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Transforming Obesity Prevention for CHILDren (TOPCHILD) Collaboration: Protocol for a Systematic Review with Individual Participant Data Meta-Analysis of Behavioural Interventions for the Prevention of Early Childhood Obesity

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BMJ Open Transforming Obesity Prevention for CHILDren (TOPCHILD) Collaboration: protocol for a systematic review with individual participant data meta-analysis of behavioural interventions for the prevention of early childhood obesity

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ABSTRACT

Introduction Behavioural interventions in early life appear to show some effect in reducing childhood overweight and obesity. However, uncertainty remains regarding their overall effectiveness, and whether effectiveness differs among key subgroups. These evidence gaps have prompted an increase in very early childhood obesity prevention trials worldwide. Combining the individual participant data (IPD) from these trials will enhance statistical power to determine overall effectiveness and enable examination of individual and trial-level subgroups. We present a protocol for a systematic review with IPD meta-analysis to evaluate the effectiveness of obesity prevention interventions commencing antenatally or in the first year after birth, and to explore whether there are differential effects among key subgroups.

Methods and analysis Systematic searches of Medline, Embase, Cochrane Central Register of Controlled Trials, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycInfo and trial registries for all ongoing

and completed randomised controlled trials evaluating behavioural interventions for the prevention of early childhood obesity have been completed up to March 2021 and will be updated annually to include additional trials. Eligible trialists will be asked to share their IPD; if unavailable, aggregate data will be used where possible. An IPD meta-analysis and a nested prospective meta-analysis will be performed using methodologies recommended by the Cochrane Collaboration. The primary outcome will be body mass index z-score at age 24±6 months using WHO Growth Standards, and effect differences will be explored among prespecified individual and trial-level subgroups. Secondary outcomes include other child weight-related measures, infant feeding, dietary intake, physical activity, sedentary behaviours, sleep, parenting measures and adverse events.

Ethics and dissemination Approved by The University of Sydney Human Research Ethics Committee (2020/273) and Flinders University Social and Behavioural Research Ethics Committee (HREC CIA2133-1). Results will be

Strengths and limitations of this study

- ▶ This will be the largest individual participant data (IPD) meta-analysis evaluating behavioural interventions for the prevention of early childhood obesity to date, and will provide the most reliable and precise estimates of early intervention effects to inform future decision-making.
- ▶ IPD meta-analysis methodology will enable unprecedented exploration of important individual and trial-level characteristics that may be associated with childhood obesity or that may be effect modifiers.
- ▶ The proposed innovative methodologies are feasible and have been successfully piloted by members of our group.
- ▶ It may not be possible to obtain IPD from all eligible trials; in this instance, aggregate data will be used where available, and sensitivity analyses will be conducted to assess inclusion bias.
- ▶ Outcome measures may be collected and reported differently across included trials, potentially increasing imprecision; however, we will harmonise available data where possible, and encourage those planning or conducting ongoing trials to collect common core outcomes following prospective meta-analysis methodology.

relevant to clinicians, child health services, researchers, policy-makers and families, and will be disseminated via publications, presentations and media releases.

PROSPERO registration number CRD42020177408.

INTRODUCTION

Childhood obesity is one of the most serious public health issues of the 21st century, and requires urgent action.^{1,2} Globally, an estimated 38 million (6%) children aged under 5 years were living with overweight or obesity in 2019,³ and prevalence is increasing across every continent as environments become more obesity conducive.^{4,5} While childhood obesity affects all sections of society, it disproportionately affects racial and ethnic minority groups^{6,7} and populations with a lower socioeconomic position (SEP), and thus is also a major health equity issue.⁴ Children with obesity are much more likely to have obesity across the lifecourse,^{8,9} and are at increased risk of short-term and long-term negative health sequelae, such as poor mental and musculoskeletal health, type 2 diabetes, asthma and cardiovascular disease.^{10,11} This places a large burden on healthcare systems,¹² and has significant economic consequences arising from increased disability and decreased productivity and life expectancy.¹³ Thus, identifying modifiable behaviours for the early prevention of childhood obesity is critical to inform the development of early intervention strategies.

There are a variety of modifiable behaviours that may influence energy balance and therefore may be implicated in childhood obesity prevention, namely, feeding practices, dietary intake, physical activity, sedentary behaviours and sleep. For instance, appropriate responsive feeding has been identified as promising for obesity prevention,^{14–16} while consumption of sugar-sweetened beverages is associated with severe obesity in children aged less than 5 years.¹⁷ Data are mixed on the protective benefits of breast feeding for the prevention of

obesity, though some studies suggest that longer duration of exclusive breast feeding may provide modest protection.^{18–23} Similarly, there may be an association between age at introduction of solids and growth,²⁴ with mixed results surrounding the direction of this association and the underlying causal mechanisms. Previous systematic reviews have reported significant inverse associations between physical activity and measures of adiposity in children.^{25–27} Conversely, sedentary behaviours such as television viewing or screen time are associated with higher body mass index (BMI) levels^{28,29} and greater adiposity³⁰ in young children. There is now also a large body of observational evidence supporting the relationship between short sleep duration and an increased risk of obesity across all age groups, including infants and young children,^{31–35} though a recent systematic review found inconsistent evidence of an association between longer infant sleep duration and healthier body composition up to age 24 months.³⁶

In addition to these behaviours, individual-level covariates known or hypothesised to be predictive for childhood obesity include prepregnancy maternal and paternal BMI, age, race, ethnicity, SEP, excess gestational weight gain, parity, smoking during pregnancy, gestational diabetes, birth mode of delivery (caesarean, vaginal), birth weight, gestational age at birth, baby's sex, intrapartum antibiotic prophylaxis and childcare attendance.^{6,7,22,37,38} Some of these covariates may also be individual-level effect modifiers, predicting how effective an intervention is likely to be, for example, SEP and race/ethnicity. Trial-level characteristics such as timing of intervention onset, setting and the level of well-child healthcare available in the community may also modify intervention effectiveness.³⁹

Limitations and evidence gaps identified in previous reviews

In the past 5 years, there have been numerous reviews of childhood obesity prevention trials encompassing a variety of intervention types, settings and age groups.^{14,40–46} Few of these focused solely on infancy, and many spanned multiple life stages from the prenatal period to 18 years of age. One review found that family-based childhood obesity prevention interventions most frequently targeted children 2–10 years of age (78%), with fewer targeting infants aged 0–1 year (24%) or the prenatal period (8%).⁴⁰ Most reviews highlighted the urgent need for further rigorous evidence to inform obesity prevention interventions in the very early childhood years.^{14,40–44,46} Given the consequences of rapid early life weight gain, associated epigenetic changes and early onset of obesity in many children,^{3,47,48} there is strong rationale to start preventive interventions early when biology is most amenable to change, and before negative obesity-conducive behavioural patterns are established.²

Most of the childhood obesity prevention reviews to date have used qualitative methodology such as narrative reviews, content analysis and systematic reviews without meta-analysis to describe variations in study design, setting, population, interventions and outcomes, and to

hypothesise that certain individual and trial-level characteristics may enhance effectiveness via proposed conceptual frameworks and intervention models.^{14 40 42–46} Yet, quantitative evaluation is required to formally test these hypotheses. Recently, Brown *et al*⁴¹ updated a Cochrane systematic review and aggregate data meta-analysis on obesity prevention in children aged 0–18 years, and found that interventions focusing on diet and physical activity combined can lead to a small reduction in BMI z-score in children aged 0–5 years of age (mean difference -0.07 , 95% CI -0.14 to -0.01). However, a huge variety in intervention approaches limited their ability to conduct meaningful comparisons, and many multicomponent interventions were originally reported as a whole package, precluding evaluation of discrete intervention characteristics. Moreover, the aggregated data were insufficient to derive conclusions on effect differences by individual-level characteristics such as ethnicity and SEP.

The Early Prevention of Obesity in Children (EPOCH) Collaboration conducted a world-first individual participant data (IPD) prospective meta-analysis (PMA) of four randomised controlled trials (RCTs) of behavioural interventions for the prevention of early childhood obesity.³⁹ They found that, compared with usual care, early childhood interventions were modestly effective in reducing BMI z-score 18–24 months after birth by 0.12 SD (which translates to a 2% decrease in obesity prevalence). However, when accounting for missing data this difference was no longer significant. There was some heterogeneity across trials, and interventions appeared to be more effective in populations with limited publicly funded existing healthcare programmes, in this instance defined as a maximum of one postnatal home visit.³⁹ However, this finding needs to be confirmed in analyses including more than four studies. EPOCH's predictive analyses of individual and trial-level factors did not have sufficient power to detect reliable differences in BMI z-score. Thus, the overall effectiveness of early obesity prevention interventions remains uncertain, as does whether there may be differential effects among subgroups.

Need for IPD meta-analysis

The limitations and evidence gaps described above highlight the need for more powerful and in-depth analyses focusing on preventive interventions in very early childhood. Since the EPOCH PMA,³⁹ we have identified more than 60 additional ongoing or completed very early obesity prevention trials worldwide with a combined sample size of more than 50 000 participants. While most trials are powered to detect some important differences in key outcomes, individually they have limited power to detect a difference in our primary outcome, BMI z-score at 24±6 months of age. In order to reliably detect a reduction in BMI z-score similar to that seen in EPOCH (-0.12),³⁹ 2920 participants are required (90% power, 2-sided 5% level of significance). Moreover, usually about four times that sample size ($n \sim 12\ 000$) is required to detect differences in subgroups.⁴⁹ The expected total

sample size for Transforming Obesity Prevention for CHILDren (TOPCHILD) will exceed these estimates (as by July 2021, 45 trials including 40 030 eligible participants have already agreed to share their IPD).

Conducting a trial of this size would be time and resource intensive. A more efficient method is to combine IPD from trials in a pooled analysis to increase the sample size and therefore statistical power. This strengthens the chance of detecting intervention effect differences, and enables us to determine the size of such effects with greater certainty,⁵⁰ while also allowing variation in study designs and population which heightens generalisability and allows a greater diversity to study effect modification for different subgroups of individuals or trial characteristics.⁵¹ Moreover, this collaborative approach maximises the use of existing data, thereby reducing research waste.

Thus, we will conduct an IPD meta-analysis with detailed subgroup analyses of all available trials to confirm whether early obesity prevention interventions commencing antenatally or in the first year after birth are effective, and whether effectiveness varies across subgroups defined by individual-level or trial-level characteristics. The knowledge generated from this study can be used to inform decision-making around the design and implementation of more effective, efficient, equitable and targeted interventions for the prevention of childhood obesity and its sequelae.

Objectives

This IPD meta-analysis will address the following research questions:

1. Compared with usual care, no intervention or attentional control, what are the effects of parent/caregiver-focused behavioural obesity prevention interventions commencing during pregnancy or infancy on:
 - a. child BMI z-score at age 24 months (± 6 months)? (primary outcome),
 - b. child BMI z-score at alternative timepoints, other child weight-related measures, infant feeding, dietary intake, physical activity, sedentary behaviours, sleep, parenting measures and adverse events? (secondary outcomes),
2. Do intervention effects vary across individual-level characteristics (eg, parental BMI, parity, SEP, birth weight)?
3. Do intervention effects vary across trial-level characteristics (eg, access to existing well-child healthcare programmes, intervention mode of delivery, timing of intervention onset)?

METHODS AND ANALYSIS

We will conduct a systematic review with IPD meta-analysis and a nested PMA according to the methods recommended by the Cochrane Collaboration.^{52 53} A nested PMA enables integration of prospective evidence into a retrospective meta-analysis, and harmonisation among planned/ongoing studies.⁵³ Lead investigators of eligible

trials will be invited to share their IPD and join the TOPCHILD Collaboration (www.topchildcollaboration.org). This protocol adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols⁵⁴ (online supplemental appendix 1).

Eligibility criteria

Types of studies

This systematic review will include RCTs only, including feasibility studies, pilot trials and definitive trials. Randomisation may occur at the individual level or by cluster (eg, child care, community), including stepped-wedge designs. Quasi-randomised trials are excluded as they may introduce bias. There are no language or date restrictions.

Trial participants

Participants will be parents/caregivers (including pregnant women) and their infant(s) aged 0–12 months (at baseline). Caregiver is defined as the person with primary responsibility for care of the child, and excludes secondary sources of support, such as child care providers and early childhood teachers. Women may be primipara or multipara, and both singletons and multiples are eligible.

Types of interventions

Interventions must be behavioural interventions targeting parents/caregivers, and include at least one component related to modifiable child behaviours that may influence overweight/obesity risk (eg, infant feeding, dietary intake, physical activity, sedentary behaviours, sleep). They may commence in the preconception or antenatal phase but must include intervention exposure targeting the birth to 12 months infancy stage, as pregnancy-only interventions are considered distinct and are currently being examined by Dodd *et al* in a separate IPD meta-analysis.⁵⁵ Only childhood obesity prevention-focused trials will be included; these are defined as trials that clearly state childhood obesity prevention as a key aim/objective. Interventions focused only on improving an obesity-related behaviour (eg, sleep, delayed introduction of solid foods), as well as those focused on treatment of obesity, stunting or underweight will be excluded. Trials with a dual focus to prevent obesity and undernutrition are eligible, though we will carefully consider and prespecify how their data will be incorporated in the statistical analysis plan. Interventions focused solely on nutritional supplements will be excluded, as they are not considered to be behavioural interventions.

Types of comparator/control

Eligible trials must have either (1) a usual care control arm, defined as existing local child healthcare, or (2) no intervention (including waitlist control) or (3) attention control (eg, child safety education).

Types of outcome measures

To be included, trials must collect at least one of the child weight-related outcomes listed in [table 1](#) post intervention

(at any age), that is, BMI/BMI z-score, prevalence of overweight/obesity, per cent fat content/adiposity, skin-fold thickness, abdominal circumference, waist-to-height ratio. This is considered a legitimate and pragmatic approach given our review is of multicomponent public health interventions focusing on obesity.⁵⁶

Eligibility for nested PMA

In accordance with PMA methodology,⁵³ only planned/ongoing trials will be eligible for the nested PMA if trial results were not yet known to the investigator/s at the time the main components of the TOPCHILD protocol (ie, aims and objectives, hypotheses, eligibility criteria, main outcomes, subgroup and sensitivity analyses) were initially agreed in December 2020. We encourage investigators of planned/ongoing studies to collect the outcomes and subgroup variables listed in [table 1](#) where possible, to facilitate data harmonisation and synthesis.

Information sources and search strategy

In March 2020, we undertook an initial systematic search for eligible trials using the following databases from their inception: Medline (Ovid), Embase (Ovid), Cochrane Central Register of Controlled Trials, CINAHL (EBSCO), PsycInfo, ClinicalTrials.gov and the WHO's International Clinical Trials Registry Platform's Search Portal. The full search strategy is available in online supplemental appendix 2. This search will be updated annually for the duration of the TOPCHILD Collaboration (currently funded until end 2023). Collaborators and contacts will also be asked to notify us of any planned, ongoing or completed trials of which they are aware that may meet the eligibility criteria.

Selection of studies for inclusion in the review

Two members of the TOPCHILD Steering Group will independently screen all retrieved records against eligibility criteria. Any discrepancies will be resolved by discussion or, if required, adjudication by a third reviewer from the Steering Group. The Principal Investigator and/or corresponding author of eligible trials will be invited by email to join the TOPCHILD Collaboration. If there is no response to initial emails and reminders, we will contact co-authors and/or other contacts listed in registration records and consult our existing networks to see if they can reach out to those they may know. If IPD cannot be obtained for an eligible trial, we will use aggregate data sourced from publications where available.

Online supplemental appendix 3 lists eligible trials identified up to March 2021.

Data collection, management and confidentiality

Data receipt/extraction

Trialists of all eligible studies will be invited to share deidentified IPD via secure data transfer platforms or via an institutional-secure email using password-protected zip files. Data will be provided according to a prespecified coding template where possible. Otherwise, data will be accepted in any format and recoded as necessary. The

Table 1 Outcomes and subgroups

<i>Variable</i>	<i>Definition/explanatory text/examples*</i>
Primary outcome	
BMI z-score at age 24 months (± 6 months)	Determined in accordance with WHO growth standards ⁶⁰
Secondary outcomes	
BMI z-score at 12 months (± 3 months)	Determined in accordance with WHO growth standards ⁶⁰
BMI z-score at 48 months (± 12 months)	Determined in accordance with WHO growth standards ⁶⁰
BMI z-score beyond 60 months	Determined in accordance with WHO growth standards ⁶⁰
Other weight-related measures	For example, prevalence of overweight/obesity (defined as BMI z-score of at least 2 SD above the WHO reference), per cent fat content/ adiposity, skinfold thickness, abdominal circumference, waist-to-height ratio, velocity of weight gain, weight-for-length, per cent excess BMI >95th percentile, adiposity rebound
Infant feeding	For example, breast feeding initiation and duration, exclusivity of breast feeding, age at introduction of solid foods (complementary feeding)
Dietary intake	For example, energy intake, intake of fruit, vegetables, energy dense nutrient poor foods, and sugar-sweetened beverages
Sedentary behaviours	For example, screen time, restrained time while awake (in prams/strollers, high-chairs, strapped on a caregiver's back or chest)
Physical activity	For example, active play duration, prone play ('tummy time'), device assessed physical activity time
Sleep	For example, sleep duration, measures of sleep quality such as frequency and duration of waking at night
Parental/caregiver measures	General and domain-specific parenting styles and practices, for example, parenting self-efficacy, parenting styles, parent feeding practices, parent physical activity practices, parent sleep practices, stress
Adverse events	For example, underweight, injuries, infection
Individual-level subgroups	
Socioeconomic position	For example, household income/country median household income, parent/caregiver highest education level, employment status
Parental weight status	For example, maternal prepregnancy BMI, paternal BMI
Race/ethnicity	Trialist defined
Maternal age	At recruitment
Maternal gestational weight gain	In kilograms
Parity	Primipara, multiparous
Mode of delivery at birth	Caesarean, vaginal
Birth weight	In grams
Weight for gestational age	Small for gestational age, appropriate for gestational age, large for gestational age
Sex	Female, male, uncertain/other
Gestational age at birth	Preterm, term
Household composition	For example, 2 versus 1 adult household, siblings, marital status
Type of pregnancy	Singleton, multiple
Maternal diabetes	Gestational, type 1, type 2
Smoking during pregnancy	yes/no
Infant's age at enrolment	In months
Child's age at final assessment	In months
Child care attendance	yes/no
Trial-level subgroups	
Delivery mode (intervention)	For example, face-to-face, letter, mobile digital device, individual versus group
Intervention setting	For example, household residence, community healthcare facility

Continued

Table 1 Continued

Variable	Definition/explanatory text/examples*
Intervention dose/intensity	For example, total number of contacts, frequency of contact, duration of contact
Fidelity	Planned, actual
Timing of intervention onset	Preconception, antenatal, postnatal
Timing of intervention completion	Child age in months
Current level of background care in the community	Descriptive, categorisation to be determined, for example, expected number of health contacts between birth and 1 year, expectation of attending prenatal programmes (yes/no), etc.
Country	Low, middle, high income
Behavioural±other intervention type	Behavioural intervention(s) alone versus behavioural+other intervention type (eg, supplement)

*Exact measures and definitions will depend on what the individual trials have collected and the degree to which harmonisation is possible. Specific details of all outcome measures will be elaborated on in our forthcoming statistical analysis plan, which will be agreed and signed off by the Collaboration before any data are analysed.
BMI, body mass index.

data management team (within the TOPCHILD Steering Group) will receive and store the data in perpetuity in a secure, customised database at the NHMRC Clinical Trials Centre, University of Sydney, and data management will follow the *University of Sydney Data Management Policy 2014*. Each trial will also be asked to provide meta-data (ie, data that provides information about their trial dataset), such as questionnaires, data collection forms and data dictionaries to aid understanding of the dataset. Trial-level data, such as setting, intervention timing, mode of delivery, comparator/control details, method of sequence generation, allocation concealment, geographical location, sample size, outcome measures and definitions will be extracted into a database and cross-checked against any published reports, trial protocols, registration records and data collection sheets.

Data processing

Data from each trial will be checked with respect to range, internal consistency, consistency with published reports and missing items. Integrity of the randomisation process will be examined by reviewing the chronological randomisation sequence and pattern of assignment, as well as the balance of participant characteristics across intervention and control groups. Any inconsistencies or missing data will be discussed with trialists and/or data managers and resolved by consensus. Once finalised, data from each of the trials will be combined into a single TOPCHILD Collaboration database.

Risk of bias assessment and certainty of evidence appraisal

Included studies will be assessed for risk of bias by two independent reviewers from the TOPCHILD Steering Group using Version 2 of the Cochrane risk-of-bias tool for randomised trials (RoB 2).⁵⁷ This tool includes five domains encompassing bias arising from: the randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result. For cluster-randomised

trials, bias arising from identification or recruitment of individual participants within clusters will also be assessed.⁴⁵ The certainty of evidence will be assessed according to Cochrane procedures⁵⁸ using the Grading of Recommendations Assessment, Development and Evaluation approach.⁵⁹ Any differences will be resolved by consensus or with a third reviewer from the TOPCHILD Steering Group.

Primary outcome

The primary outcome will be BMI z-score at age 24 months (± 6 months), determined in accordance with WHO growth standards.⁶⁰ We selected BMI z-score, over other measures such as weight-for-length, in light of accumulating evidence that it is more highly correlated with weight status in infancy and is better at predicting future obesity risk.^{61–65} In addition, WHO BMI for age charts are applicable to all infants/children regardless of SEP or ethnicity, which aligns with the global nature of the TOPCHILD Collaboration.⁶⁶

Secondary outcomes

All outcomes are detailed in [table 1](#). Where possible, definitions will be standardised, otherwise outcomes will be used as defined within each trial. Secondary outcomes include BMI z-score at other timepoints, other measures of child weight, infant feeding (including breast feeding and introduction of solid foods), dietary intake, sedentary behaviours, physical activity and sleep, as well as parent/caregiver-related measures. We will also assess any adverse events, such as underweight or poor weight gain.

Subgroups

All included subgroups are listed in [table 1](#). Individual-level and trial-level subgroup analyses will be conducted for the primary outcome of BMI z-score at age 24 months (± 6 months). Those of primary interest at the individual level include SEP, race/ethnicity, prepregnancy maternal/paternal BMI, maternal age, gestational weight gain and

parity, and at the trial level include timing of intervention onset, current level of background care in the community, recruitment country and mode of delivery.

Where possible, outcomes and subgroups will be collected as continuous variables to maximise power to detect intervention effects and interactions, and enable exploration of any non-linear relationships.⁶⁷ Dichotomous and categorical variables will also be collected to aid interpretation, and if data are insufficient for the prespecified subgroup analyses, categories will be collapsed prior to any analyses being conducted.

Data analysis

A detailed statistical analysis plan will be prepared and agreed on by the TOPCHILD Collaboration members prior to any analyses being undertaken. Analyses will follow the intention-to-treat principle and include all randomised infant–parent/caregiver dyads for which data are available (including any that were excluded from the original study analysis). For cluster RCTs, correlated data will be taken into account by fitting the models using generalised estimating equations to derive appropriate standard errors. Correlations between multiples also will be accounted for in the analyses.

The primary analysis for all outcomes will be conducted using a one-stage approach combining all available IPD and aggregate data (where IPD are unavailable) to reduce the risk of availability bias.^{68 69} The combined dataset will be analysed including trial as a random effect. Models will be chosen appropriate to the outcome type. Generalised linear models with appropriate distributions and link functions will be used for continuous and binary outcomes, while Cox proportional hazards regression will be used to analyse time-to-event outcomes subject to censoring. For example, linear models will be used for the primary outcome while relative risk binomial regression with log link function will be used for prevalence of overweight/obesity, and Cox models will be used for breast feeding duration. Where possible, continuous outcomes and subgroup variables will be analysed on their continuous scale to maximise utility of available data.⁶⁷

Heterogeneity of intervention effects across trials will be investigated using quantitative measures (I^2) supplemented by graphical presentations as recommended in the Cochrane Handbook.⁷⁰ Any notable heterogeneity identified will be explored further to ascertain if the combination of trials is appropriate.

Results will be reported using appropriate estimates of intervention effect (relative risks, mean differences or hazard ratios) with 95% CIs and associated two-sided p values. For trials with multiple intervention arms, we will present the data for each intervention arm compared with the control arm, with the number of participants in the control arm adjusted to ensure no double counting.⁴¹ Missing data will be explored in sensitivity analyses using appropriate methods. All analyses will be performed using the open-source software R.⁷¹

Differences in intervention effect between the prespecified subgroups will be examined by testing a treatment by subgroup interaction term within the 1-stage-model. Findings of subgroup analyses will be reported as exploratory,⁷² and summarised using a 1-stage-approach supplemented by graphical presentation in a forest plot using a 2-stage-approach. Non-linear relationships will be explored for continuous subgroup variables using a multivariate meta-analysis of the trend.⁶⁷

Other exploratory analyses for the primary outcome will include graphical presentation of BMI z-score distributions to investigate any differences beyond mean differences and examine any non-linear relationships. The potential for mediation and moderator analyses using parent/caregiver measures will be explored and detailed in a statistical analysis plan after we have extracted information about relevant variables collected by included trials.

Assessment of selection or publication bias

Potential selection bias and publication bias will be investigated by conducting a nested PMA and comparing prospectively versus retrospectively included trials in a sensitivity analysis.⁵³ We will also seek to include any unreported outcomes sourced from each trial's IPD, which may alleviate selective outcome reporting bias.⁵² Lastly, contour-enhanced funnel plots will be used to examine whether there are differences in results between more and less precise studies.

Adjustments for multiple testing

Only one primary outcome was selected for this study (table 1). For secondary outcomes and subgroup analyses, no formal adjustments will be made for the potential inflation of type 1 error rates due to multiple testing. Instead, we will follow Schulz and Grimes' approach⁵⁴ and recommendations of the Cochrane Collaboration.⁷⁰ This involves cautious interpretation of the magnitudes of effect, patterns and consistency of results across related outcomes and clinical/biological plausibility rather than focusing on any single statistically significant result in isolation which can be extremely misleading.^{70 72}

Planned sensitivity analyses

Where possible, the following sensitivity analyses will be conducted for the primary outcome:

- ▶ Two stage approach.
- ▶ Including IPD only, that is, excluding trials without IPD available.⁵⁵
- ▶ Including prospectively included trials only (nested PMA), that is, planned/ongoing trials for which results were not yet known to investigator/s at the time the main components of the TOPCHILD protocol were agreed.⁵³
- ▶ Adjusting for birth weight as a covariate.
- ▶ Excluding trials with a high risk of bias for sequence generation and/or allocation concealment and/or loss to follow-up.

- ▶ Excluding trials with a significant conflict of interest (eg, funded by industry).
- ▶ The impact of missing data on conclusions about the intervention effect (if appropriate).

Project management

Membership of the TOPCHILD Collaboration includes trial representatives from each of the trials contributing IPD to the project, a Steering Group and an Advisory Group. Trial representatives have the opportunity to contribute their expert knowledge to the TOPCHILD Collaboration and provide input into the protocols, statistical analysis plan and final results manuscript. The Steering Group will be responsible for data collection, management and analysis, as well as communication within the Collaboration, including newsletter updates, maintenance of the TOPCHILD website and organisation of virtual or face-to-face collaborator meetings. The Advisory Group will comprise invited experts in childhood obesity prevention, IPD meta-analysis, statistics, behaviour change theory/methods and policy implementation.

ETHICS AND DISSEMINATION

Ethical considerations

IPD will be provided by each included trial on the stipulation that ethical approval has been provided by their respective Human Research Ethics Committees (or equivalent), and participants gave informed consent before enrolment to participate in the initial individual trials. Trialists remain the custodians of their own data, which will be deidentified before being shared with the TOPCHILD Collaboration. Ethical approval for this project has been granted by The University of Sydney Human Research Ethics Committee (2020/273) and Flinders University Social and Behavioural Research Ethics Committee (project no. HREC CIA2133-1).

Publication policy

TOPCHILD manuscripts will be prepared by the Steering Group in consultation with the Advisory Group, and circulated to the full Collaboration for comment, revision and approval prior to submission for publication. Any reports of the results of this study will be published either in the name of the collaborative group, or by representatives of the collaborative group on behalf of the TOPCHILD Collaboration, as agreed by members of the collaborative group.

DISCUSSION

This will be the largest IPD meta-analysis to date of trials evaluating behavioural obesity prevention interventions commencing in very early childhood. The findings will inform next generation obesity prevention initiatives that are effective, efficient and equitable. Such interventions could set children on a better health trajectory early on

and reduce the potentially life-long burden of disease associated with obesity.

The main strengths of this study arise from use of IPD meta-analysis methodology, which is considered the 'gold standard'.⁷³ It involves collecting the raw line-by-line data for each participant in each study from the original trialists. This can improve the quality of data, and enables more in-depth and precise analyses than would be possible using only published aggregate data.⁵² In particular, IPD meta-analysis will enable thorough exploration of individual-level and trial-level subgroups, so that we may quantify any differential effects and uncover the key determinants of successful outcomes. This addresses the limitations identified in previous reviews of childhood obesity prevention,^{39 41 46} where such detailed and sufficiently powered analyses were simply not possible.

A potential limitation of this study is the risk of not obtaining IPD from all eligible studies, resulting in inclusion bias. Where available, we will include aggregate data from these studies, and conduct sensitivity analyses with inclusion of IPD only to explore potential bias.⁷⁴ Further, there may be variations across studies in how measures are collected and reported, which may lead to some imprecision and difficulties pooling the data. We will seek to address this using nested PMA methodology, whereby researchers of planned or ongoing trials are encouraged to harmonise their trial design and collect core outcome measures to facilitate meta-analysis and interpretation.⁵³ For completed studies, we will derive common outcome variables by cleaning, recoding and converting existing measures where possible.

We plan to complete the first round of study identification and IPD collection by early 2021, then conduct the primary analyses and disseminate the results by the end of 2022. Trials that are not completed in time to provide data for this cycle will remain a part of the TOPCHILD Collaboration, and their data will be included in future updates of TOPCHILD. Depending on data availability, we may consider collecting additional emerging variables of interest, such as intrapartum antibiotic prophylaxis and the microbiome, for future TOPCHILD cycles.

This IPD meta-analysis will be conducted in parallel with a complementary TOPCHILD project (Johnson *et al*⁷⁵ unpublished), which aims to deconstruct childhood obesity interventions into their components (ie, delivery features, target behaviours and behaviour change techniques) using systematic, internationally recognised frameworks and both published and unpublished trial materials. In future, the resulting dataset curated from these two projects will be used for predictive modelling of intervention component effectiveness at an individual participant level, facilitating a personalised or precision medicine approach to public health prevention.

The TOPCHILD Collaboration will maximise use of existing trial data that will enable us to understand and use the most effective intervention components for specific population groups and contexts. It will provide urgently needed evidence to inform development and

implementation of effective, efficient and equitable interventions for the prevention of early childhood obesity. The results will be of prime importance for guideline developers, policy-makers, consumers and the research community. Further information and updates on the TOPCHILD Collaboration can be found at www.topchildcollaboration.org

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Patient and public involvement statement The TOPCHILD Collaboration involves a broad range of stakeholders including health professionals, policy-makers and trialists. In addition, the Advisory Group includes a parent representative and intervention facilitator/nurse. They have given input into and feedback on this protocol and will be involved in discussion and interpretation of results.

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Supplementary file 1: 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	1,3
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	4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	19
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	n/a
Support:			
Sources	5a	Indicate sources of financial or other support for the review	20
Sponsor	5b	Provide name for the review funder and/or sponsor	20
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	20
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8
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	8-10
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	10
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 2
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11
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)	10
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	11
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	12-14
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	12-14

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	11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	14
	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)	14-15
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	12, 16
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	n/a
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	15
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11-12

*** 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):g764

Supplementary file 2: TOPCHILD 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 behavior?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

Embase Classic+Embase

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. (high fat* or low fat* or fatty food*).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 behavior?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 61
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
66. (pregnan* or perinatal* or prenatal* or antenatal or postnatal*).ti,ab
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. exp clinical trial/
74. exp Randomized Controlled Trial/
75. randomization/
76. clinical trial.tw.
77. random\$.tw.
78. Comparative Study/
79. (comparison group\$ or control group\$).tw.
80. 73 or 74 or 75 or 76 or 77 or 78 OR 79
81. 72 and 80

EBM Reviews - Cochrane Central Register of Controlled Trials

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 61
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.
66. (pregnan* or perinatal* or prenatal* or antenatal or postnatal*).ti,ab.
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

CINAHL Complete (EBSCO Host)

S77	S67 AND S75
S76	S67 AND S75
S75	S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S74
S74	TX comparison group*
S73	TX random*
S72	(PT "CLINICAL TRIAL")
S71	(MH "Clinical Trials")
S70	(MH "Random Sample+")
S69	(MH "Random Assignment")
S68	(MH "Comparative Studies")
S67	S65 NOT S66
S66	(MH "Animals+")
S65	S56 AND S64
S64	S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63
S63	(TI parent\$ or care giver or caregiver or guardian or family or families or mother\$ or father\$ OR maternal OR paternal) OR (AB (parent\$ or care giver or caregiver or guardian or family or families or mother\$ or father\$ OR maternal OR paternal)
S62	(MH "Parents")
S61	(TI pregnan* or perinatal* or prenatal* or antenatal* or postnatal*) OR (AB pregnan* or perinatal* or prenatal* or antenatal* or postnatal*)
S60	(AB babies or baby or boy? or girl? or child* or infan* or kid? or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or toddler?)
S59	(TI babies or baby or boy? or girl? or child* or infan* or kid? or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or toddler?)
S58	(MH "Infant+")
S57	(MH "Child+")
S56	S17 AND S55
S55	S31 OR S44 OR S51 OR S54
S54	S52 OR S53
S53	(TI sleep) OR (AB sleep)
S52	(MH "Sleep")
S51	S45 OR S46 OR S47 OR S48 OR S49 OR S50
S50	(TI "tummy time") OR (AB "tummy time")

S49	(TI play) OR (AB play)
S48	(TI screen time) OR (AB screen time)
S47	(TI sedentary behavior?) or (AB sedentary behavior?)
S46	(TI physical activity or physical inactivity) OR (AB physical activity or physical inactivity)
S45	(MH "Exercise")
S44	S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43
S43	(MH "Eating Behavior")
S42	(TI healthy eating) OR (AB healthy eating)
S41	(TI "responsive feed*") OR (AB "responsive feed*")
S40	(TI "complementary feeding") OR (AB "complementary feeding")
S39	(AB nutrition N2 modif*) or (AB nutrition N2 strateg*) or (AB nutrition N2 intervention*) or (AB nutrition N2 advice) or (AB nutrition N2 program*) or (AB nutrition N2 class*) or (AB nutrition N2 counsel*) or (AB nutrition N2 educat*) or (AB nutrition N2 instruct*) or (AB nutrition N2 teach*) or (AB nutrition N2 train*) or (AB nutrition N2 guidance) or (AB nutrition N2 lesson*) or (AB nutrition N2 workshop*) or (AB nutrition N2 module*) or (AB nutrition N2 consultation*) or (AB nutrition N2 sess ...
S38	(AB diet* N2 modif*) or (AB diet* N2 strateg*) or (AB diet* N2 intervention*) or (AB diet* N2 advice) or (AB diet* N2 program*) or (AB diet* N2 class*) or (AB diet* N2 counsel*) or (AB diet* N2 educat*) or (AB diet* N2 instruct*) or (AB diet* N2 teach*) or (AB diet* N2 train*) or (AB diet* N2 guidance) or (AB diet* N2 lesson*) or (AB diet* N2 workshop*) or (AB diet* N2 module*) or (AB diet* N2 consultation*) or (AB diet* N2 session*)
S37	(TI nutrition N2 modif*) or (TI nutrition N2 strateg*) or (TI nutrition N2 intervention*) or (TI nutrition N2 advice) or (TI nutrition N2 program*) or (TI nutrition N2 class*) or (TI nutrition N2 counsel*) or (TI nutrition N2 educat*) or (TI nutrition N2 instruct*) or (TI nutrition N2 teach*) or (TI nutrition N2 train*) or (TI nutrition N2 guidance) or (TI nutrition N2 lesson*) or (TI nutrition N2 workshop*) or (TI nutrition N2 module*) or (TI nutrition N2 consultation*) or (TI nutrition N2 sess ...
S36	(TI diet* N2 modif*) or (TI diet* N2 strateg*) or (TI diet* N2 intervention*) or (TI diet* N2 advice) or (TI diet* N2 program*) or (TI diet* N2 class*) or (TI diet* N2 counsel*) or (TI diet* N2 educat*) or (TI diet* N2 instruct*) or (TI diet* N2 teach*) or (TI diet* N2 train*) or (TI diet* N2 guidance) or (TI diet* N2 lesson*) or (TI diet* N2 workshop*) or (TI diet* N2 module*) or (TI diet* N2 consultation*) or (TI diet* N2 session*)
S35	(MH "Infant Feeding")
S34	(MH "Infant Food")
S33	(MH "Infant Nutritional Physiology")
S32	(MH "Breast Feeding")
S31	S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30
S30	(TI counselling or counseling) OR (AB counselling or counseling)
S29	(TI peer N2 support) OR (AB peer N2 support)
S28	(TI home visit) OR (AB home visit)
S27	(TI education N2 intervention*) OR (TI education N2 program*) OR (TI education N2 class*) OR (TI education N2 counsel*) OR (TI education N2 teach*) OR (TI education N2 workshop) OR (TI education N2 module*) OR (TI education N2 consultation*) OR (TI education N2 session*) (AB education N2 intervention*) OR (AB education N2 program*) OR (AB education N2 class*) OR (AB education N2 counsel*) OR (AB education N2 teach*) OR (AB education N2 workshop) OR (AB education N2 module*) OR (AB education N2 c ...
S26	(MM "Behavior Modification")
S25	(MM "Behavioral Changes")

S24	(TI behaviour change) OR (AB behaviour change) OR (TI behavior change) OR (AB behavior change)
S23	(MH "Health Promotion")
S22	(MH "Health Education")
S21	(MH "Mother-Child Relations") OR (MH "Mother-Infant Relations")
S20	(MH "Maternal Health Services") OR (MH "Maternal-Child Health")
S19	(MH "Early Childhood Intervention")
S18	(MH "Child Health Services")
S17	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16
S16	(TI waist-hip ratio or waist circumference) OR (AB waist-hip ratio or waist circumference)
S15	(TI skin fold thickness) OR (AB skin fold thickness)
S14	(TI weight change*) OR (AB weight change*)
S13	(TI body weight) OR (AB body weight)
S12	(TI adiposity) OR (AB adiposity)
S11	(TI BMI or body mass index) OR (AB BMI or body mass index)
S10	(TI weight gain) OR (AB weight gain)
S9	(TI overweight or over weight) OR (AB overweight or over weight)
S8	(TI obese or obesity) OR (AB obese or obesity)
S7	(MH "Waist Circumference")
S6	(MH "Waist-Hip Ratio")
S5	(MH "Skinfold Thickness")
S4	(MH "Body Weight")
S3	(MH "Body Mass Index")
S2	(MH "Weight Gain") OR (MH "Body Weight Changes")
S1	(MH "Obesity") OR (MH "Pediatric Obesity")

APA PsycInfo

1	obesity/
2	overweight/
3	Weight Gain/
4	Body mass index/
5	Body weight/
6	obes*.tw.
7	(overweight or over weight or over-weight).tw.
8	weight gain.tw.
9	(BMI or body mass index).tw.
10	adiposity.tw.
11	body weight.tw.
12	weight change\$.tw.
13	skin fold thickness.tw.
14	waist-hip ratio.tw.
15	waist circumference.tw.
16	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
17	Mother-Child Relations/
18	preventive health services/
19	health education/
20	health promotion/

21	((behaviour or behavior) and change).ti,ab.
22	(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.
23	((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.
24	(peer adj2 support).ti,ab.
25	(education* adj1 (intervention* or program* or class* or counsel* or teach* or workshop* or module* or consultation* or session*)).ti,ab.
26	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27	Breast Feeding/
28	((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.
29	((child or toddler or infant\$) adj1 (food or feeding or nutrition\$)).ti,ab.
30	((responsive or complementary) adj1 feeding).ti,ab.
31	healthy eating.ti,ab.
32	Feeding behavior/
33	27 or 28 or 29 or 30 or 31 or 32
34	Exercise/
35	Sedentary Behavior/
36	(physical activity or physical inactivity).ti,ab.
37	sedentary behavio?r.ti,ab.
38	screen time.ti,ab.
39	play.ab,ti.
40	"tummy time".ab,ti.
41	34 or 35 or 36 or 37 or 38 or 39 or 40
42	Sleep/
43	Sleep.ti,ab.
44	42 or 43
45	(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.
46	(pregnan* or perinatal* or prenatal* or antenatal or postnatal*).ti,ab.
47	Parents/
48	(parent\$ or care giver or caregiver or guardian or family or families or mother\$ or father\$ or maternal or paternal).tw.
49	45 or 46 or 47 or 48
50	26 or 33 or 41 or 44
51	16 and 50
52	49 and 51
53	(exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.
54	52 not 53
55	exp experimental design/
56	randomi#ed.ti,ab.
57	randomly.ab.
58	exp clinical trials/
59	trial.ti.
60	exp randomized controlled trial/

61	55 or 56 or 57 or 58 or 60
62	54 and 61
63	limit 62 to yr="2020 - 2021"

WHO ICTRP

Basic search
1. babies AND obesity
2. babies AND obese
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29. toddlers AND obese
30. toddlers AND overweight
31. kids AND obesity
32. kids AND obese
33. kids AND overweight

Clinicaltrials.gov

Advanced search
<u>Condition or disease:</u> overweight OR obesity OR obese OR adiposity OR BMI OR weight gain
<u>Other Terms:</u> baby OR infant OR child OR paediatric OR pediatric OR toddler OR offspring

Supplementary file 3: Eligible randomised controlled trials for the Transforming Obesity Prevention for Children (TOPCHILD) Collaboration

This table shows all trials that we have identified up to March 2021 as being eligible for inclusion in TOPCHILD. Trials marked in **blue** have already agreed to join the Collaboration and share their data and unpublished intervention materials.

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
Australia (Campbell) ¹	ISRCTN81847050 ² (2008)	2008 ³	2013 ¹	2008/2010	542	First-time parent regularly attending first-time parent group	Dietary intake
Australia (Campbell) ⁴	ACTRN12611000386932 ⁵ (2011)	2016 ⁴	na	2011/2020	560	First-time parent groups with children aged 3-4 months	Anthropometry: height, weight, waist circumference, BMI z-score at 18 and 36 months of age
Australia (Daniels) ⁶	ACTRN12608000056392 ⁷ (2008)	2009 ⁸	2013 ⁶	2008/2009	698	First-time mothers of healthy term infants	Food intake, food preferences, and feeding behaviour
Australia (Wen) ⁹	ACTRN12607000168459 ¹⁰ (2007)	2007 ¹¹	2012 ⁹	2007/2010	782	Women expecting their first child, between 24-34 weeks pregnancy	BMI at 2 years of age
Australia (Wen) ¹²	ACTRN12616001470482 ¹³ (2016)	2019 ¹⁴	2020 ¹²	2017/2020	1150	Women in their third trimester	BMI, breastfeeding duration, and timing of introduction of solids
Belarus (Oken/Kramer) ¹⁵	ISRCTN37687716 ¹⁶ (2005) NCT01561612 ¹⁷ (2012)	na	2009 ¹⁵	1996/1998	17,046	Mother-infant pairs consisting of full-term singleton infants weighing at least 2500 g and their healthy mothers who intended to breastfeed	Duration of any breastfeeding, prevalence of predominant & exclusive breastfeeding at 3 & 6 months of life, occurrence of 1 or more episodes of gastrointestinal tract infection, 2 or more episodes of respiratory tract infection, and atopic eczema during the first 12 months of life
Belgium (Verbestel) ¹⁸	na	na	2013 ¹⁸	2009/2009	203	Parents of children aged 9–24 months	BMI z-score, children's lifestyle behaviours
Brazil (Vitolo) ¹⁹	NCT00629629 ²⁰ (2008)	na	2010 ¹⁹	2001/2003	500	Newborn infants with birthweight ≥ 2500 g and gestational age ≥ 37 weeks	Exclusive breastfeeding at 1 year, lipid profile at 7-8 years of age
Brazil (Vitolo) ²¹	NCT00635453 ²² (2008)	na	2019 ²¹	2008/2010	715	Pregnant women in their third trimester	Exclusive breastfeeding at 4 months

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
Canada (Dennis) ²³	ISRCTN13308752 ²⁴ (2019)	2021 ²³	na	2019/2022	5230	Non-pregnant mother with no child or one child between 3-12 months	Proportion of infants with a BMI>85 percentile using World Health Organization growth reference range by sex and measured at 5 years of age
China (Huang) ²⁵	ChiCTR1800017773 ²⁶ (2018)	na	na	2018/2029	4500	Women between 20-42 years of age, planning pregnancy in the next 6 months or <14 weeks pregnant, singleton pregnancy	Obesity and overweight at 5 years of age
China (Xia) ²⁷	NCT04661449 ²⁷ (2020)	na	na	2021/2023	138	Term infants that are large for gestational age	Rate of overweight/obesity at 2 years old and 7 years old
Denmark (Pryds) ²⁸	NCT01235663 ²⁹ (2010)	na	2013 ²⁸	2010/2013	226	Obese mothers and healthy infants born at term (>258 days of gestation), postnatal age > 48h. Women who intended to breastfeed and had participated in the Treatment of Obese Pregnant study (TOP-study)	Breastfeeding, infant anthropometrics at 6 months of age
Denmark (Skovgaard) ³⁰	NCT04601779 ³⁰ (2020)	na	na	2023/2024	1000	Children who have been assessed as having three or more problems at age 9-10 months at assessment	Child mental health at 24 months, social and emotional development at 24 months
Finland (Virtanen) ³¹	NCT01204489 ³¹ (2010)	na	na	2010/2012	148	all families at their child's standard 6-month child welfare clinic visit	Changes in family's dietary choices, knowledge and attitudes at 8 months
France (Parat) ³²	NCT00804765 ³³ (2008)	na	2019 ³²	2008/2013	275	Women at ≤21 gestational weeks with BMI >25 kg/m ²	Excessive infancy weight gain defined as >0.67 change in weight SD score
Guatemala (Acero) ³⁴	NCT03399617 ³⁵ (2018)	2020 ³⁴	na	2018/2021	1500	Women in third trimester or with children up to 3 months of age	Infant and young child feeding practices, height, weight gain rate, haemoglobin, obesity, stunting, anaemia
India (Kumaran) ³⁶	ISRCTN20161479 ³⁷ (2020) CTRI/2020/12/03013 ³⁸	2021 ³⁶	na	2021/2028	6000	Women of reproductive age	Adiposity at 5 years of age

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
	(2020)						
Ireland, UK, Spain, Australia (O'Reilly) ³⁹	ACTRN12620001240932 ³⁹ (2020)	na	na	2021/2024	800	Pregnant women aged 18-50 years at high risk of developing gestational diabetes	Maternal: BMI at 12 months postpartum; Infants: weight, height, head circumference at age 12 months
Italy (Maffei) ⁴⁰	NCT03131284 ⁴¹ (2017)	na	2019 ⁴⁰	2014/2017	562	Healthy full-term newborns	BMI at two years of age
Netherlands (Corpeleijn) ⁴²	NCT01127412 ⁴³ (2010)	na	2014 ⁴²	2006/2010	161	Infants aged up to 2 weeks	Growth (weight, length), body composition (waist circumference, hip circumference, skinfold thickness, bioelectrical impedance analyses) all assessed regularly during the first 2.5 years of life
Netherlands (Karssen) ⁴⁴	NL6727/NTR6938 ⁴⁵ (2017)	2021 ⁴⁴	na	2018/2019	300	Parents with a child aged 7-11 months	BMI at 6 and 12 months
Netherlands (Mesman) ⁴⁶	NCT03348176 ⁴⁷ (2017) NL6397/NTR6572 ⁴⁸ (2017)	2019 ⁴⁶	na	2016/2020	255	First-time mothers of healthy term infants 4 months to 3 years of age	Vegetable intake, vegetable liking, self-regulation of energy intake
Netherlands (Raaij) ⁴⁹	NL1721/NTR1831 ⁵⁰ (2009)	2013 ⁵¹	2017 ⁴⁹	2008/2013	2102	Newborn children and their parents	BMI and energy-balance related behaviours
New Zealand (Taylor) ⁵²	NCT00892983 ⁵³ (2009)	2011 ⁵⁴	2017 ⁵²	2009/2017	802	Women aged over 16 before 34 weeks' gestation. Babies excluded if they are not full-term	Weight at 6, 12 and 24 months of age; BMI at 24 months of age
New Zealand (Taylor) ⁵⁵	ACTRN12612001133820 ⁵⁶ (2012)	2015 ⁵⁷	2017 ⁵⁵	2012/2016	206	Pregnant women aged 16 or over, before 34 weeks' gestation. Babies excluded if they are not full-term	BMI at 12 months
Norway (Helle) ⁵⁸	ISRCTN13601567 ⁵⁹ (2016)	2017 ⁶⁰	2019 ⁵⁸	2015/2021	718	Parent and 5.5-month-old child	Child eating behaviour, child food intake, child mealtime routines, maternal feeding practices
Norway (Øverby) ⁶¹	ISRCTN45864056 ⁶² (2016)	na	2017 ⁶¹	2012/2015	110	Parents and 4-6 month old infant	Food intake when infants are 6, 15 and 24 months of age

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
Norway (Røed) ⁶³	ISRCTN92980420 ⁶⁴ (2017)	2019 ⁶³	2021 ⁶⁵	2015/2022	298	Children close to 12 months and one of their parents	Child diet quality and food variety, assessed at inclusion, 18, 24, and 48 months
South Africa (Norris) ⁶⁶	PACTR201903750173871 ⁶⁶ (2019)	na	na	2019/2021	6000	18-25 year old women preconception and child	Dual-energy X-ray absorptiometry-derived fat mass index of the index-child at age 5 years
Spain (López) ⁶⁷	NCT03444415 ⁶⁷ (2018)	na	na	2015/2018	414	Pregnant women with a gestational age of 12-16 weeks	BMI at 2 years of age
Sweden (Marcus) ⁶⁸	NCT01198847 ⁶⁹ (2010)	2011 ⁶⁸	na	2010/2019	123	At least one obese (BMI ≥ 30) or two overweight (BMI ≥ 25) parents with a one-year-old child	BMI at 6 years of age
Sweden (Rasmussen) ⁷⁰	ISRCTN16991919 ⁷¹ (2013)	2014 ⁷²	2016 ⁷⁰	2008/2015	1039	First-time mothers and their children recruited at child health care centres at 9-10 months of age	BMI and waist circumference of children & their mothers at age 4
UK (Bryant) ⁷³	ISRCTN56735429 ⁷⁴ (2013)	na	2016 ⁷³	2012/2012	120	Overweight/obese pregnant women (BMI ≥ 25) at 10–12 weeks' gestation and infants from birth	Child's weight
UK (Bryant) ⁷⁵	NCT03333733 ⁷⁶ (2017)	2018 ⁷⁷	2021 ⁷⁵	2017/2019	115	Parents and at least 1 child aged 6 months - 5 years	Feasibility, child BMI z-score
UK (Lakshman) ⁷⁸	ISRCTN20814693 ⁷⁹ (2011)	2015 ⁸⁰	2018 ⁷⁸	2011/2015	669	Parents (mainly mothers) and their babies (aged 2 to 14 weeks) who are formula-fed	The change in infant weight standard deviation score from birth to age 12 months
USA (Barlow) ⁸¹	NCT03101943 ⁸² (2017)	na	2020 ⁸¹	2017/2019	134	Mothers aged ≥ 13 years, their infant aged < 14 weeks, self-reported Native American	Infant consumption of sugar-sweetened beverages, change in complementary feeding and responsive parenting practices
USA (Barlow) ⁸³	NCT03334266 ⁸⁴ (2017)	2019 ⁸³	na	2017/2021	338	Expectant Native American mothers aged 14-24 who are having their first or second baby	Percentage of parents who meet breastfeeding and complementary feeding recommendations, child feeding styles, fruit & vegetable intake, physical activity levels, screen time, BMI

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
USA (Beck) ⁸⁵	NCT02257203 ⁸⁶ (2014)	na	2017 ⁸⁵	2014/2015	82	Parents self-identify as Latino and have a child between the ages of 6 months and 5 years	Proportion of parents reporting that their child had consumed a sugar-sweetened beverage on the day prior at a 2-week follow up
USA (Beck) ⁸⁷	NCT03438721 ⁸⁷ (2018)	na	na	2018/2021	240	Parents who self-identify as Latino and their newborn infants	Child dietary intake and screen time, parent health-related quality of life
USA (Birch/Paul) ⁸⁸	NCT00359242 ⁸⁹ (2006)	na	2011 ⁸⁸	2006/2009	160	Mother-newborn dyads, primiparous, singleton, gestational age ≥ 34 weeks	Weight-for-length percentile at age 1 year
USA (Bonuck) ⁹⁰	NCT00756626 ⁹¹ (2008)	na	2014 ⁹⁰	2008/2011	300	Children 11-13 months old consuming >2 bottles of milk or juice per day	Bottle use frequency
USA (Caballero) ⁹²	na	na	2015 ⁹²	na/na	292	Healthy newborns with ≥ 2000g body weight	Anthropometry (weight, height, triceps, and subscapular skinfolds), child feeding practices and dietary assessment
USA (Puerto Rico) (Campos) ⁹³	NCT03517891 ⁹⁴ (2018)	2020 ⁹³	na	2018/2022	480	Low-income women in third trimester, intend to participate in the Special Nutrition Women, Infants & Children Program; infants included from birth	Adequate weight gain during the first year (gender adjusted Z score).
USA (Clouiter) ⁹⁵	NCT02052518 ⁹⁶ (2014)	2015 ⁹⁷	2018 ⁹⁵	2013/2016	57	Mother/newborn dyads in low-income neighbourhoods	Breastfeeding, Infant weight-for-length, BMI, introduction of solids and juice/sugar-sweetened beverages
USA (de la Haye) ⁹⁸	na	na	2019 ⁹⁸	na	50	Mother-infant dyads receiving home visiting program (HVP)	Feasibility, mother BMI, infant weight-for-length z-score, mother and infant diet, mother physical activity
USA (de la Haye & Salvy) ⁹⁹	NCT03529695 ¹⁰⁰ (2018)	2019 ⁹⁹	na	2018/2022	300	Mother-child dyads enrolled in home visitation programs; Infants aged between birth to 24 months	Weight of mothers, rate of weight gain of infants, waist circumference of mother

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
USA (Fiks) ¹⁰¹	NCT02037490 ¹⁰² (2014)	na	2017 ¹⁰¹	2014/2015	87	Pregnant women, Medicaid insured, BMI ≥ 25	Feasibility
USA (Gesell) ¹⁰³	NCT01081340 ¹⁰³ (2010)	na	na	2010/2011	41	Latina women who are less than 24 weeks pregnant, have not carried a pregnancy to term, have not had a termination of a previous pregnancy prior to 20 weeks	Gestational weight gain and postpartum weight loss
USA (Goran) ¹⁰⁴	NCT03141346 ¹⁰⁴ (2017)	na	na	2017/2022	240	Latina mothers who are habitual consumers of sugar sweetened beverages/juices and singleton infants less than one month	infant length, maternal height, maternal weight, maternal BMI, infant weight, infant weight z-scores, infant body composition (body fat, lean mass, total body water, free body water) at 6, 12 and 24 months
USA (Groner) ¹⁰⁵	NCT01565525 ¹⁰⁶ (2012)	2009 ¹⁰⁷	2012 ¹⁰⁵	2005/2007	292	Mother-infant dyads were enrolled at their first well-child visit to 3 urban paediatric clinics	Infant weight for height
USA (Hodges) ¹⁰⁸	NCT04502979 ¹⁰⁸ (2020)	na	na	2017/2019	71	Parents must be able to read and write English or Spanish and infants must be at least 3 months of age at time of recruitment	Infant weight for length z-score at 6 months
USA (Horodyski) ¹⁰⁹	ACTRN12610000415000 ¹¹⁰ (2010)	2011 ¹¹¹	2017 ¹⁰⁹	2010/2013	547	Economically and educationally disadvantaged African American, Hispanic, and Caucasian mothers with infant ≤4 months of age	Maternal responsiveness, maternal feeding style, maternal feeding practices, infant growth pattern at 6 and 12 months of age
USA (Horodyski) ¹¹²	NCT02244424 ¹¹³ (2014)	2015 ¹¹²	na	2014/2016	164	Low-income adolescent (aged 14-19 years), first-time mothers of infants ≤2 months of age	Maternal responsiveness, maternal feeding style, maternal feeding practices, infant weight
USA (Puerto Rico) (Joshipura) ¹¹⁴	NCT01771133 ¹¹⁵ (2013)	na	2019 ¹¹⁴	2013/2015	31	Overweight/obese women with a singleton pregnancy <16 weeks' gestation and their infant from birth	Gestational weight gain

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
USA (Karasz) ¹¹⁶	NCT03077425 ¹¹⁷ (2017)	2018 ¹¹⁶	na	2017/2021	360	Mother-child dyads where child is <6 months old	Number and amount of sippy cups and bottles per day consumed by child
USA (Lavner) ¹¹⁸	NCT03505203 ¹¹⁹ (2018)	2019 ¹¹⁸	na	2018/2021	300	First-time African American mothers and their full-term infants	Change in infants' weight for age from 3 weeks to 16 weeks
USA (Linares) ¹²⁰	NCT03903146 ¹²¹ (2019)	na	2019 ¹²⁰	2016/2018	39	Hispanic pregnant women who intended to breastfeed and their baby	Exclusive breastfeeding from birth to 6 months old
USA (Messito) ¹²²	NCT01541761 ¹²³ (2012)	na	2016 ¹²²	2012/2020	533	Pregnant women with a singleton uncomplicated pregnancy	Infant feeding practices and material infant feeding knowledge
USA (Puerto Rico, Hawaii) (Palacios) ¹²⁴	NCT02903186 ¹²⁵ (2016)	2017 ¹²⁶	2018 ¹²⁴	2016/2016	202	Caregivers of healthy term infants 0-2 months participating in the Women, Infants and Children Program	Infant weight-for-length percentile
USA (Paul) ¹²⁷	NCT00125580 ¹²⁷ (2005)	na	na	2005/2006	40	Infant at ≥37 weeks' gestation, primiparous mother, singleton, breast or bottle-fed, birth weight ≥2500g	The rate of sleeping through the night at 8 weeks of age
USA (Paul) ¹²⁸	NCT01167270 ¹²⁹ (2010) NCT03555331 ¹³⁰ (2018)	2014 ¹³¹	2018 ¹²⁸	2012/2023	316	Full term singleton infants born to primiparous mothers	BMI z-score at age 3 years
USA (Reifsnider) ¹³²	NCT01905072 ¹³³ (2013)	2013 ¹³⁴	2018 ¹³²	2012/2017	177	Mexican American mother, pre-pregnant BMI ≥25, aged 18-40 years; Singleton infants, >38 weeks' gestational age, birthweight > 2500g	Child weight-for-length BMI at 3 years
USA (Rothman & Perrin) ¹³⁵	NCT01040897 ¹³⁶ (2009)	na	2021 ¹³⁵	2010/2014	865	Child presenting for 2 month well-child check-up (between 6-16 weeks of age) with an intervention-trained resident physician, caregiver able to speak Spanish or English	Percent of children overweight or obese at 2 years

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
USA (Dutton & Salvy) ¹³⁷	NCT03433456 ¹³⁸ (2018)	2018 ¹³⁷	na	2018/2022	596	Mother or caregiver and 0-4 year old child	Change in mother and infants' body weight from baseline to follow-up at 12 and 24 months
USA (Savage) ¹³⁹	NCT03482908 ¹⁴⁰ (2018)	2018 ¹³⁹	na	2016/2019	289	Mother and infant <2 months, birthweight ≥ 2500g and gestational age ≥ 37 weeks	Sex-specific z-scores for infant growth measures at birth, and at 2, 5 and 7 months after birth; Sex-specific z-scores for infant rapid weight gain from birth to 6 months
USA (Stephens) ¹⁴¹	NCT03249324 ¹⁴² (2017)	2015 ¹⁴¹	na	2014/2017	58	Mothers 18-35 years of age who are eligible for care within the Military Health System; Infants from birth	Maternal weight gain
USA (Stough) ¹⁴³	NCT03597061 ¹⁴³ (2018)	na	na	2018/2020	34	Parent and infant born > 38 weeks' gestation, above 10 th percentile of length-for-weight, aged 2-3 months	Weight-for-Length percentile, appetite regulation, fruit and vegetable variety at 3 and 9 months of age
USA (Taveras) ¹⁴⁴	NCT04477577 ¹⁴⁵ (2020)	2021 ¹⁴⁴	na	2020/2022	500	Parental dyads planned involvement for first year of life, singleton pregnancy, first child for both parents, lives within 25km radius of Boston, and planning to receive post-partum and pediatric care for child at any pediatric practice within the MassGeneral Brigham (Partners) Healthcare system	Weight-for-Length z-score at 6 and 12 months, Weight-for-Length ≥ 97.7 percentile at 12 months, and Weight-for-Length ≥ 95 percentile at 12 months
USA (Thomas) ¹⁴⁶	NCT03601299 ¹⁴⁶ (2018)	na	na	2018/2022	804	Children 0-5 years of age	BMI, traditional food content
USA (Thomson) ¹⁴⁷	NCT01746394 ¹⁴⁸ (2012)	2014 ¹⁴⁹	2018 ¹⁴⁷	2013/2016	82	Pregnant women at least 18 years of age, < 19 weeks pregnant and their infant from birth	Maternal: weight gain at 9 months' gestation, weight retention at 12 months postpartum, dietary intake, physical activity; Infant: dietary

Trial Country/ies (PI)	Registration number (registration year)	Protocol publication year	Main results publication year	Start year/ completion year	Sample size	Participants	Primary outcome/s
							intake, activity, BMI at age 12 months
USA (Virudachalam) ¹⁵⁰	NCT01710423 ¹⁵⁰ (2012)	na	na	2012/2013	47	Families with children ages 0 to 3	Change in healthfulness of the diet
USA (Wasser) ¹⁵¹	NCT01938118 ¹⁵² (2013)	2017 ¹⁵³	2020 ¹⁵¹	2013/2017	430	Non-Hispanic black mothers enrolled at 28 weeks' pregnancy and infants from birth to 15 months postpartum	Infants' mean weight-for-length z-score at 15 months of age
USA (Widen) ¹⁵⁴	NCT04177472 ¹⁵⁴ (2019)	na	na	2019/2023	150	Mothers and assisting caregivers with babies 4-5 months of age	BMI percentile at 12 months of age

na = not available, BMI = body mass index

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