Understanding, comparing and learning from the four EPOCH early childhood obesity prevention interventions: A multi-methods study

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Summary
Background: Childhood obesity is a global problem. Early obesity prevention interventions are complex and differ in effectiveness. Novel frameworks, taxonomies and experience from the Early Prevention of Obesity in Children (EPOCH) trials were applied to unpack interventions.

Objectives: Deconstruct interventions into their components (target behaviours, delivery features and behaviour change techniques [BCTs]).

Identify lessons learned and future recommendations for intervention planning, delivery, evaluation and implementation.

Methods: This multi-methods study deconstructed the four EPOCH interventions into target behaviours, delivery features and BCTs from unpublished and published materials using systematic frameworks. Additionally, semi-structured interviews were conducted with intervention facilitators and principal investigators.

Results: Each trial targeted between 10 and 14 obesity-related behaviours. Key variations in delivery features related to intensity, delivery mode and tailoring. BCTs consistently used across trials included goal-setting, social support, shaping knowledge, role-modelling and credible source. Recommendations from interview analyses include the importance of stakeholder collaboration and consideration of implementation throughout the study process.

Conclusions: The combination of frameworks, methodologies and interviews used in this study is a major step towards understanding complex early obesity prevention interventions. Future work will link systematic intervention deconstruction with quantitative models to identify which intervention components are most effective and for whom.

KEYWORDS
behaviour change techniques, childhood obesity, early prevention, obesity, prospective meta-analysis
INTRODUCTION

Childhood obesity is a major public health and equity issue that sets children on a lifelong negative health trajectory.1-3 Globally, 41 million children under the age of five had overweight or obesity in 2016.4 Since children with obesity are five times more likely to have obesity as adults, a high number of those affected in the early years will be living with obesity for most of their lives.4 Childhood obesity has been linked to many adverse chronic health conditions and poorer mental health.5

Obesity prevention should start early when biology is most amenable to change, and before obesogenic behavioural patterns are established.6 Previous systematic reviews have explored the effectiveness of early obesity prevention interventions conducted in a range of settings such as homes and primary care, highlighting the growing number of trials in the area in the last decade.7-9 The Early Prevention of Obesity in CHildren (EPOCH) Collaboration10 includes four landmark randomised controlled trials (RCT) to target very early childhood obesity prevention. All of the trials started within the first 6 months of life, and two began in pregnancy. Whilst all four interventions aimed to prevent early childhood obesity through behavioural and lifestyle components, they differed in design, intervention content, mode and intensity.

Through the EPOCH Collaboration, a core set of outcomes was identified to enable a prospective meta-analysis to be undertaken.11 On average, the EPOCH interventions were effective in reducing body mass index (BMI) z-scores at 18 to 24 months of age by 0.12 standard deviations (95% confidence interval 0.02 to 0.22, P = .17), which translates into a 2% reduction in obesity prevalence.12 Individually, the trials had less statistical power (all <0.35) to detect an effect of this size on BMI z-score, compared to the combined analysis which had a power of 0.83 (as each trial was powered to detect differences in their respective primary outcomes). Only the Healthy Beginnings trial13 showed a significant reduction in BMI z-score; however, all trials were successful in reducing some obesity-related behaviours such as reducing television times and improving feeding practices.14-16 Further work is needed to unpack the similarities and differences across the interventions. This information will aid replication and translation of interventions as they are adapted for different populations and contexts or delivered at scale.

Standardised taxonomies and frameworks have been proposed to help develop, understand, compare and replicate complex intervention components. The multidisciplinary taxonomy of Behaviour Change Techniques (BCTs)17 offers an internationally recognised system to classify the smallest, measurable and reproducible behaviour change components ("active ingredients") of interventions. The Template for Intervention Description and Replication (TIDier)18 checklist offers a clear, standardised approach for reporting and understanding intervention features. Applying these taxonomies and frameworks provides a consistent language to synthesise and compare characteristics and lessons across multiple interventions.

The practicalities of conducting complex early childhood obesity interventions can be challenging.19 These interventions target parent behaviours to influence or change child outcomes. In this age group, most of the child’s life takes place within the family environment, so the interventions need to be focused on the family. Interventions are delivered at an age where development happens very rapidly, and it is key to deliver appropriate intervention content at the right time point. In addition, a number of stakeholders and theoretical frameworks need to be taken into account, and recruiting and engaging parents to such complex and time-intensive interventions can be difficult. Furthermore, the design of trials in a competitive funding environment can be challenging, with little funding support for the development and piloting of content. The principal investigators and intervention facilitators of the four EPOCH interventions have extensive expertise in planning, conducting and scaling early childhood obesity prevention programs. The UK Medical Research Council guide for designing and evaluating complex interventions is based on the development-implementation process and considers in detail the elements of a complex intervention.20 Using this framework as an interview schedule to learn from the EPOCH trialists can create a deep understanding of barriers and facilitators of early childhood obesity interventions, which can aid the development and scaling up of future interventions.

Previous studies have attempted to apply these taxonomies and frameworks to enhance understanding of complex interventions.21-26 However, these studies were either reviews of the published literature, which were limited by the scarcity of information from published records, or were focussed on single interventions, thereby only offering one perspective. The EPOCH Collaboration offers a unique opportunity to obtain in-depth information on four different interventions, taking into account the perspectives and experiences of their investigators and facilitators.

In the current study, we aimed to capitalise on the recently developed approaches to understanding interventions presented above and the experience and resources from the EPOCH collaboration to look into the "black box" of complex early childhood obesity interventions. The objectives of this study were to:

1. Deconstruct early childhood obesity prevention interventions into their components (ie, target behaviours, delivery features and behaviour change techniques)
2. Qualitatively identify lessons learned and future recommendations for the planning, delivery, evaluation and implementation/scaling of early childhood obesity prevention interventions

METHODS

This multi-methods study included the four randomised controlled trials that form the EPOCH Collaboration.10 Three trials, the Healthy Beginnings Trial (HBT),13,27 NOURISH16,28 and the Infant Feeding Activity and Nutrition Trial (InFANT)14,29 were conducted in Australia (New South Wales, South Australia and Queensland, and Victoria, respectively), whilst the Prevention of Overweight in Infancy (POI)21,30 study was conducted in Otago, New Zealand. All four interventions were delivered between 2007 and 2012, and their study protocols, ethics approval details and outcomes have been published.
previously. Interventions started antenatally or within the first 6 months of the child’s life and continued for at least 18 months postnatailly. All trials included a lifestyle-related component (eg, early feeding, parenting and physical activity) with the primary goal of preventing overweight and obesity. The present study utilised two key approaches to better understand the EPOCH interventions; (a) deconstructing intervention and (b) qualitative interviewing of key trial personnel.

### 2.1 Deconstructing interventions into components

Intervention content was deconstructed into target behaviours, delivery features and behaviour change techniques using systematic frameworks to provide a consistent language for comparison across trials.\(^{17,18}\) Published materials (protocols, outcome and other publications resulting from the trials) were used for analysis, along with unpublished intervention materials sourced directly from trial investigators, including protocol documents, facilitator handbooks, slide shows, videos and parent resources.

The behavioural targets of the interventions were extracted from the study protocols and tabulated by SM. The TIDieR checklist was applied by four independent coders (ALS, KEH, BJJ and CEM) to describe intervention delivery features,\(^ {18}\) including intervention materials and procedures, intervention facilitators (who delivered the intervention), how and where the intervention was delivered, when the intervention occurred, the number and frequency of sessions (duration and intensity), how consistently the intervention was delivered (fidelity) and whether any tailoring (planned personalisation, titration or adaptation) or modification of interventions occurred. Behaviour Change Techniques (BCTs) were coded using the BCT Taxonomy version 1.\(^ {17}\) Four trained coders (ALS, KEH, BJJ and CEM) independently coded the interventions. Each intervention was coded twice with discrepancies discussed until consensus was reached. Coding followed a standardised process, with only BCTs that were clearly supported by evidence in published and/or unpublished content being coded as present.\(^ {17}\) Coder agreement was assessed by prevalence-adjusted, bias-adjusted Kappa.\(^ {32}\) Results were tabulated and summary statistics were calculated.

### 2.2 Qualitative interviews

Semi-structured interviews were conducted between March and April 2019. One principal investigator and one intervention facilitator from each of the four trials were invited to participate. Each was provided with the study protocol, participant information sheet, interview guide and consent form. Participants were known to authors, due to their involvement in the EPOCH Collaboration, and all were invited to be co-authors on this manuscript. Interviews were conducted using the video conference software Zoom (http://www.ZOOM.us), and prospective verbal consent was provided. Ethics approval was granted by the University of Sydney Human Research Ethics Committee (2018/986).

The interviews explored the planning, delivery, evaluation and implementation of the complex interventions and contextual factors that enabled or hindered their delivery. The interview guide (see Table S1) was informed by the UK Medical Research Council development-evaluation-implementation process framework,\(^ {20}\) as well as by consultation with experts in the area of qualitative research in childhood obesity prevention (including ST) and relevant literature.\(^ {25,33}\) Particular focus was placed on exploring key lessons and recommendations for researchers and policy makers developing, evaluating and implementing interventions. Interview questions were pilot-tested with an experienced researcher (SM) and modified for flow. All interviews were conducted by ME, a doctoral student who is trained and experienced in qualitative research methods. Interviews lasted, on average, 53 minutes, were digitally recorded, transcribed verbatim and transcripts were cross-checked against recordings to ensure accuracy.

Inductive thematic analysis was used to analyse the interviews.\(^ {34}\) Two researchers (ALS and KEH) independently conducted the coding and analysis in consultation with a senior qualitative researcher (ST) using NVIVO software (version 12). This process firstly involved familiarisation with all of the interview transcripts. Each researcher then independently reviewed two transcripts to identify initial codes, and these codes were then combined in a preliminary coding framework through a consensus process. The researchers then independently coded four transcripts each using this framework, adding additional codes where necessary. This iterative process involved regular coding meetings (ALS, KEH and ST) to develop and define the themes until a final framework was achieved, and applied to all interviews.

### 3 RESULTS

#### 3.1 Deconstructing intervention components

##### 3.1.1 Target behaviours

Table 1 presents the target behaviours and delivery features of each intervention. Each trial targeted between 10 and 14 (mean = 12) obesity-related behaviours. Behaviours targeted by all four trials included introducing solids, amounts or frequency of feeding, limiting sugar-sweetened beverages and certain foods (eg, sweets), parent response to hunger and satiety cues, increasing tummy time, play or activity, and limiting television or screen time. One trial (POi.NZ) included sleep-related behaviours such as sleep timing and environment.

##### 3.1.2 Delivery features

Interventions were primarily delivered face-to-face by a trained health professional (such as dietitians and early childcare nurses), to a group
| TABLE 1 | Intervention characteristics by EPOCH trial |
|---------|------------------------------------------|
|          | Healthy Beginnings Trial | InFANT | NOURISH | POL.nz |
| Why – theory: | Health belief model | Anticipatory guidance framework | Anticipatory guidance framework | Anticipatory guidance framework |
| Social Learning Theory | | Attachment theory | | |
| What – target behaviours: | Promote/sustain breast feeding | Bottle feeding advice | Bottle feeding advice | Promote/sustain breast feeding |
| Bottle feeding advice | | | Bottle feeding advice | |
| Introduction of solids | Introduction of solids | Introduction of solids | Introduction of solids | |
| Amount or feeding frequency | Amount or feeding frequency | Amount or feeding frequency | Amount or feeding frequency | |
| Limit SSB | Limit SSB | Limit SSB | Limit SSB | |
| Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | |
| Repeat food exposure | Repeat food exposure | Repeat food exposure | Repeat food exposure | |
| Response hunger/satiety cues | Response hunger/satiety cues | Response hunger/satiety cues | Response hunger/satiety cues | |
| Fussy eating | Fussy eating | Fussy eating | Fussy eating | |
| Promote tummy time | Promote tummy time | Promote tummy time | Promote tummy time | |
| Promote play or activity | Promote play or activity | Promote play or activity | Promote play or activity | |
| Limit TV/screen time | Limit TV/screen time | Limit TV/screen time | Limit TV/screen time | |
| Limit SSB | Limit SSB | Limit SSB | Limit SSB | |
| Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | Limit certain foods (eg, sweets) | |
| Repeat food exposure | Repeat food exposure | Repeat food exposure | Repeat food exposure | |
| Response hunger/satiety cues | Response hunger/satiety cues | Response hunger/satiety cues | Response hunger/satiety cues | |
| Fussy eating | Fussy eating | Fussy eating | Fussy eating | |
| Promote tummy time | Promote tummy time | Promote tummy time | Promote tummy time | |
| Promote play or activity | Promote play or activity | Promote play or activity | Promote play or activity | |
| Limit TV/screen time | Limit TV/screen time | Limit TV/screen time | Limit TV/screen time | |
| Sleep timing | Sleep timing | Sleep timing | Sleep timing | |
| Sleep environment | Sleep environment | Sleep environment | Sleep environment | |
| What – materials: | Written | Written | Written | Written |
| PowerPoint slides | PowerPoint slides | PowerPoint slides | PowerPoint slides |
| Newsletters | Newsletters | Newsletters | Newsletters |
| DVD | DVD | DVD | DVD |
| What – procedures: | Participant led discussion guided by checklist | Brief didactic sessions | Didactic sessions | Face-to-face individual sessions |
| Group discussion | Group discussion | Group discussion | Group physical activity sessions |
| Peer support | Peer support | Peer support | |
| Exploration of perceived barriers | Exploration of perceived barriers | Exploration of perceived barriers | Monitoring/discussion of progress at home |
| Intervention delivered by: | Community nurse | Dietitian | Dietitian and Psychologist | Trained researchers and lactation consultants |
| Training intervention delivery: | Yes | Not reported | Yes | Yes |
| Delivery mode: | Face-to-face | Face-to-face | Face-to-face | Face-to-face |
| Telephone | Telephone (if missed session) | Telephone (if missed session) | Telephone (if missed session) | |
| Paper mail (newsletter) | Paper mail (newsletter) | Paper mail (newsletter) | Paper mail (newsletter) | |
| Individual/Group delivery: | Individual | Group | Group | Individual and Group |
| **TABLE 1** (Continued) | Healthy Beginnings Trial | InFANT | NOURISH | POL.nz |
|-------------------------|--------------------------|--------|---------|--------|
| Intervention setting:   | Home                     | Maternal and Child Health centres | Child health services | Home |
|                        |                          | Clinic | Community hub | Community hub |
| Intervention dose:      | 24 months                | 15 months | 12 months | 18 months |
| Duration                |                          |        |          |        |
| Intervention dose:      | Once antenatally (30-36 weeks’ gestation), and at 1, 3, 5, 9, 12, 18, 24 months after birth | 3 monthly | Two intervals of 6 sessions over a 12 week period, with a 6 month period with email support in between intervals | 2×2 factorial design: |
| Schedule (frequency)    |                          |        |          |        |
| Number of sessions      | 8                        | 6      | 12      | FAB group: 8 |
| Length of each session  | 1-2 hours                | 2 hours | 2 hours | Sleep group: 2 (up to an additional 3 if sleep problems) |
| Tailoring:              | Yes                      | No     | No      | Combined group: 10 (up to an additional 3 if sleep problems) |
| Modifications:         | No                       | No     | No      |        |
| Fidelity: planned       | No                       | Independent assessment using standardised process | Independent assessment using standardised process | No |
| Fidelity: actual        | Nurses documented aspects of visit, and provided reports on questions/issues arising | 68% of participants attended 4 or more of the 6 sessions; 9% attended <2 sessions | 45%-65% of participants attended ≥2 sessions of 6 sessions (i.e., per module) | Not reported |

Abbreviations: FAB, Food, physical activity and breastfeeding; SSB, sugar-sweetened beverages.
in a clinic setting or one-on-one in the home. Interventions consisted of between two and 12 sessions of approximately 1 to 2 hours per session over 12 to 24 months, with frequency of sessions varying between trials. All interventions used written materials, often in combination with slide shows or videos. Elements of tailoring and fidelity varied across trials; tailoring occurred more in one-on-one intervention delivery modes whilst fidelity monitoring occurred more in group-focused delivery.

### TABLE 2  Presence of behaviour change techniques in published content and all available intervention materials

| BCT number and description\(^a\) | Healthy Beginnings Trial | InFANT | NOURISH | POiNZ |
|--------------------------------|--------------------------|--------|---------|-------|
| 1.1 Goal setting (behaviour)   | X                        |        |         |       |
| 1.2 Problem solving            | X                        |        | X       | X     |
| 1.4 Action planning            |                         |        |         |       |
| 1.5 Review behaviour goal(s)   | X                        |        |         |       |
| 1.6 Discrepancy between current behaviour and goal | X | | | |
| 2.2 Feedback on behaviour      |                         |        |         |       |
| 2.3 Self-monitoring of behaviour |                      |        |         |       |
| 3.1 Social support (unspecified) |        |        |         |       |
| 3.2 Social support (practical) |                         |        |         |       |
| 3.3 Social support (emotional) |                         |        |         |       |
| 4.1 Instruction on how to perform a behaviour | X | | | |
| 4.2 Information about antecedents |                     |        |         |       |
| 5.1 Information about health consequences |    | X       |         |       |
| 5.2 Salience of consequences   |                         |        |         |       |
| 5.3 Information about social and environmental consequences | X | X | X |       |
| 5.6 Information about emotional consequences | X | X | X | X |
| 6.1 Demonstration of the behaviour | X |        |         |       |
| 6.2 Social comparison          |                         |        |         |       |
| 7.1 Prompts/cues               |                         |        |         |       |
| 7.8 Associative learning        |                         |        |         |       |
| 8.1 Behavioural practice/rehearsal |                    |        |         |       |
| 8.2 Behavioural substitution    |                         |        |         |       |
| 8.4 Habit reversal              |                         |        |         |       |
| 8.7 Graded tasks               |                         |        |         |       |
| 9.1 Credible source            |                         |        |         |       |
| 9.2 Pros and cons              |                         |        |         |       |
| 9.3 Comparative imagining of future outcomes |        |         |       |
| 11.2 Reduce negative emotions  |                         |        |         |       |
| 11.3 Conserving mental resources |                     |        |         |       |
| 12.1 Restructuring the physical environment | X | X | X |       |
| 12.2 Restructuring the social environment | X | | | |
| 12.3 Avoidance/reducing exposure to cues for the behaviour | X | | | |
| 12.5 Adding objects to the environment | | | | X |
| 13.1 Identification of self as role model | X | X | X | X |
| 13.2 Framing/reframing          |                         |        |         |       |
| **Total BCTs present**          | **13**                   | **23** | **21**  | **25** |
| Coder agreement PABAK           | 0.94                     | 0.70   | 0.70    | 0.70   |

 Note: Bold indicates most frequently used BCTs (used by three to four trials).

\(^{a}\)Note only BCTs coded are presented. Behaviour change techniques as defined in the BCTTv1.17
3.1.3 | Behaviour change techniques

Across the four trials, 35 of the possible 93 unique BCTs were coded (Table 2). Only five to ten BCTs per trial were coded from published trial content, with an additional eight to 17 BCTs (63% increase in BCTs) coded using unpublished intervention materials.

Nine BCTs were used in all four trials. These included problem solving (BCT 1.2); unspecified and practical social support (BCT 3.1, 3.2); instruction on how to perform a behaviour (BCT 4.1); information about health, social and environmental and emotional consequences (BCT 5.1, 5.3, 5.6); credible source (BCT 9.1); and identification of self as role model (BCT 13.1). A further seven BCTs were used in three of four trials, including goal setting (behaviour) (BCT 1.1); action planning (BCT 1.4); self-monitoring of behaviour (BCT 2.3); demonstration of the behaviour and practice/rehearsal (BCT 6.1, 8.1); pros and cons (BCT 9.2); and restructuring the physical environment (BCT 12.1). Examples of applications of the most commonly used techniques are presented in Table 3.

There was variation in the use of the remaining coded BCTs with six additional BCTs used in two trials and an additional 13 BCTs used in only one trial. The BCTs used less frequently were those related to reviewing and comparing goals and behaviour (BCT 1.5, 1.6, 2.2); social support (emotional) (BCT 3.3); ways to make behaviours and consequences more salient (BCT 4.2,

### TABLE 3 Examples of the application of most frequently used Behaviour Change Techniques

| BCT number and label | Example excerpt from one of the EPOCH trials | Trial | Source |
|----------------------|---------------------------------------------|-------|--------|
| 1.1 Goal setting (behaviour) | "What two goals would you like to set for this coming week?" | NOURISH | Unpublished |
| 1.2 Problem solving | "The group format promoted discussion of strategies, successes and overcoming barriers to key messages." | InFANT | Published |
| 1.4 Action planning | "What would you like to do when feeding your toddler? When will you try it? How?" | NOURISH | Unpublished |
| 2.3 Self-monitoring of behaviour | "You may like to keep a record of your time spent in 'screen time' that is not work related for the next week. It can be interesting to take a look at your own behaviours." | InFANT | Unpublished |
| 3.1 Social support (unspecified) | "Use of group discussion and peer support" | InFANT | Published |
| 3.2 Social support (practical) | "Accept other’s help with washing, meals, house work, ... anything!" | POLNZ | Unpublished |
| 4.1 Instruction on how to perform a behaviour | "Discuss introduction of solids guidelines, recommendations; behavioural signs baby is ready for solids, what to give baby." | HBT | Unpublished |
| 5.1 Information about health consequences | "Being active and mobile assists growth and bone development." | NOURISH | Unpublished |
| 5.3 Information about social and environmental consequences | "Breastfeeding is cheap compared to formula feeding." | HBT | Unpublished |
| 5.6 Information about emotional consequences | "Children need to be active; by helping your child to get active you help them develop intellectually, emotionally, socially, spiritually and physically. You help them develop their body, confidence, and feel secure and loved." | POLNZ | Unpublished |
| 6.1 Demonstration of the behaviour | Instructional booklet with pictures demonstrating alternative ways of doing tummy time | HBT | Unpublished |
| 8.1 Behavioural practice/rehearsal | "Practice drinking from a cup every day and be patient" | POLNZ | Unpublished |
| 9.1 Credible source | "Co-led by a dietitian and psychologist with paediatric experience." | NOURISH | Published |
| 9.2 Pros and cons | "What are the rewards and challenges of letting your baby walk" | InFANT | Unpublished |
| 12.1 Restructuring the physical environment | "Buy these foods occasionally (red foods). That way they are not always in the house tempting you and you don’t have to say no to your children all the time." | POLNZ | Unpublished |
| 13.1 Identification of self as role model | "Be a good role model. Eat a variety of foods and eat with your child." | HBT | Unpublished |

Abbreviation: HBT, Healthy Beginnings Trial.
*A Behaviour change techniques as defined in the BCTTv1* 17
### TABLE 4  Key interview themes and subthemes

| Themes | Sub themes | Illustrative quotes |
|--------|------------|---------------------|
| **PLANNING - Themes about the conception and planning stage of the study** | | |
| Collaboration | ● Work with a variety of stakeholders, seek different sources of input, for example, other researchers, service providers, parents, community, clinicians, government |
| | ● Fit in with existing stakeholders and health services, that is, ensure the intervention aligns with current agenda and care |
| | ● Work with community and work with your colleagues (...) that’s probably the most important part (...) there won’t be success if you work alone. |
| | ● A key to our success has been involving government from the start. We have never been researchers on our own. We’ve always been co-designing every aspect of the programme. |
| Theoretical background, guidelines and evidence | ● Anticipatory guidance |
| | ● Other theories and guidelines, for example, Stages of Change- Literature |
| | ● Making sure that the messages we delivered were at key ages and stages |
| | ● We made sure that we aligned that with the evidence |
| | ● We really didn’t have any other interventions to guide us (...) so it was imperative to take all of this observational descriptive evidence |
| Consider implementation | ● Be aware of scalability and real-life constraints |
| | ● Consider target group(s) and target behaviours |
| | ● Could we actually afford for maternal child health nurses to deliver this over time? |
| | ● Understand who your implementation audience would be. Because you might find your programme of work is very different once you’ve talked to them. |
| | ● You need to understand what determines the behaviours that you’re targeting (...) So if it’s a behaviour that requires skill as opposed to knowledge, your intervention will have a different spin. |
| **DELIBERATION - Themes relating to the process of delivering interventions** | | |
| Mode of delivery | ● Group benefits: efficient, pragmatic, cost effective, interactive, peer modelling, social support |
| | ● Group limitations: attendance, accessibility and engagement barriers |
| | ● Individual home visits benefits: tailored advice, convenience, rapport building, opportunity to observe interaction between mother and infant |
| | ● Individual home visits limitations: inefficient, expensive, nurse safety |
| | ● Get that cost effectiveness in terms of delivering to a group as opposed to an individual |
| | ● We felt that by role modelling with each other and sharing information there would be a lot more support to actually pick up some of our key messages |
| | ● I think group sessions are very difficult to get people to |
| | ● But when you’re there in the home visit you might pick up on some body language or you might look at mum and go, ‘Are you getting enough sleep? You look exhausted.’ You have a more personal response. |
| Flexibility/Tailoring | ● Adapt intervention to participants, participant-led sessions, rapport building, interactive conversations instead of directive instructional sessions (but may conflict with fidelity) |
| | ● Flexibility with timing of intervention delivery |
| | ● It was really led by the lady we were visiting more than led by the nurse, which I think is really valuable |
| | ● Staff were flexible, they often visited in the evenings or weekends and I think that was appreciated by participants |
| Fidelity | ● Plan to monitor fidelity through checklists, observation, etc. |
| | ● Use standardised intervention materials |
| | ● Reduce personal bias (via facilitator training) |
| | ● Ensuring that staff were adequately trained in what we were delivering and that they were giving consistent messages across the board. We found that we employed some great people, but they also liked to do things their own way, and so they put their own spin on things (...) and it wasn’t always correct. |
| Repetition of key messages | ● Information retention - re-emphasise key messages |
| | ● Simple and snappy messages |
| | ● We always needed to be reemphasizing and re-going over our key messages. There needed to be a lot of repetition because, as I said, a lot of the mums missed things the first time around. |
| **EVALUATION - Themes to do with evaluating the intervention, such as feedback from participants and facilitators, and the evaluation process** | | |
| Intervention content | ● Developing self-efficacy and empowerment |
| | ● Feeding and parenting style |
| | ● Introducing solids |
| | ● Raise awareness of childhood obesity |
| | ● Low-cost solutions for participants/practical advice |
| | ● Recognising baby cues |
| | ● Wide exposure to healthy and little exposure to unhealthy food |
| | ● Developing the intervention was around the key things that a mum needed to know. So we made sure that we aligned that with the evidence |
| | ● We gave a lot of practical advice around things that a mum could do in her home |
| | ● We did lots of work around cues and being able to read your baby. So knowing when your baby’s hungry, what that cry’s like, when they’re ready to play, when they’re fussy |
3.2 | Qualitative interviews

Of the eight eligible participants, all agreed to be interviewed. Analysis of the transcripts resulted in the generation of four main themes: Planning, Delivery, Evaluation and Implementation/Scalability. Several

| Themes | Illustrative quotes |
|--------|---------------------|
| **Reach** | • We still struggled to get to the harder-to-reach ones. It would have been better to have a different system for that. |
| | • With the non-English speaking groups, I think we tried to cater for them as much as we could but I don't think we were prepared. |
| | • I think group sessions are very difficult to get people to... they tend to be the worried well, the ones who are going to come to you anyway |
| | • I think group sessions are very difficult to get people to... they tend to be the worried well, the ones who are going to come to you anyway |
| | • I think it’s very, very important that you look at having your resources so that they can be modified and very applicable across socioeconomic groups, across different cultures. |

| themes | Sub themes | Illustrative quotes |
|--------|------------|---------------------|
| **Minimum effective intervention** | • Focus on successful content, find minimal intervention to make a difference | • I’d like to go back and look at that data again and just say, well, if those mediators didn’t affect the outcome, maybe they shouldn’t be in the model. You know, maybe they shouldn’t be part of the intervention. The intervention (...) had too much in it. |
| | | • What’s the sort of minimal intervention that I can do and still make a difference? |

| **Sustainability** | • Importance of intervention fitting with existing services |
| | • Political factors |
| | • Cost and feasibility: reflect on resources available for scaling at planning stage, for example, time, delivery mode, intervention intensity, staff, etc. Consider cheaper delivery modes, such as phones, online modes, combination of face-to-face and technology |
| | • Discontinuation of intervention (fade-out effect): External influences can dilute intervention effect over time |
| | • It has to be embedded in service (...) It certainly can’t be run by universities. |
| | • How do you support local government areas to adopt a programme (...) that is going to be scalable over time (...) sitting within funding frameworks that are sustainable |
| | • Just providing it online isn’t going to be the answer (...) it needs to be a mix. I think mother’s need a choice. |
| | • I was very aware of the relationships with whole of government if you wanted to get a programme up and running. I was always very mindful of the potential for scaling up. |
| | • You embed a lot of really good knowledge into that family environment, but then a lot of other influences come into a kid’s life when they start child care or grandparents look after them or lots of other things happen (...) that learning might get dissolved |

| **TABLE 4 (Continued)** |
|-------------------------|--------------------------|
| Themes | Sub themes | Illustrative quotes |
|--------|------------|---------------------|
| **Sleep - lactation/breastfeeding** | • They were happy that we had hit the target with the things that we thought were important that they also thought were important (...) certainly breastfeeding, introduction to solids, when can my child eat with the family and eat family food. And a lot of emphasis on healthy food not take away. And with physical activity, definitely a lot of anxious mums around Tummy Times. So very happy with lots of the support around Tummy Time that we were able to provide. |
| **How to play with your baby** | |
| | • They were happy that we had hit the target with the things that we thought were important that they also thought were important (...) certainly breastfeeding, introduction to solids, when can my child eat with the family and eat family food. And a lot of emphasis on healthy food not take away. And with physical activity, definitely a lot of anxious mums around Tummy Times. So very happy with lots of the support around Tummy Time that we were able to provide. |

5.2, 9.3); social comparison (BCT 6.2); prompts and associations (BCT 7.1, 7.8); forming of habits (BCT 8.2, 8.4, 8.7); managing mental resources and perspectives (BCT 11.2, 11.3, 13.2); restructuring social environment and physical cues and resources (BCT 12.2, 12.3, 12.5).
sub-themes were identified across each of the main themes. The themes Planning, Delivery and Evaluation mainly focus on the participants’ experiences with each phase of the trial, whilst the Implementation/Scalability theme focuses on the participants’ reflections, recommendations and improvements to scale up the interventions. Table 4 provides a summary of the main findings.

3.2.1 Planning

Participants described factors during the planning phase of the intervention, which they felt influenced the uptake and success of the trial. Across all four trials, participants emphasised the importance of collaboration with stakeholders throughout all intervention stages, from planning to implementation/scaling. In particular, they highlighted that researchers should seek input from a variety of sources to incorporate diverse perspectives into the development and implementation of the intervention to ensure it aligns with existing services and current practice. The mentioned sources of input included other researchers, clinicians, health services, government bodies, parents and the community.

“A key to our success has been involving government from the start. We have never been researchers on our own. We’ve always been co-designing every aspect of the programme.”

Most participants mentioned that intervention design should be informed by theory, current guidelines and available evidence. The most commonly mentioned theory was Anticipatory Guidance, which involves proactive advice on key developmental milestones for the child. Other theories utilised in the planning stages were Health Belief Model, Social Cognitive Theory, Behaviour Change Theory and Attachment Theory. Some interviewees noted the lack of literature available to inform intervention planning, and suggested this was because the preventive approach was quite novel at the time.

Most of the interviewees pointed out the necessity to gain an in-depth understanding of the target groups and target behaviours when planning the intervention, to ensure appropriate, efficient and effective design.

“You need to understand what determines the behaviours that you’re targeting (...) So if it’s a behaviour that requires skill as opposed to knowledge, your intervention will have a different spin.”

A recurring theme was the need to consider implementation and scalability issues, such as cost-effectiveness, feasibility and sustainability, early on during the planning stages (rather than at the completion of the RCT). In particular, some respondents emphasised the importance of being cognisant of real-life constraints that may limit implementation and translation into practice.

“Could we actually afford for maternal child health nurses to deliver this over time?”

3.2.2 Delivery

Themes related to the process of delivering interventions differed based on the mode of delivery within individual trials. For group-based interventions, interviewees noted the advantages of interaction, social support and peer-modelling, in addition to efficiency and cost-effectiveness. One respondent mentioned the ability to magnify learning opportunities by having multiple voices in a room and sharing experiences.

“We felt that by role modelling with each other and sharing information there would be a lot more support to actually pick up some of our key messages.”

Delivering an intervention using a group-based model was described as pragmatic, in that, it fitted well with pre-existing mothers’ group structures. However, barriers to group sessions include limited attendance, accessibility and engagement of participants. The group setting may not favour more reserved parents who are reluctant to speak up, whilst more outgoing parents may dominate sessions and spread erroneous information. It is thus crucial for the facilitator to obtain a balance between participant engagement and ensuring the discussion remains in line with key messages. For individual home-based interventions, key advantages included comfort and convenience for the mother, the opportunity to deliver tailored advice and observe mother/infant interactions, and rapport building. Limitations included high cost, inefficiency and nurse/facilitator safety issues.

“They feel more comfortable in their home environment to discuss health issues.”

Common themes across delivery modes were the need for flexibility and fidelity. Flexibility in session timing can be important, to cater for baby’s sleeping patterns and the many other conflicting responsibilities of first-time mothers. Many noted the importance of adapting interventions to participants, and facilitating interactive participant-led discussions rather than directive instructional sessions. However, these needed to be balanced with maintaining fidelity around key messages. Methods recommended to monitor fidelity included checklists and observation. Standardised handbooks/resources and facilitator training were considered important to reduce personal bias in the delivered messages. Repetition of key simple messages was often reported as an important factor for information retention.

“So what are the core components, how do we make sure they’re being delivered?”

3.2.3 Evaluation

Interviewees positively evaluated a variety of content that was covered in the interventions, for example, feeding and parenting style, introducing solids, sleep, tummy time and breastfeeding. Many noted the importance of developing self-efficacy and empowerment amongst parents. For example, the “Parent provide, child decide” message was described as “enlightening.” Most interventions aimed to provide practical and low-cost solutions that parents could easily practice at home. Many interviewees raised the importance of ongoing process evaluations, so that the intervention could be continually enhanced based on feedback from facilitators, researchers and parents. For example, one trial removed a module on house safety due to lack of
interest amongst participants when it moved into the small-scale implementation phase. Reach and accessibility of the intervention were key themes raised in many interviews. Respondents often reported difficulties in recruiting participants from diverse and vulnerable populations, such as low socio-economic position groups and those living in regional and rural areas. It was commonly recommended that how best to reach these groups should be carefully considered, and intervention materials should be adjusted to cater for factors such as low literacy and cultural sensitivities.

“It's very, very important that you look at having your resources so that they can be modified and very applicable across socioeconomic groups, across different cultures.”

3.2.4 | Implementation/scalability

Two important and interrelated themes were those of a minimum effective intervention and sustainability. The concept of a minimum effective intervention refers to focussing on successful content and discarding ineffective or inefficient components to deliver a more targeted, effective and streamlined intervention.

"I'd like to go back and look at that data again and just say, well, if those mediators didn't affect the outcome, maybe they shouldn't be in the model. You know, maybe they shouldn't be part of the intervention. The intervention (...) had too much in it.”

The concept of sustainability refers to implementing an intervention program that can be sustained over time, and that has long-term effects. Many interviewees noted the importance of embedding a program within existing services, and particularly getting the government and existing local services involved. Cost and feasibility were repeatedly raised as important considerations. Consideration of potentially cheaper delivery modes such as phone, online and a combination of face-to-face and technology was recommended. Some interviewees raised concerns about dilution of the intervention effect after discontinuation due to external influences (fade-out effect). One noted a gap in support between 2 years of age and the commencement of pre-school, and suggested additional intervention may be required during this period to reinforce and sustain positive behaviours.

4 | DISCUSSION

Our multi-methods study combines the systematic description and deconstruction of intervention content from four landmark very early obesity prevention randomised controlled trials with qualitative interviews with investigators and intervention facilitators exploring the planning, delivery, evaluation and implementation of these interventions. Trials commonly targeted dietary, physical activity and parenting behaviours, through face-to-face delivery by trained health professionals. Key variations in delivery features related to dose/intensity of the intervention, group vs individual delivery approach, tailoring (personalisation, titration or adaptation) and fidelity monitoring. There was large variation between trials in the use of BCTs, with more than half of the BCTs identified being used in only one or two of the four trials. BCTs that were consistently used across trials were those related to goal setting, social support, how and why to change a behaviour, being a role model and persuasion by a credible source. The interviews highlighted the importance of collaboration and the need to consider implementation (eg, by involving policy makers) throughout the study process. Whilst some interviewees highlighted the benefits of group delivery including social support and cost-effectiveness, others emphasised the advantages of participant-led, accessible delivery through individual home visits. Key recommendations resulting from the current study are summarised in Box 1.

4.1 | Possibilities to streamline to find minimum effective interventions

When implementing interventions, a key question for policy makers, in light of scarce resources, is: what is the minimum intervention that can be implemented to make a meaningful difference? The importance of finding the minimum effective intervention was also a key theme across the interviews. In this study, we took a key step toward being able to identify the “essential components” of four very early childhood obesity prevention interventions, by deconstructing them into their components to enable future considerations about which interventions worked in which way. The trials targeted a large number of obesity-related behaviours utilising a range of BCTs over numerous sessions. When planning future interventions for scale, researchers should consider which behaviour change approaches and dose can be leveraged, including less frequently used BCTs that have been shown to be promising in other studies. For example, BCTs related to reviewing goals (BCT 1.5) and forming habits (BCT 8.2, 8.4, 8.7), may help to maintain progress during and after the intervention to mitigate fade-out.

These BCTs could be particularly important given improved opportunities for e-health, allowing tailored messaging and goal setting after the main face-to-face intervention has been completed. Importantly, minimum effective interventions may vary across different populations.

In addition to the systematic coding of BCTs, our study provides detailed description and comparison of the intervention delivery features of the four trials. Interventions commonly targeted dietary, physical activity and parenting behaviours, through face-to-face delivery by a trained health professional, often combining written and visual materials. Interventions delivered in a group setting enabled better monitoring of fidelity, whilst interventions delivered in an individual setting allowed the integration of additional elements of tailoring. Intervention procedures (what) and intensity (when and how much) varied between trials. A reason for this may be that there is no one best approach, but instead, future studies and implementation efforts may choose the approach most suitable to their context and population.

Applying the recommendations resulting from the current study (Box 1) may help to refine the key delivery features and BCTs for the local context to deliver the minimum effective intervention for each target group. As a next step, we recommend that investigators seek to
develop streamlined or minimum effective interventions, which would maintain effect size when translated from research into practice and when delivered at scale, by determining which of the identified BCTs and intervention characteristics are associated with effectiveness. The newly formed TOPCHILD Collaboration will address the questions stemming from this current study (www.topchildcollaboration.org).

4.2 Adaptation to different target groups and populations

A key consideration raised during interviews with trial principal investigators and facilitators was the need to adapt current intervention programs to suit the needs of the most vulnerable populations, such as families with lower socio-economic position, different cultural and linguistic backgrounds and those from rural environments. This includes carefully defining the intervention target group in the planning stage, and then tailoring and delivering the intervention to suit their needs. For instance, to reach the target population it may be important to translate material into other languages, or to modify content to acknowledge cultural sensitivities. Other target groups may require flexible delivery times due to work commitments or on-site childcare to enable attendance with children. This also becomes relevant when implementing successful interventions into other settings. As a first step, the needs and context of the target group should be analysed, and the minimum effective intervention should be adapted...
to best suit their requirements. For this purpose, it is crucial for researchers to work with their communities to design effective and well-received interventions. Yet, in a competitive funding environment, this can be difficult to achieve. The expectation to present a fully planned randomised controlled trial to receive research funding limits the ability for process evaluation and piloting of different intervention components.

4.3 | Feasibility of interventions at scale

The present results add to the growing body of evidence examining factors that need to be considered when designing an intervention to be delivered at scale. Specifically, our findings align with previous research by emphasising the need to ensure that facilitators are appropriately trained, key messages are repeated throughout a program and delivery occurs across childhood to avoid fade-out effects of health gains. A key message from the interviews was the need to seamlessly align the intervention with other efforts to prevent childhood obesity. A common recommendation was to offer novel interventions through existing health services, which can ensure alignment of interventions and also reduce cost and organisational strain, thereby improving the scalability of interventions. Additionally, aligning new early childhood obesity prevention interventions with existing interventions in later childhood, adolescence and adulthood in a variety of settings (eg, home, primary care and broader environment) can prevent fade-out effects and may also improve overall effectiveness by providing continuity.

4.4 | Moving the field forward through collaboration and co-design

The importance of co-design for effective health interventions has been documented previously, and our findings support this. Collaboration and co-design with existing stakeholders, health services and governments were pointed out throughout the interviews as key to the success of the EPOCH interventions and their translation efforts. In each interview, collaboration with a variety of stakeholders was extensively discussed, and communication and co-design with policy makers were highlighted as a key factor for successful implementation efforts. In trials where implementation was unsuccessful, frequently cited reasons were lack of interest from the relevant policy makers and political factors such as government changes or limited funding for prevention efforts.

The EPOCH prospective meta-analysis is a prime example of a successful collaboration of researchers to build a program of research and move their field forward. Collaborating in a prospective meta-analysis enabled successful synthesis of study results upon completion to detect that very early interventions are successful in reducing childhood obesity, at least in the short term. In this current study, the collaboration enabled a deep understanding of interventions from a variety of perspectives and the derivation of recommendations for future interventions. Previous reviews have deconstructed the EPOCH interventions using only published material (protocol and results papers). Access to unpublished intervention materials enabled us to identify more than double the number of BCTs compared with these previous reviews, thereby allowing a new level of insight to the interventions. Direct access to investigators and facilitators enabled us to conduct interviews and compare and contrast lessons from the four trials. Prospective meta-analysis is an emerging collaborative approach, and this study is an important example of how this approach can enable new insights that progress the research agenda and implementation of interventions.

4.5 | Improving intervention transparency

Research into the “black box” of complex interventions depends on transparent reporting of intervention content and components. The introduction of standards such as TIDieR and CONSORT has improved the quality of research reporting. However, guidance for the detailed reporting of intervention content remains limited. Future studies should use systematic frameworks such as those outlined in the Behaviour Change Wheel to guide comprehensive reporting. The development of a repository of intervention materials would also enable transparent reporting and avoidance of research waste (eg, no repeat of testing strategies less likely to work). This study uses systematic frameworks to describe intervention features and behaviour change content. Increased transparency through the use of frameworks, reporting guidelines and taxonomies in the development and reporting of new interventions could improve the ability to understand and replicate interventions, and would enable quantitative modelling of effective components across trials, thereby enabling researchers to work together to find the most effective interventions.

4.6 | Strengths and limitations

Our study provides important insight into trial components, and reflections by experienced investigators on what did and did not work, across multiple family-focused childhood obesity prevention trials that were independently planned and conducted. A major strength of this study was the coding of intervention features and behaviour change content using both published and unpublished intervention resources, and the direct access to intervention facilitators and principal investigators. Inclusion of unpublished intervention resources allowed coding of an additional 12 to 19 BCTs per trial compared with those coded by Matvienko-Sikar and colleagues using only published manuscripts. The combination of different frameworks and methodologies used in this study was a key step towards enhancing our understanding of complex interventions in this field. These methodologies will be important for deconstructing interventions used in future trials and ultimately to quantitatively determine the effectiveness of each intervention component.

There are several limitations. Due to reporting and overlap of intervention content, we only coded whether BCTs were applied in a trial, but not which target behaviour a BCT was coded to, nor could
we determine the dose or effectiveness of BCTs. For instance, we did not differentiate whether goal setting was applied to the target behaviour physical activity or diet, and whether it was applied only once or multiple times. Instead, we only coded whether goal setting was present in a trial. Furthermore, we did not code BCTs that parents were encouraged to expose their children to, but that were not actually delivered as part of the intervention. For instance, we only coded the BCT behavioural practice if physical activity sessions were directly offered as part of the intervention, but not, if parents were simply told that they could improve their child’s fitness through physical activity sessions. In addition, the trials were planned and implemented several years ago; therefore, interviews may be subject to recall bias.

4.7 | Conclusion

Our study provides rich insights to inform future very early childhood obesity prevention initiatives that can be delivered cost-effectively at scale. The deconstruction of multiple early obesity prevention trials into their components, highlights both similarities and differences in intervention characteristics and behaviour change content. Behaviour change content that was consistent between studies included goal setting, social support, how and why to change a behaviour, being a role model and persuasion by a credible source. Interviewing trialists and facilitators across multiple interventions provides understanding of the challenges of and recommendations for intervention planning, delivery, evaluation and implementation. We recommend that researchers, policy makers and health service delivery practitioners collaborate in the planning and implementation of minimum effective interventions to ensure both scalability and sustainability. Future research will explore the development of quantitative models to answer important questions about how these complex interventions work, for whom, and under what circumstances. For this purpose, a global trials registry is being established through the EPOCH and TOPCHILD Collaborations (www.topchildcollaboration.org) to quantitatively explore the key components of these complex interventions that are associated with effectiveness.

CONFLICTS OF INTEREST
All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the EPOCH prospective meta-analysis was funded by the Australian National Health and Medical Research Council (NHMRC, Grant ID: 1028555 and 1101675) with seed funding from Meat Livestock Australia (Grant ID: QUT2010001469); three of the included trials (NOURISH, Healthy Beginning Trial, InFANT) were funded by the Australian NHMRC, and one trial (POI.nz) was funded by the Health Research Council of New Zealand.

AUTHOR CONTRIBUTIONS
Anna Lene Seidler together with Kylie E. Hunter, Chelsea E. Mauch and Brittany J. Johnson conceived the idea for the study and developed the concept. Anna Lene Seidler wrote the study proposal, all authors reviewed it and gave critical input. Anna Lene Seidler, Kylie E. Hunter, Chelsea E. Mauch and Brittany J. Johnson deconstructed the interventions into their components using the behaviour change technique taxonomy and TIDieR checklist, Brittany J. Johnson analysed and summarised the results. Seema Mhrshahi identified the target behaviours. Anna Lene Seidler, Kylie E. Hunter, Malakalshmi Ekambareswar and Sarah Taki developed the interview guide. Malakalshmi Ekambareswar conducted the interviews. Karen J. Campbell, Lynne Daniels, Rachael W. Taylor, Li M. Wen, Rebecca Byrne, Julie Lawrence, Robyn Perlstein and Karen Wardle were interviewees. Anna Lene Seidler and Kylie E. Hunter under the supervision of Sarah Taki coded and analysed the interviews. All authors critically reviewed and discussed the results. Anna Lene Seidler, Kylie E. Hunter, Brittany J. Johnson, Chelsea E. Mauch, Rebecca K. Golley and Malakalshmi Ekambareswar wrote the first draft of the manuscript. All authors edited and reviewed the manuscript and approved the final version for publication. We would like to acknowledge Penelope Love for providing additional information and resources from the InFANT trial.

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