, policy makers, researchers and trialists. In addition, the Collaboration includes a parent representative and an intervention facilitator/nurse who have given input into and feedback on this protocol and will be involved in the interpretation of results.

ETHICS AND DISSEMINATION

The study has been approved by The University of Sydney Human Research Ethics Committee (project no. 2020/273) and Flinders University Social and Behavioural Research Ethics Committee (project no. HREC CIA2133-1). If any amendments to this published protocol are required, they will be documented in the PROSPERO registration record (no. CRD42020177408).

Findings from the current study will be disseminated through peer-reviewed publications, conference presentations, and targeted communication with key stakeholders, such as intervention designers. Disseminating findings to intervention designers will impart knowledge about common intervention approaches used in the field of early obesity prevention as well as less commonly used but potentially effective BCTs and delivery features that can be explored in future interventions.

DISCUSSION

Our study will characterise infant obesity prevention interventions commencing antenatally or in the first 12 months after birth, by specifying the targeted behaviours, delivery features and applied BCTs. Key strengths of this study include the comprehensive systematic search to identify planned, ongoing, and completed early childhood obesity prevention trials that will provide a broad

understanding of the behaviour change content and delivery features used around the world. By looking into the 'black box' of interventions, this study will provide detailed summaries of methodologies used in early childhood obesity prevention interventions globally. We are extending previous methods by coding BCTs in both unpublished and published materials and performing cross validation of coding with trialists through the TOPCHILD Collaboration. In addition, we are exploring patterns in BCT use across four key obesity prevention parental behaviour clusters; namely infant feeding practices, food provision and parent feeding practices, movement practices, and sleep health practices. We will use standardised coding taxonomies (i.e. BCTTv1), and pilot test new ontologies from the Human Behaviour Change Project[22] to systematically code intervention source, mode of delivery and intervention setting. This study will provide preliminary insights into which intervention components are more effective than others. However, because BCTs are not used in isolation and interventions include multiple components, it is not possible to isolate the individual effects of each BCT or component within a trial or across trials from the effects of other BCTs, and there may be confounding through unobserved trial-level effects. Intervention coding will be limited to indicating the presence or absence of a BCT in intervention materials. Coding will not address whether techniques were in fact delivered to each participant (i.e. fidelity of BCT) or BCT dose. Nevertheless, we hope that this exploratory analysis will provide preliminary insight into which intervention components may be more effective than others.

A systematic understanding of the components of early obesity prevention interventions will lay the groundwork for conducting quantitative predictive modelling in future research projects. The current study will generate a comprehensive database of intervention components for each trial in the TOPCHILD Collaboration in standardised terminology and classified by target behaviours, delivery features and BCTs. The resulting database will be combined with individual participant data obtained from TOPCHILD trialists (see Hunter et al, unpublished protocol) in a future study to perform quantitative predictive modelling. Predictive modelling will further our understanding of effective intervention components for reducing childhood obesity, including identification of components that are particularly effective for key population groups. Project updates will be publicly available on the TOPCHILD Collaboration website at https://www.topchildcollaboration.org/.

REFERENCES

1. United Nations Children's Fund (UNICEF), World Health Organization, International Bank for Reconstruction and Development/The World Bank. Levels and trends in child malnutrition: Key Findings of the 2020 Edition of the Joint Child Malnutrition Estimates. Geneva: World Health Organization, 2020.

2. Abarca-Gómez L, Abdeen ZA, Hamid ZA, et al. Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128·9 million children, adolescents, and adults. *The Lancet* 2017;390(10113):2627-42. doi: https://doi.org/10.1016/S0140-6736(17)32129-3
3. Prentice AM. The emerging epidemic of obesity in developing countries. *International Journal of Epidemiology* 2005;35(1):93-99. doi: 10.1093/ije/dyi272 %J International Journal of Epidemiology
4. Finegood DT, Merth TD, Rutter H. Implications of the foresight obesity system map for solutions to childhood obesity. *Obesity* 2010;18 (Suppl 1):S13-S16. doi: 10.1038/oby.2009.426
5. World Health Organisation. Childhood overweight and obesity 2020 [Available from: https://www.who.int/dietphysicalactivity/childhood/en/ accessed 26 May 2020.
6. World Health Organization. Report of the Commission on Ending Childhood Obesity. Geneva, Switzerland: World Health Organization, 2016:50.
7. Yavuz HM, van Ijzendoorn MH, Mesman J, et al. Interventions aimed at reducing obesity in early childhood: a meta-analysis of programs that involve parents. 2015;56(6):677-92. doi: 10.1111/jcpp.12330
8. Golan M, Crow S. Parents are key players in the prevention and treatment of weight-related problems. *Nutrition Reviews* 2004;62(1):39-50. doi: 10.1301/nr.2004.jan.39-50
9. Paul IM, Savage JS, Anzman SL, et al. Preventing Obesity during Infancy: A Pilot Study. *Obesity* 2011;19(2):353-61. doi: 10.1038/oby.2010.182
10. Döring N, Hansson LM, Andersson ES, et al. Primary prevention of childhood obesity through counselling sessions at Swedish child health centres: design, methods and baseline sample characteristics of the PRIMROSE cluster-randomised trial. *BMC Public Health* 2014;14(1):335. doi: 10.1186/1471-2458-14-335
11. Verbestel V, De Coen V, Van Winckel M, et al. Prevention of overweight in children younger than 2 years old: a pilot cluster-randomized controlled trial. *Public Health Nutrition* 2014;17(6):1384-92. doi: 10.1017/S1368980013001353 [published Online First: 2013/05/23]
12. Campbell K, Hesketh K, Crawford D, et al. The Infant Feeding Activity and Nutrition Trial (INFANT) an early intervention to prevent childhood obesity: Cluster-randomised controlled trial. *BMC Public Health* 2008;8(1):103. doi: 10.1186/1471-2458-8-103
13. Daniels LA, Magarey A, Battistutta D, et al. The NOURISH randomised control trial: Positive feeding practices and food preferences in early childhood - a primary prevention program for childhood obesity. *BMC Public Health* 2009;9(1):387. doi: 10.1186/1471-2458-9-387
14. Taylor BJ, Heath A-LM, Galland BC, et al. Prevention of Overweight in Infancy (POI.nz) study: a randomised controlled trial of sleep, food and activity interventions for preventing overweight from birth. *BMC Public Health* 2011;11(1):942. doi: 10.1186/1471-2458-11-942
15. Wen LM, Baur LA, Rissel C, et al. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health* 2007;7(1):76. doi: 10.1186/1471-2458-7-76
16. Blake-Lamb T, Locks L, Perkins M, et al. Interventions for childhood obesity in the first 1,000 days a systematic review. *Am J Prev Med* 2016;50(6):780-89.
17. Askie LM, Espinoza D, Martin A, et al. Interventions commenced by early infancy to prevent childhood obesity-The EPOCH Collaboration: An individual participant data prospective meta-analysis of four randomized controlled trials. *Pediatr Obes* 2020;15(6):e12618. doi: 10.1111/ijpo.12618 [published Online First: 2020/02/07]
18. Brown T, Moore THM, Hooper L, et al. Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews* 2019(7) doi: 10.1002/14651858.CD001871.pub4
19. Tate DF, Lytle LA, Sherwood NE, et al. Deconstructing interventions: Approaches to studying behavior change techniques across obesity interventions. *Transl Behav Med* 2016;6(2):236-43. doi: 10.1007/s13142-015-0369-1

20. Byrne M. Gaps and priorities in advancing methods for health behaviour change research. *Health Psychol Rev* 2020;14(1):165-75. doi: 10.1080/17437199.2019.1707106 [published Online First: 2019/12/21]
21. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46(1):81-95. doi: 10.1007/s12160-013-9486-6
22. Michie S, Thomas J, Johnston M, et al. The Human Behaviour-Change Project: Harnessing the power of artificial intelligence and machine learning for evidence synthesis and interpretation. *Implement Sci* 2017;12(Article no. 121):1-12. doi: 10.1186/s13012-017-0641-5
23. Kok G, Gottlieb NH, Peters GJ, et al. A taxonomy of behaviour change methods: an Intervention Mapping approach. *Health Psychol Rev* 2016;10(3):297-312. doi: 10.1080/17437199.2015.1077155 [published Online First: 2015/08/12]
24. Google Scholar. Citations for: 'The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions' 2020 [Available from: https://scholar.google.com.au/scholar?cites=17280621799253216609&as_sdt=2005&sciodt=0,5&hl=en accessed Nov 12 2020.
25. Samdal GB, Eide GE, Barth T, et al. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. *International Journal of Behavioral Nutrition and Physical Activity* 2017;14(1):42. doi: 10.1186/s12966-017-0494-y
26. Ashton LM, Sharkey T, Whatnall MC, et al. Which behaviour change techniques within interventions to prevent weight gain and/or initiate weight loss improve adiposity outcomes in young adults? A systematic review and meta-analysis of randomized controlled trials. *Obes Rev* 2020;21(6):e13009. doi: 10.1111/obr.13009 [published Online First: 2020/02/18]
27. Golley RK, Hendrie GA, Slater A, et al. Interventions that involve parents to improve children's weight-related nutrition intake and activity patterns - what nutrition and activity targets and behaviour change techniques are associated with intervention effectiveness? *Obes Rev* 2011;12(2):114-30. doi: 10.1111/j.1467-789X.2010.00745.x
28. Johnson BJ, Zarnowiecki D, Hendrie GA, et al. How to reduce parental provision of unhealthy foods to 3- to 8-year-old children in the home environment? A systematic review utilizing the Behaviour Change Wheel framework. *Obes Rev* 2018;19(10):1359-70. doi: 10.1111/obr.12702
29. Matvienko-Sikar K, Toomey E, Delaney L, et al. Effects of healthcare professional delivered early feeding interventions on feeding practices and dietary intake: A systematic review. *Appetite* 2018;123:56-71. doi: 10.1016/j.appet.2017.12.001 [published Online First: 2017/12/12]
30. Martin J, Chater A, Lorencatto F. Effective behaviour change techniques in the prevention and management of childhood obesity. *Int J Obes* 2013;37(10):1287-94. doi: 10.1038/ijo.2013.107
31. JaKa MM, Wood C, Veblen-Mortenson S, et al. Applying the Behavior Change Technique Taxonomy to Four Multicomponent Childhood Obesity Interventions. *West J Nurs Res* 2020:193945920954782. doi: 10.1177/0193945920954782 [published Online First: 2020/09/11]
32. Ash T, Agaronov A, Young TL, et al. Family-based childhood obesity prevention interventions: a systematic review and quantitative content analysis. *International Journal of Behavioral Nutrition and Physical Activity* 2017;14(1):113. doi: 10.1186/s12966-017-0571-2
33. Seidler AL, Hunter KE, Johnson BJ, et al. Understanding, comparing and learning from the four EPOCH early childhood obesity prevention interventions: A multi-methods study. *Pediatr Obes* 2020;15(11):e12679. doi: 10.1111/ijpo.12679

34. de Bruin M, Black N, Javornik N, et al. Underreporting of the active content of behavioural interventions: a systematic review and meta-analysis of randomised trials of smoking cessation interventions. *Health Psychology Review* 2020:1-19. doi: 10.1080/17437199.2019.1709098
35. Moher D, Shamseer L, Clarke M, et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. . *Syst Rev* 2015;4(1):1.
36. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687-99.
37. BCT Taxonomy v1 Online Training 2020 [Available from: https://www.bct-taxonomy.com/ accessed 20 Mar 2020.
38. Carey RN, Connell LE, Johnston M, et al. Behavior Change Techniques and their mechanisms of action: A synthesis of links described in published intervention literature. *Ann Behav Med* 2018;53(8):693-707. doi: 10.1093/abm/kay078
39. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33(1):159-74.

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Authors' contributions

ALS together with KEH, BJJ, LA, RKG conceived the idea for the study.

BJJ, KEH, ALS, RKG, LA developed the research question and protocol registration.

BJJ wrote the first draft of the manuscript.

KEH, BJJ, ALS, RKG, LA developed the eligibility criteria and KH developed the search strategy.

KEH, MA, AB, BJJ, SL, ALS performed the search and screening.

BJJ, PC, RKG developed the coding procedure.

AJH, CTW, CR, DE, DAO'C, ICM, KPR, LAB, LPS, LW, MS-S, PC, RWT, ST, SM, WS provided critical review and feedback at each stage of the process.

All authors critically revised the manuscript for intellectual content, and agreed and approved the final manuscript. BJJ is the guarantor of the manuscript.

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Competing interests statement

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Supplementary file 1: Completed PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page No
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	11
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	2-4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6 - n/a
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	n/a
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	6 - n/a

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Supplementary file 2: Example of the TOPCHILD Collaboration search strategy

Medline Search Strategy:
Ovid MEDLINE(R) ALL 1946 to March 16, 2020

1. pediatric obesity/
2. Weight Gain/
3. obes*.ti,ab
4. (weight gain).ti,ab
5. (overweight or over weight).ti,ab
6. weight change*.ti,ab
7. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. social support/
10. ((behaviour or behavior) and change).ti,ab
11. ((behavio?r*) adj (therapy or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
12. ((lifestyle or life style) adj (chang* or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
13. social support.ti,ab
14. (peer adj2 support).ti,ab
15. counsel?ing.ti,ab
16. education* adj1 (intervention* or program* or class* or counsel* or teach* or workshop* or module* or consultation* or session*)).ti,ab
17. home visit*.ti,ab
18. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. exp Breastfeeding/
20. Infant Nutritional Physiological Phenomena/
21. Child Nutrition Sciences/
22. Infant Food/
23. ((child or toddler or infant$) adj1 (food or feeding or nutrition$)).tw.
24. ((responsive or complementary) adj1 feeding).ti,ab
25. ((diet* or nutrition) adj (modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
26. (healthy eating).ti,ab
27. (fruit or vegetable*).ti,ab
28. (high fat* or low fat* or fatty food*).ti,ab
29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. exp Exercise/
31. exercis*.ti,ab
32. (physical activity or physical inactivity).ti,ab
33. sedentary behavio?r.ti,ab
34. (screen time).ti,ab
35. 30 or 31 or 32 or 33 or 34
36. Sleep/
37. Exp Primary prevention

38. exp Health Promotion/
39. exp Health Education/
40. prevention.mp
41. prevent*.ti,ab
42. (health promotion or health education or health communication).ti,ab
43. exp Obesity/pc (Prevention and Control)
44. exp Overweight/pc (Prevention & Control)
45. (obesity adj2 prevent*).ti,ab
46. (overweight adj2 prevent*).ti,ab
47. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
48. 8 and (18 or 29 or 35 or 36) and 47
49. exp child/ or exp infant/
50. ((child* or infant* or baby or toddler* or pediatr* or paediatr*) not adolescen*).ti,ab
51. (pregnan* or antenatal or parent or parent$1 or care giver or caregiver or guardian or family or families or mother$1 or father$1).ti,ab
52. 49 or 50 or 51
53. 48 and 52
54. (exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.
55. 53 not 54
56. controlled clinical trial.pt.
57. randomi#ed.ti,ab.
58. randomly.ab.
59. (clinical trials as topic or controlled clinical trials as topic).sh.
60. trial.ti.
61. exp randomized controlled trial/ or exp randomized controlled trials as topic/
62. 56 or 57 or 58 or 59 or 60 or 61
63. 55 and 62

WHO ICTRP

Search string
Basic search
1. infant AND obesity prevention
2. infant AND prevention of obesity
3. infant AND overweight prevention
4. infant AND prevention of overweight
5. infant AND prevent AND obesity
6. child AND obesity prevention
7. child AND prevention of obesity
8. child AND overweight prevention
9. child AND prevention of overweight
10. child AND prevent AND obesity
Advanced search
1. Title: prevent AND obesity Recruitment Status: All Limit: Search for clinical trials in children
2. Title: prevent AND overweight

	Recruitment Status: All Limit: Search for clinical trials in children
3.	Title: prevent OR prevention Condition: obesity OR overweight Recruitment Status: All Limit: Search for clinical trials in children

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Unpacking the behavioural components and delivery features of early childhood obesity prevention interventions in the TOPCHILD Collaboration: a systematic review and intervention coding protocol

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TITLE

Unpacking the behavioural components and delivery features of early childhood obesity prevention interventions in the TOPCHILD Collaboration: a systematic review and intervention coding protocol

ABSTRACT

Introduction: Little is known about how early (e.g., commencing antenatally or in the first 12 months after birth) obesity prevention interventions seek to change behaviour and which components are or are not effective. This study aims to 1) characterise early obesity prevention interventions in terms of target behaviours, delivery features, and behaviour change techniques (BCTs), 2) explore similarities and differences in BCTs used to target behaviours, and 3) explore effectiveness of intervention components in preventing childhood obesity.

Methods and analysis: Annual comprehensive systematic searches will be performed in Epub Ahead of Print/MEDLINE, Embase, Cochrane (CENTRAL), CINAHL, PsycINFO, as well as clinical trial registries. Eligible randomised controlled trials of behavioural interventions to prevent childhood obesity commencing antenatally or in the first year after birth will be invited to join the TOPCHILD Collaboration. Standard ontologies will be used to code target behaviours, delivery features and BCTs in both published and unpublished intervention materials provided by trialists. Narrative syntheses will be performed to summarise intervention components and compare applied BCTs by types of target behaviours. Exploratory analyses will be undertaken to assess effectiveness of intervention components.

Ethics and dissemination: The study has been approved by The University of Sydney Human Research Ethics Committee (project no. 2020/273) and Flinders University Social and Behavioural Research Ethics Committee (project no. HREC CIA2133-1). The study's findings will be disseminated through peer-reviewed publications, conference presentations, and targeted communication with key stakeholders.

Registration PROSPERO registration no. CRD42020177408

KEYWORDS

Early childhood obesity, behaviour change techniques, intervention components, infants

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This will be the most comprehensive examination of the target behaviours, behaviour change techniques and delivery features used in early childhood obesity prevention trials.
- Extends previous methods by coding behaviour change techniques in published and unpublished intervention materials and performing cross validation with trial investigators.
- We will use standardised coding taxonomies and pilot test new ontologies from the Human Behaviour Change Project.
- Examination of behaviour change technique effectiveness will be limited to exploratory analysis.
- It may not be possible to obtain unpublished intervention materials from all eligible trials, however we may perform sensitivity analyses coding only published materials.

INTRODUCTION

Childhood overweight and obesity are a global concern, with 2019 estimates indicating that 38 million children under the age of five years are affected.[1] Increasing rates of overweight and obesity have been observed in young children in low- and middle-income countries, highlighting this widespread issue and the overlap of undernutrition and obesity as a double burden for public health systems.[2 3] The causes of childhood obesity are multifaceted, including genetic, epigenetic, environmental, social and behavioural factors.[4] Many suggest that obesity prevention should start early in life, if not prenatally or prior to conception, to establish healthy behavioural patterns in young children and avoid metabolic programming that will continue across the life course.[5 6]

Parents and caregivers play a key role in shaping children's developmental environment and behaviours, particularly in the first year after birth when children are dependent on their parents' and caregivers' guidance.[7 8] While infant behavioural outcomes are the focus for early obesity prevention, parents and caregivers are the key agents of change.[8] Parents and caregivers should be supported to obtain the knowledge and acquired behaviour to act in ways that provide infants with home environments to develop optimal energy-balance related behaviours, resulting in favourable infant feeding, dietary intake, physical activity, sedentary behaviour, and sleep.

Trials commencing antenatally or in the first 12 months after birth are from here on referred to as early obesity prevention interventions. Many of the first of such complex trials began in 2006-2009 (e.g. [9-15]). These trials aimed to modify several parent behaviours known to be associated with infant obesity risk. Since the first trials, the number of early obesity prevention interventions has grown

substantially, providing an extensive evidence base to inform how we seek to prevent the global issue of childhood obesity. This evidence base continues to grow as more early obesity prevention interventions are developed and tested.[16] Interventions published to date, vary in their effectiveness to reduce childhood obesity and energy-balance related behaviours.[7 16-18] A potential source of variation in intervention effectiveness may be the components of the interventions.

Intervention components can differ, such as behaviours targeted, delivery features (e.g. mode, setting) and behaviour change techniques (BCTs). Little is known about which components are included in early obesity prevention interventions seeking to change behaviour, and which of those included specific components are and are not effective.[19] Interventions designed to modify the trajectory of a young child's growth trajectory are hypothesized to exert their effect by changing parental behaviours that influence children's energy balance. Traditionally, the different components of behaviour change interventions are under-specified in published reports contributing to a poor understanding of the ways in which effective interventions have their impact (i.e. the 'black box' problem).[19] This limits the ability of researchers and practitioners to optimise, implement and scale up effective interventions that are needed to prevent childhood obesity.[19 20] Exploring the extent to which the target behaviours, delivery features and BCTs differ between interventions may help to understand why some interventions work better than others.

Deconstructing interventions into their components can provide important information about the parental behaviours that were targeted for change, how an intervention was delivered (i.e. delivery features), and the behaviour change techniques (BCTs; i.e. the smallest, measurable and reproducible behaviour change components)[21] used to change parents' behaviour. Deconstructing interventions in this way is possible through the use of ontologies to systematically categorise various intervention components.[21-23] While there are several reporting checklists, taxonomies and ontologies available to describe behaviour change interventions, the BCT Taxonomy v1 (BCTTv1) to specify BCTs is one of the most commonly used, including examination of obesity-related interventions among adults.[24-26]

Researchers have explored BCTs in parent-focused interventions targeting child obesity-related behaviours, including infant feeding practices, dietary behaviours and physical activity patterns.[27-31] The proposed work builds on prior work by Martin and colleagues[30] and Matvienko-Sikar and colleagues[29] that identified components of interventions targeting obesity, focused on physical activity and eating, and infant feeding interventions (in 2 to 18 year old children and infants,

respectively). The current project advances previous reviews by examining interventions commencing antenatally or within one year of birth, covering all obesity-relevant behaviours (relating to infant feeding, dietary intake, physical activity, sedentary behaviour, sleep), drawing on unpublished material describing interventions and using the most comprehensive BCT taxonomy (i.e. BCTTv1).[29 30 32] To date, no review has comprehensively explored the intervention components of early obesity prevention interventions across multiple behaviours or utilised unpublished intervention materials.

Members of our research team have previously applied a comprehensive approach to better understand factors contributing to the effectiveness of four early obesity prevention interventions undertaken in Australia and New Zealand.[33] The approach included analysing the content of interventions using descriptions of interventions in both published peer reviewed articles and unpublished materials (e.g. participant manuals, telephone scripts, videos). The number of BCTs identified from published materials only (1 to 11 BCTs per trial)[29] was much smaller than when including unpublished materials (13 to 25 BCTs per trial),[33] reinforcing the importance of analysing unpublished intervention materials to obtain a more accurate understanding of such interventions.[34] This prior work was limited to four trials in one geographical region and results may not be generalisable on a global level. Furthermore, small sample sizes hindered exploration of BCTs by the types of behaviours targeted. We propose extending this innovative approach to include all ongoing and completed trials in this field and analysing BCTs to address all relevant target behaviours in both published and unpublished intervention materials.

The current study will answer the following questions:

1) What are the targeted behaviours, delivery features and behaviour change techniques used in early obesity prevention interventions?
2) What are the similarities and differences in behaviour change techniques used to target different behaviours?
3) Are particular intervention components more effective at reducing obesity risk among children aged around 24 months (i.e. body mass index z-score) than others?

To address these questions, we will code intervention content and evaluate the effectiveness of components to prevent obesity.

METHODS AND ANALYSIS

This study has been prospectively registered on PROSPERO International prospective register of systematic reviews (CRD42020177408). The current project will complement our individual participant data meta-analysis assessing the effectiveness of early child obesity prevention interventions (Hunter et al. unpublished). A systematic search has been used to identify trials eligible to join the Transforming Obesity in CHILDren (TOPCHILD) Collaboration (www.topchildcollaboration.org), and all eligible trials will be able to contribute to both the current review and the individual participant data meta-analysis. This protocol follows the Preferred Reporting Items for Systematic review and Meta-Analysis protocols (PRISMA) checklist (Supplementary File 1).[35]

Eligibility criteria

Trials will be included if they 1) are a randomised controlled trial for which randomisation can occur at the individual level or by cluster, including stepped-wedge designs; 2) involve parents/caregivers (including pregnant women) and their infant(s) aged 0 to 12 months at baseline; 3) are evaluating an intervention which continues beyond pregnancy, is child obesity prevention focused and includes at least one behavioural component related to parent feeding practices, early feeding, diet quality, activity/sedentary behaviour or sleep; 4) include a usual care control arm, no intervention or attentional control; 5) include at least one measure of child adiposity measured at the end of intervention (e.g. BMI z-score, prevalence of overweight/obesity, skinfold thickness). Trials will be excluded if they focus solely on obesity in pregnancy, or include non-behavioural interventions (e.g. supplements). See our companion paper for further details (Hunter et al. unpublished).

Information sources and search strategy

Systematic searches will be conducted annually to identify eligible trials for the duration of the TOPCHILD Collaboration (currently funded until the end of 2023). An initial systematic search was performed on the 18th of March 2020 in the following databases: Medline (Ovid), Embase (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL (EBSCO), PsycINFO. No limits were placed on publication date or language. A search strategy for Medline is presented in Supplementary File 2.

We also searched ClinicalTrials.gov (24th March 2020) and other trial registries via the World Health Organization's International Clinical Trials Registry Platform (13th May 2020) search portal to identify planned and ongoing trials. Additional trials will be identified by collaborators and contacts notifying the research team of any planned, ongoing or completed trials of which they are aware and will be screened for eligibility.

Selection process

Two reviewers will independently screen title/abstracts and full text articles against the eligibility criteria, in Covidence systematic review software (Veritas Health Innovation, Melbourne Australia). Agreement between reviewers will be calculated as percent agreement for title/abstract and full text screening. Any disagreements will be resolved by discussion or consulting a third reviewer.

Data extraction and risk of bias

Eligible trials will be invited by email to nominate a representative/s to join the TOPCHILD Collaboration. Trial representatives (i.e. trialists) will be contacted via email to share unpublished intervention materials for this current review, in English language where possible. Primary analyses will only include trials that have provided both published and unpublished intervention materials, allowing comprehensive intervention coding to be performed. If required, sensitivity analyses will be undertaken to compare intervention components using intervention descriptions reported in published materials of trials that have not shared intervention materials to address potential selection bias. Two reviewers will independently extract general trial characteristics (e.g. author, publication date, intervention name, method of sequence generation and allocation concealment, geographical location, participants) and outcome measures, and record them in FileMaker (FileMaker Pro 18 Advanced; Claris International Inc., Santa Clara, CA, USA). Risk of bias will be assessed for the complementary review examining intervention effectiveness; however, is not required for the current study focused on describing the content of interventions.

Coding of target behaviours, delivery features and behaviour change techniques

Outcomes for which data will be sought are the discrete intervention components that will be coded by the study team, namely target behaviours, delivery features and BCTs. A standardised procedure will be followed to code intervention materials with a brief training session held to ensure all coders are familiar with the processes to assist consistency in coding target behaviours, delivery features and BCTs. All coders will have completed at minimum the University College London online training for the Behaviour Change Technique Taxonomy v1 (BCTTv1; http://www.bct-taxonomy.com/) and, where possible, have experience in coding BCTs in past projects. All material will be coded by two independent coders, when possible, exceptions may include when unpublished materials are only available in languages other than English. Agreement between coders will be calculated. Any discrepancies in coding will be resolved through discussion; or if no consensus is reached, a third coder will be consulted to reach consensus. The standardised procedure will be used whenever

possible, however where unpublished materials are provided in languages other than English a modified procedure will be followed, such as using one coder fluent in the required language resulting in a subset of unpublished materials from a trial being coded once. If necessary, translation services will be sought to ensure the intervention components can be appropriately coded.

Target behaviours will be coded to capture the parental behaviour(s) addressed in each intervention. **Table 1** provides examples of behaviours that may be targeted in early obesity prevention interventions. Additional behaviours extracted from trials will be iteratively added to this pre-specified list. Behaviours will be grouped into clusters of behavioural topics, and these may include infant feeding practices, food provision and parent feeding practices, movement practices and sleep health practices (**Table 1**). While eligible interventions can commence antenatally, this study is focused on understanding the behavioural content relating to parental behaviours directed towards infants in the first 12 to 24 months after birth, rather than focusing on parents own health behaviours.

Table 1: Examples of specific parental behaviours grouped into clusters of behavioural topics

Target parental behaviour cluster	**Example of specific parental behaviours**
Infant feeding practices	Promoting and/or sustaining breastfeeding, including exclusive breastfeeding to 6 months of age Feeding formula appropriately, if necessary (e.g. making formula per package instructions, feeding in response to the infant's hunger/satiety cues, feeling with suitable types of formula) Avoiding unnecessary overfeeding with breastmilk and supplementing with formula Delaying introduction of solid foods (complementary feeding) until 6 months of age
Food provision and parent feeding practices	*Behaviours related to dietary intake* Providing appropriate types of foods (e.g. vegetables, meat and alternatives, fruits, whole grains, dairy) Providing age-appropriate portions of each food group (i.e. portion sizes; incl. limiting portions of milk) Limiting provision of certain foods and drinks (e.g. energy-dense, nutrient poor foods, sugar-sweetened beverages) *Behaviours related to feeding practices* Offering foods repeatedly that have previously been rejected Offering foods and drinks in response to infants' hunger/satiety cues (e.g. letting the infant decide how much they eat, not pressuring to eat) Avoiding use of food to control (or reward) the infant's emotions, behaviour or consumption of other foods Providing regular meal routines (incl. eating together, limiting distractions)
Movement practices	*Behaviours related to physical activity* Placing infant on their stomach for prone play ('tummy time')

	Promoting age appropriate physical activity such as active play, outdoor play, activities relating to fundamental movement skills Providing toys that promote movement such as balls and toys on wheels *Behaviours related to sedentary behaviour* Limiting the amount of time the infant is restrained (e.g. prams/strollers, high chairs, strapped on a caregivers back) Limiting the amount of time the infant is exposed to screens (e.g. television, mobile devices) Providing alternatives to screen time
Sleep health practices	Promoting regular sleep routine (e.g. calm, quiet, soothing) Letting the infant settle back to sleep when stirring/crying during sleep cycle (e.g. leaving the room, only picking up infant when awake) Promoting a positive sleep environment (e.g. quiet, darkened, warm) Placing infant in cot/bassinet while awake and letting infant learn to fall asleep (e.g. following infant's signs of tiredness) Avoiding bed-sharing / co-sleeping (i.e. sleeping with the infant in the same bed) Maximising day-night differences (e.g. lights on and play in the day, lights off and sleep at night)

Delivery features refer to a broad number of intervention characteristics that relate to how an intervention is delivered. Delivery features will include items in the Template for Intervention Description and Replication (TIDieR) reporting checklist,[36] such as who conducted the intervention, how (mode of delivery), where (setting), when and how much (intensity), how well the intervention was delivered (fidelity), and if there were modifications made at the intervention level (**Table 2**). Draft ontologies from the Human Behaviour Change Project[22] will be used to code the intervention setting (Intervention Setting Ontology), mode of delivery (Mode of Delivery Ontology) and source delivering the intervention (Intervention Source Ontology). Such ontologies provide a common language to describe and compare several delivery features across interventions. Delivery features that cannot be classified using existing checklists/ontologies will be added as additional categories.

Table 2: Delivery features and corresponding Human Behaviour Change Project ontologies and project-developed categories based on the TIDieR framework

Delivery features[1]	**Example categories**
Why – theory: Rational, theory or goal	*Theory name and / or factors identified as needing to change reported in intervention*
What – materials: Physical or informational materials, including provided to participants	DVD / video Written materials Newsletters PowerPoint slides Website Mobile application
What – procedures: Procedures, activities, processed used in the intervention	Didactic sessions Group discussion Peer support

Who provided – intervention delivered by: Expertise, background and any specific training (for each intervention provider)	*Intervention Source Ontology* e.g. Nursing professional Community health worker Dietician and Nutritionist
How – delivery mode: (includes delivery to individuals or groups)	*Mode of Delivery Ontology* e.g. Face to face Letter Mobile digital device
Where – intervention setting: Location	*Intervention Setting Ontology* e.g. Household residence Community healthcare facility
When and how much – intervention dose:	Total number of contacts Frequency of contact: < weekly, weekly to <monthly; monthly or greater Duration of contact: brief, moderate, extended
Tailoring: If the intervention was planned to be personalised, titrated or adapted at the participant level	Yes – there was an element of tailoring in the intervention No Not described
Modifications: If the intervention was modified during the study at the intervention level	Yes – the intervention was modified No Not described
Fidelity: Planned and Actual	*Fidelity of the intervention extracted as reported in the intervention*

TIDieR: Template for Intervention Description and Replication

[1] Adapted from Hoffmann et al.[36]

Behaviour Change Techniques will be coded using the BCTTv1.[21] This taxonomy was developed through a consensus process with experts from a range of disciplines from several countries, and selected for the current study as a multidisciplinary standardised language to categorise intervention content.[21] Standard coding procedures will be followed, for example the whole intervention description will be read before coding.[2] Behaviour Change Techniques that are clearly present in the intervention from the description provided will be coded as 'Yes', and BCTs that are likely present but with insufficient evidence will be coded as 'Maybe'.[37 38] To be coded as 'Yes' the BCTs are required to target parents (i.e. target population) and a parental behaviour related to the target behavioural clusters as described in Table 1. Due to the complex number of different target behaviours across eligible trials and the scope of this project, BCTs will be coded to the target behaviour cluster rather than each individual target behaviour. Each BCT identified will be coded to the relevant target behaviour cluster/s when there is sufficient detail to separate content in this way. When this is not possible BCTs will be coded to 'unspecified behavioural cluster'. Intervention content will be coded from both published (e.g. protocols, main results, and follow-up publications) and unpublished intervention materials (e.g. participant manuals, telephone scripts, videos). Access

to unpublished materials is important to understand details of an intervention and allow coding of additional BCTs not reported in published descriptions.[19 34] Control arms will also be coded for the presence of BCTs relevant to the target population and behaviours, and only BCTs unique to the intervention arm will be used in the results synthesis.[20] Two trained coders will perform and record coding in Microsoft Excel. Agreement of initial coding between coders will be calculated by kappa and prevalence-adjusted bias-adjusted kappa (PABAK) statistics to assess strength of agreement.[39]

Following agreement between coders, a validation process will be undertaken. Coded BCTs for each target behaviour cluster from published and unpublished materials for each trial will be sent to the respective trialists to validate the coding. Where possible, a virtual meeting will be organised for the coder to discuss the coding with the trial representative and to minimize reliance on trialists knowledge of BCTs. If there are discrepancies between the coder and trial representative, these will be discussed to reach consensus, including referring to the intervention materials as the primary source of evidence.

Synthesis of results

To address the first research question, a structured summary will be prepared to describe the targeted behavioural clusters, delivery features and BCTs used in early obesity prevention interventions. To address the second research question, narrative comparisons of BCTs used by target behaviour clusters will be made to explore the similarities and differences in BCTs used to target different behaviours. To address the third research question, exploratory analyses will be undertaken to provide preliminary information about the effectiveness of commonly used intervention components in reducing body mass index (BMI) z-scores at 2 years of age (+/- 6 months). For this purpose, a meta-regression analysis will be performed for each commonly used intervention component (i.e. used in 5 or more interventions), to compare infant BMI z-score for trials including the intervention component compared to trials not including the intervention component. Our proposed approach will take into account small sample sizes and importantly the variability of the observed effect sizes, however, will not be able to determine independent effects of each component.

Patients and public involvement

The TOPCHILD Collaboration involves a broad range of stakeholders including health professionals, policy makers, researchers and trialists. In addition, the Collaboration includes a parent

representative and an intervention facilitator/nurse who have given input into and feedback on this protocol and will be involved in the interpretation of results.

ETHICS AND DISSEMINATION

The study has been approved by The University of Sydney Human Research Ethics Committee (project no. 2020/273) and Flinders University Social and Behavioural Research Ethics Committee (project no. HREC CIA2133-1). If any amendments to this published protocol are required, they will be documented in the PROSPERO registration record (no. CRD42020177408).

Findings from the current study will be disseminated through peer-reviewed publications, conference presentations, and targeted communication with key stakeholders, such as intervention designers. Disseminating findings to intervention designers will impart knowledge about common intervention approaches used in the field of early obesity prevention as well as less commonly used but potentially effective BCTs and delivery features that can be explored in future interventions.

DISCUSSION

Our study will characterise infant obesity prevention interventions commencing antenatally or in the first 12 months after birth, by specifying the targeted behaviours, delivery features and applied BCTs. Key strengths of this study include the comprehensive systematic search to identify planned, ongoing, and completed early childhood obesity prevention trials that will provide a broad understanding of the behaviour change content and delivery features used around the world. By looking into the 'black box' of interventions, this study will provide detailed summaries of methodologies used in early childhood obesity prevention interventions globally. We are extending previous methods by coding BCTs in both unpublished and published materials and performing cross validation of coding with trialists through the TOPCHILD Collaboration. In addition, we are exploring patterns in BCT use across four key obesity prevention parental behaviour clusters; namely infant feeding practices, food provision and parent feeding practices, movement practices, and sleep health practices. We will use standardised coding taxonomies (i.e. BCTTv1), and pilot test new ontologies from the Human Behaviour Change Project[22] to systematically code intervention source, mode of delivery and intervention setting. This study will provide preliminary insights into which intervention components are more effective than others. However, because BCTs are not used in isolation and interventions include multiple components, it is not possible to isolate the individual effects of each BCT or component within a trial or across trials from the effects of other BCTs, and there may be confounding through unobserved trial-level effects. Intervention coding will be limited

to indicating the presence or absence of a BCT in intervention materials. Coding will not address whether techniques were in fact delivered to each participant (i.e. fidelity of BCT) or BCT dose. Nevertheless, we hope that this exploratory analysis will provide preliminary insight into which intervention components may be more effective than others.

A systematic understanding of the components of early obesity prevention interventions will lay the groundwork for conducting quantitative predictive modelling in future research projects. The current study will generate a comprehensive database of intervention components for each trial in the TOPCHILD Collaboration in standardised terminology and classified by target behaviours, delivery features and BCTs. The resulting database will be combined with individual participant data obtained from TOPCHILD trialists (see Hunter et al, unpublished protocol) in a future study to perform quantitative predictive modelling. Predictive modelling will further our understanding of effective intervention components for reducing childhood obesity, including identification of components that are particularly effective for key population groups. Project updates will be publicly available on the TOPCHILD Collaboration website at https://www.topchildcollaboration.org/.

REFERENCES

1. United Nations Children's Fund (UNICEF), World Health Organization, International Bank for Reconstruction and Development/The World Bank. Levels and trends in child malnutrition: Key Findings of the 2020 Edition of the Joint Child Malnutrition Estimates. Geneva: World Health Organization, 2020.
2. Abarca-Gómez L, Abdeen ZA, Hamid ZA, et al. Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128·9 million children, adolescents, and adults. *The Lancet* 2017;390(10113):2627-42. doi: https://doi.org/10.1016/S0140-6736(17)32129-3
3. Prentice AM. The emerging epidemic of obesity in developing countries. *International Journal of Epidemiology* 2005;35(1):93-99. doi: 10.1093/ije/dyi272 %J International Journal of Epidemiology
4. Finegood DT, Merth TD, Rutter H. Implications of the foresight obesity system map for solutions to childhood obesity. *Obesity* 2010;18 (Suppl 1):S13-S16. doi: 10.1038/oby.2009.426
5. World Health Organisation. Childhood overweight and obesity 2020 [Available from: https://www.who.int/dietphysicalactivity/childhood/en/ accessed 26 May 2020.
6. World Health Organization. Report of the Commission on Ending Childhood Obesity. Geneva, Switzerland: World Health Organization, 2016:50.
7. Yavuz HM, van Ijzendoorn MH, Mesman J, et al. Interventions aimed at reducing obesity in early childhood: a meta-analysis of programs that involve parents. 2015;56(6):677-92. doi: 10.1111/jcpp.12330
8. Golan M, Crow S. Parents are key players in the prevention and treatment of weight-related problems. *Nutrition Reviews* 2004;62(1):39-50. doi: 10.1301/nr.2004.jan.39-50
9. Paul IM, Savage JS, Anzman SL, et al. Preventing Obesity during Infancy: A Pilot Study. *Obesity* 2011;19(2):353-61. doi: 10.1038/oby.2010.182
10. Döring N, Hansson LM, Andersson ES, et al. Primary prevention of childhood obesity through counselling sessions at Swedish child health centres: design, methods and baseline sample

characteristics of the PRIMROSE cluster-randomised trial. *BMC Public Health* 2014;14(1):335. doi: 10.1186/1471-2458-14-335
11. Verbestel V, De Coen V, Van Winckel M, et al. Prevention of overweight in children younger than 2 years old: a pilot cluster-randomized controlled trial. *Public Health Nutrition* 2014;17(6):1384-92. doi: 10.1017/S1368980013001353 [published Online First: 2013/05/23]
12. Campbell K, Hesketh K, Crawford D, et al. The Infant Feeding Activity and Nutrition Trial (INFANT) an early intervention to prevent childhood obesity: Cluster-randomised controlled trial. *BMC Public Health* 2008;8(1):103. doi: 10.1186/1471-2458-8-103
13. Daniels LA, Magarey A, Battistutta D, et al. The NOURISH randomised control trial: Positive feeding practices and food preferences in early childhood - a primary prevention program for childhood obesity. *BMC Public Health* 2009;9(1):387. doi: 10.1186/1471-2458-9-387
14. Taylor BJ, Heath A-LM, Galland BC, et al. Prevention of Overweight in Infancy (POI.nz) study: a randomised controlled trial of sleep, food and activity interventions for preventing overweight from birth. *BMC Public Health* 2011;11(1):942. doi: 10.1186/1471-2458-11-942
15. Wen LM, Baur LA, Rissel C, et al. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health* 2007;7(1):76. doi: 10.1186/1471-2458-7-76
16. Blake-Lamb T, Locks L, Perkins M, et al. Interventions for childhood obesity in the first 1,000 days a systematic review. *Am J Prev Med* 2016;50(6):780-89.
17. Askie LM, Espinoza D, Martin A, et al. Interventions commenced by early infancy to prevent childhood obesity-The EPOCH Collaboration: An individual participant data prospective meta-analysis of four randomized controlled trials. *Pediatr Obes* 2020;15(6):e12618. doi: 10.1111/ijpo.12618 [published Online First: 2020/02/07]
18. Brown T, Moore THM, Hooper L, et al. Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews* 2019(7) doi: 10.1002/14651858.CD001871.pub4
19. Tate DF, Lytle LA, Sherwood NE, et al. Deconstructing interventions: Approaches to studying behavior change techniques across obesity interventions. *Transl Behav Med* 2016;6(2):236-43. doi: 10.1007/s13142-015-0369-1
20. Byrne M. Gaps and priorities in advancing methods for health behaviour change research. *Health Psychol Rev* 2020;14(1):165-75. doi: 10.1080/17437199.2019.1707106 [published Online First: 2019/12/21]
21. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46(1):81-95. doi: 10.1007/s12160-013-9486-6
22. Michie S, Thomas J, Johnston M, et al. The Human Behaviour-Change Project: Harnessing the power of artificial intelligence and machine learning for evidence synthesis and interpretation. *Implement Sci* 2017;12(Article no. 121):1-12. doi: 10.1186/s13012-017-0641-5
23. Kok G, Gottlieb NH, Peters GJ, et al. A taxonomy of behaviour change methods: an Intervention Mapping approach. *Health Psychol Rev* 2016;10(3):297-312. doi: 10.1080/17437199.2015.1077155 [published Online First: 2015/08/12]
24. Google Scholar. Citations for: 'The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions' 2020 [Available from: https://scholar.google.com.au/scholar?cites=17280621799253216609&as_sdt=2005&sciodt=0,5&hl=en accessed Nov 12 2020.
25. Samdal GB, Eide GE, Barth T, et al. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. *International Journal of Behavioral Nutrition and Physical Activity* 2017;14(1):42. doi: 10.1186/s12966-017-0494-y

26. Ashton LM, Sharkey T, Whatnall MC, et al. Which behaviour change techniques within interventions to prevent weight gain and/or initiate weight loss improve adiposity outcomes in young adults? A systematic review and meta-analysis of randomized controlled trials. *Obes Rev* 2020;21(6):e13009. doi: 10.1111/obr.13009 [published Online First: 2020/02/18]
27. Golley RK, Hendrie GA, Slater A, et al. Interventions that involve parents to improve children's weight-related nutrition intake and activity patterns - what nutrition and activity targets and behaviour change techniques are associated with intervention effectiveness? *Obes Rev* 2011;12(2):114-30. doi: 10.1111/j.1467-789X.2010.00745.x
28. Johnson BJ, Zarnowiecki D, Hendrie GA, et al. How to reduce parental provision of unhealthy foods to 3- to 8-year-old children in the home environment? A systematic review utilizing the Behaviour Change Wheel framework. *Obes Rev* 2018;19(10):1359-70. doi: 10.1111/obr.12702
29. Matvienko-Sikar K, Toomey E, Delaney L, et al. Effects of healthcare professional delivered early feeding interventions on feeding practices and dietary intake: A systematic review. *Appetite* 2018;123:56-71. doi: 10.1016/j.appet.2017.12.001 [published Online First: 2017/12/12]
30. Martin J, Chater A, Lorencatto F. Effective behaviour change techniques in the prevention and management of childhood obesity. *Int J Obes* 2013;37(10):1287-94. doi: 10.1038/ijo.2013.107
31. JaKa MM, Wood C, Veblen-Mortenson S, et al. Applying the Behavior Change Technique Taxonomy to Four Multicomponent Childhood Obesity Interventions. *West J Nurs Res* 2020:193945920954782. doi: 10.1177/0193945920954782 [published Online First: 2020/09/11]
32. Ash T, Agaronov A, Young TL, et al. Family-based childhood obesity prevention interventions: a systematic review and quantitative content analysis. *International Journal of Behavioral Nutrition and Physical Activity* 2017;14(1):113. doi: 10.1186/s12966-017-0571-2
33. Seidler AL, Hunter KE, Johnson BJ, et al. Understanding, comparing and learning from the four EPOCH early childhood obesity prevention interventions: A multi-methods study. *Pediatr Obes* 2020;15(11):e12679. doi: 10.1111/ijpo.12679
34. de Bruin M, Black N, Javornik N, et al. Underreporting of the active content of behavioural interventions: a systematic review and meta-analysis of randomised trials of smoking cessation interventions. *Health Psychology Review* 2020:1-19. doi: 10.1080/17437199.2019.1709098
35. Moher D, Shamseer L, Clarke M, et al. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. . *Syst Rev* 2015;4(1):1.
36. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687-99.
37. BCT Taxonomy v1 Online Training 2020 [Available from: https://www.bct-taxonomy.com/ accessed 20 Mar 2020.
38. Carey RN, Connell LE, Johnston M, et al. Behavior Change Techniques and their mechanisms of action: A synthesis of links described in published intervention literature. *Ann Behav Med* 2018;53(8):693-707. doi: 10.1093/abm/kay078
39. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33(1):159-74.

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Authors' contributions

ALS together with KEH, BJJ, LA, RKG conceived the idea for the study.

BJJ, KEH, ALS, RKG, LA developed the research question and protocol registration.

BJJ wrote the first draft of the manuscript.

KEH, BJJ, ALS, RKG, LA developed the eligibility criteria and KH developed the search strategy.

KEH, MA, AB, BJJ, SL, ALS performed the search and screening.

BJJ, PC, RKG developed the coding procedure.

AJH, CTW, CR, DE, DAO'C, ICM, KPR, LAB, LPS, LW, MS-S, PC, RWT, ST, SM, WS provided critical review and feedback at each stage of the process.

BJJ, KEH, RKG, PC, AB, MA, SL, LA, RWT, KPR, SM, DAO'C, AJH, LW, CTW, LAB, CR, LPS, ST, WS, MS-S, ICM, DE, JLT, JKL, VV, COS, S-JS, SLO'R, LTK, FER, MJM, RSG, MB, IMP, LMW, KDH, CGA, KC, NCØ, AML, HMW, KJJ, CP, CM, ALT, AG, RL, JCB, EO, MCR, ABP-E, BJT, JSS, MR, MG, KdlH, SA-F, ALS critically revised the manuscript for intellectual content, and agreed and approved the final manuscript. BJJ is the guarantor of the manuscript.

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Competing interests statement

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Supplementary file 1: Completed PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page No
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	11
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	2-4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6 - n/a
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	n/a
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	6 - n/a

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Supplementary file 2: Example of the TOPCHILD Collaboration search strategy

Medline Search Strategy:
Ovid MEDLINE

1. obesity/
2. pediatric obesity/
3. overweight/
4. Weight Gain/
5. body-weight trajectory/
6. Body mass index/
7. Adiposity/
8. Body weight/
9. Body Weight Changes/
10. Skinfold thickness/
11. Waist-hip-ratio/
12. Waist circumference/
13. obes*.tw
14. (overweight or over weight or over-weight).tw
15. (weight gain).tw
16. (BMI or body mass index).tw
17. adiposity.tw
18. (body weight).tw
19. (weight change$).tw
20. (skin fold thickness).tw
21. (waist-hip ratio).tw
22. (waist circumference).tw
23. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24. child health services/
25. early intervention, educational/
26. maternal-child health services/
27. Maternal-Child Health Centers/
28. maternal health services/
29. Mother-Child Relations/
30. preventive health services/
31. health education/
32. health promotion/
33. ((behaviour or behavior) and change).ti,ab
34. ((behavio?r*) adj (therapy or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
35. ((lifestyle or life style) adj (chang* or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
36. (peer adj2 support).ti,ab
37. education* adj1 (intervention* or program* or class* or counsel* or teach* or workshop* or module* or consultation* or session*).ti,ab
38. 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37
39. Breastfeeding/
40. Infant Nutritional Physiological Phenomena/
41. Infant Food/

42. Diet, Healthy/
43. ((diet* or nutrition or feeding) adj (modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
44. ((child or toddler or infant$) adj1 (food or feeding or nutrition$)).ti,ab
45. ((responsive or complementary) adj1 feeding).ti,ab
46. (healthy eating).ti,ab
47. Feeding behavior/
48. 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47
49. Motor activity/
50. Exercise/
51. Sedentary Behavior/
52. (physical activity or physical inactivity).ti,ab
53. sedentary behavio?r.ti,ab
54. (screen time).ti,ab
55. play.ab,ti
56. "tummy time".ab,ti
57. 49 OR 50 OR 51 OR 52 OR 53 OR 54 OR 55 OR 56
58. Sleep/
59. Sleep.ti,ab
60. 58 OR 59
61. 38 OR 48 OR 57 OR 60
62. 23 AND 56
63. exp child/
64. exp infant/
65. (babies or baby or boy? or child* or girl? or infan* or kid? or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or toddler?).ti,ab,kf.
66. (pregnan* or perinatal* OR prenatal* OR antenatal OR postnatal*).ti,ab,kf
67. Parents/
68. (parent$ or care giver or caregiver or guardian or family or families or mother$ or father$ OR maternal OR paternal).tw
69. 63 or 64 or 65 or 66 or 67 or 68
70. 62 AND 69
71. (exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.
72. 70 not 71
73. randomized controlled trial.pt.
74. controlled clinical trial.pt.
75. randomi#ed.ab.
76. clinical trials as topic.sh.
77. randomly.ab.
78. trial.ti.
79. 73 or 74 or 75 or 76 or 77 or 78
80. 72 AND 79

WHO ICTRP

Basic search
1. babies AND obesity
2. babies AND obese
3. babies AND overweight
4. infant AND obesity
5. infant AND obese

6. infant AND overweight
7. infants AND obesity
8. infants AND obese
9. infants AND overweight
10. child AND obesity
11. child AND obese
12. child AND overweight
13. children AND obesity
14. children AND obese
15. children AND overweight
16. childhood AND obesity
17. childhood AND obese
18. childhood AND overweight
19. pediatric AND obesity
20. paediatric AND obesity
21. pediatric AND obese
22. paediatric AND obese
23. pediatric AND overweight
24. paediatric AND overweight
25. toddler AND obesity
26. toddler AND obese
27. toddler AND overweight
28. toddlers AND obesity
29. toddlers AND obese
30. toddlers AND overweight
31. kids AND obesity
32. kids AND obese
33. kids AND overweight