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Supplementary appendix

Parent-focused behavioural interventions for the prevention of early childhood obesity: results of the TOPCHILD systematic review and individual participant data meta-analysis

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ALS, KEH, BJJ, RKG, LA, RWT, PMC, LAB, KDH, LMW, AJH, VB acquired funding. KEH, ALS, DN wrote the original draft. KEH, DN, SL, JGW, MA, JA, BJJ, AB, JXS, NS, TP, SP, ALS were part of the project team responsible for formal analysis, investigation, data curation, revising the initial manuscript, preparing data and figures, project administration. Only KEH, DN, SL, JGW, MA, JA, BJJ, AB, JXS, NS, TP, ALS were located at or affiliated to, the data management centre (National Health and Medical Research Council Clinical Trials Centre, Australia) and had access to all raw individual participant data because data sharing agreements with participating trials and our ethics approval required data to be securely hosted locally. KEH, DN, SL, JGW, ALS accessed and verified the data. All members of the project team were independent from all trials. KEH, DN, SL, JGW, JA, BJJ, RG, LAB, ALS were members of the TOPCHILD Steering Group, which provided supervision for all the mentioned activities, conceptualisation, and methodology. LW, RWT, VB, CTW, ST, HSY, AJH, DAO, WS, DeE, LA, PMC, CR, ACW, PJG were members of the TOPCHILD Advisory Group which contributed to conceptualisation, and methodology. KDH, MB, JLT, RL, AGF, CH, COS, KKO, LK, JKL, AML, MM, LMW, EO, NØ, CP, IMP, EMP, FER, ER, RLR, RAB, TMR, SJS, HMW, ALT, AG, BJT, CM, HX, JSS, KJJ, KdlH, MR, BC, NG, RSG, SAF, JB were TOPCHILD trial investigators and provided data and resources, were involved in data curation for their trial and were invited to review and contribute to methodology, and results from formal analysis and visualisation. All authors were invited to virtual meetings held throughout the project to receive updates and provide input. All authors have responsibility for the final decision to submit the manuscript for publication and contributed to the writing and revision of this report.

Collaborator conflicts of interest

TOPCHILD trial representatives comprised lead investigators of trials included in this meta-analysis. Trial representatives did not have input on study eligibility, data integrity assessments, data extraction, or risk of bias assessments for their own studies. Trial representatives did not make final decisions on certainty of evidence ratings. Trials did not provide any funding for the study but did contribute time. Funding for included trials has been disclosed as individually required. KEH declares support for the current study as an investigator from NHMRC (GNT1186363, GNT2006999), had travel supported by EPOCH-Translate CRE (2023, 2024). RKG declares support for the current study as an investigator from NHMRC (GNT1186363, GNT2006999, GNT1101675, and for BJJ salary support). LAB and LMW declare grant funding from NHMRC (GNT393112, GNT1003780) and Centre for Research Excellence (GNT1101675, GNT2006999). JXS is supported by a NHMRC Postgraduate Research Scholarship. LW declares salary support from NHMRC Investigator Grant Scheme. RWT declares salary support from the Karitane Products Society. PJG is supported by the UK Medical

Research Council (MC_UU_00004/06). LMS declares funding for their included trial 'Greenlight' from Patient-Cantered Outcomes Research Institute. KPR declares they are supported by the NHMRC (investigator grant 2025-2029). VB declares support for the current study as an investigator from NHMRC (GNT2006999). AJH declares payments to their institution from NHMRC (GNT1186363). KDH declares grant funding from NHMRC (GNT425801 and GNT1008879), and Future Leader Fellowship funding from Heart Foundation Australia (105929). LA declares support for the current study as an investigator from NHMRC (GNT1186363, GNT2006999). MB declares salary support as the PI of their included trial 'HENRY' from NIHR, has a role as member of the Board of Trustees, UK Association for the Study of Obesity (Chair 2019 – 2022). AGF declares grants or contracts from NIH, PCORI, AHRQ, received consulting fees from UCLA, Rutgers, PCORI, Duke University, was paid for presentations by Emory University, had travel supported by NIH, PCORI, participated on DSMB for NIH trials, has a role in the American Academy of Pediatrics, declares funding for their included trial from University Research Council faculty grant at the University of Cincinnati. KKO declares programme funding from the UK Medical Research Council (MC_UU_00006/2), has a role as Chair of the Maternal and Child Nutrition Subgroup of the UK Scientific Advisory Committee on Nutrition. LK declares they were supported by the Behavioural Science Institute, Radboud University. JKL declares salary and included trial support from Fonds NutsOhra (100.939). AML declares funding for their included trial from NIH (UL1TR000117 and UL1TR001998). MJM declares support for their included trial from USDA NIFA (2011-68001-30207 and 2017-68001-26350). IMP declares that payment to support their time was received from NIDDK (R01DK088244), received consulting fees from Danone North America. ER declares they are the recipient of a grant from NIH, has a role as President of the Southern Nursing Research Society. RLR declares funding for their trials 'Greenlight' from NIH and 'Greenlight Plus' from PCORI, declares they have received grants or contracts from AHRQ, PCORI, NIH, CDC, Cardiohealth Alliance. TMR declares funding for their included trial 'THRIVE' from NIDDK (T32 DK063929), declares they have received grants or contracts from NIDDK (R01DK135497), Cincinnati Children's Hospital Medical Center. HMW declares funding for their included trial 'Mothers and Others' from NICHD (R01HD073237), declares their time was funded by NIDDK (K01DK111793). ALT declares funding for their included trial 'Mothers and Others' from NICHD (R01HD073237). HX declares support for trial 'Healthy Beginnings' involvement was provided by SLHD. KJJ declares salary support as the PI of their included trial from NIH. KdlH declares funding for their involvement from NICHD (1R01HD092483). BC declares funding for their included trial 'HENRY III' from NIHR (NIHR135081). RSG declares support and has received funding from NIH, USDA. JB declares funding and travel support from Hawaii Community Foundation, USDA, Kellog Foundation, received payments for presentations through various organisations. ALS declares support for the current study as an investigator from NHMRC (GNT1186363, GNT1101675, GNT2006999, GNT2009432). All other authors have no competing interests.

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Consumers providing input into protocol

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B: Statistical Analysis Plan

Transforming Obesity Prevention for CHILDren

Transforming **O**besity **P**revention for **CHILD**ren (TOPCHILD) Collaboration: systematic review with individual participant data meta-analysis of behavioural interventions for the prevention of early childhood obesity

Statistical Analysis Plan

FINAL

9th February 2024

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Contents

List of abbreviations

Abbreviation	Definition
AD	Aggregate data
BMI	Body mass index
CCA	Complete case analysis
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
EDNP	Energy dense nutrient poor
FCS	Fully conditional specification
FFQ	Food frequency questionnaire
GLMM	Generalised linear mixed model
ICH-E9	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E9 Statistical Principles
ICTRP	International Clinical Trials Registry Platform
ID	Identification
IPD	Individual participant data
IQR	Interquartile range
IRB	Institutional review board
MAR	Missing at random
MICE	Multiple imputation by chained equations
ML	Maximum Likelihood
N/A	Not applicable
NHMRC	National Health and Medical Research Council
OR	Odds ratio
ORCiD	Open Researcher and Contributor iD
PMA	Prospective meta-analysis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
REML	Residual Maximum Likelihood
ROB	Risk of bias
SAP	Statistical analysis plan

SD	Standard deviation
SSB	Sugar sweetened beverages
TOPCHILD	Transforming Obesity Prevention for CHILDren
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

1 Administrative information

1.1 Study identifiers

- Protocol: version 3.0, 9 February 2024
- International Prospective Register of Systematic Reviews (PROSPERO) number: CRD42020177408
- Ethics approval:
    - The University of Human Research Ethics Committee (2020/273)
    - Flinders University Social and Behavioural Research Ethics Committee (HREC CIA2133-1)
- Funding:
    - Australian National Health and Medical Research Council Ideas Grant: APP1186363

1.2 Revision History

Version	Date	Changes made to document	Authors
1.0	10/11/2023	Draft document completed	Kylie Hunter, Lene Seidler, Mason Aberoumand, Sol Libesman, Angie Barba, Brittany Johnson
2.0	20/12/2023	Feedback from TOPCHILD Advisory Group incorporated	Kylie Hunter, Lene Seidler, Brittany Johnson, Sol Libesman, Mason Aberoumand
3.0	09/02/2024	Feedback from TOPCHILD trial representatives incorporated	Kylie Hunter, Lene Seidler, Brittany Johnson

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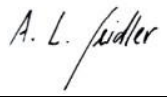
1.3.2 Approvals

The undersigned have reviewed this plan and approve it as final. They find it to be consistent with the requirements of the protocol as it applies to their respective areas. They also find it to be compliant with ICH-E9 principles and, in particular, confirm that this analysis plan was developed in a completely blinded manner (i.e. without knowledge of the effect of the intervention(s) being assessed).

Anna Lene Seidler		9th February, 2024
Kylie Hunter		9th February, 2024
Brittany Johnson		9th February, 2024

2 Introduction and overview

2.1 Study overview

2.1.1 Study design

We will conduct a systematic review with IPD meta-analysis and a nested PMA according to the methods recommended by the Cochrane Collaboration.[1 2] A nested PMA enables integration of prospective evidence into a retrospective meta-analysis, and harmonisation among planned/ongoing studies.[2] Lead investigators of eligible trials will be invited to share their IPD and join the TOPCHILD Collaboration (www.topchildcollaboration.org). The TOPCHILD Collaboration includes a complementary project examining intervention components.[3]

2.1.2 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 body mass index (BMI) z-score at 24 months (±6 months) of age? (primary outcome),
    b. child BMI z-score at 12 months (±3 months) of age, 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 (e.g., maternal BMI, maternal age, parity/first time parent and measures of socio-economic position)?
3. Do intervention effects vary across intervention/trial-level characteristics (e.g., location, intervention mode of delivery, timing of intervention commencement)?

All outcome measures, subgroups (including individual and intervention/trial-level characteristics) and covariates are defined in detail in sections 3.3.3 – 3.3.5.

2.1.3 Inclusion criteria

Types of studies

This systematic review will include RCTs only, including feasibility, pilot and definitive trials. Randomisation may occur at the individual level or by cluster (e.g., childcare, 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 people) and their infant(s) aged 0–12 months (at baseline) or at birth for interventions starting antenatally. Caregiver is defined as the person with primary responsibility for care of the child, and excludes secondary sources of support, such as childcare providers and early childhood teachers. People giving birth 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 (e.g., 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.[4] 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 (e.g., 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 how their data will be incorporated if applicable. 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 (e.g. child safety education).

Types of outcome measures

To be included, trials must collect at least one of the following child weight-related outcomes post intervention (at any age): BMI/BMI z-score, prevalence of overweight/obesity, per cent fat content/adiposity, skinfold thickness, abdominal circumference, waist-to-height (or waist-to-length) ratio. This is considered a legitimate and pragmatic approach given our review is of multicomponent public health interventions focusing on obesity.[5]

Unpublished eligible trials for which no data are available

For unpublished trials that have been identified as eligible for TOPCHILD (primarily via searches of trial registers), and for which no data are available, we will conduct additional checks to determine whether the study ever proceeded or there are plans to proceed. For example, we will review the study status and currency of registration records, look for evidence of ethics approval or funding, and attempt to contact trial investigators for confirmation. If there is insufficient evidence that a study proceeded and generated results, we will assume the study never went ahead, and record this in our PRISMA diagram.

Summary of eligible studies

As of 7th February 2023, we have identified 63 completed studies (with >37,000 participants) that are eligible for inclusion in the first cycle of TOPCHILD. Of those, 34 (with a total of 30,365 participants) have already provided data. We have identified an additional 28 planned or ongoing studies that are eligible for the nested PMA in future cycles of TOPCHILD. Of these, 15 studies (adding a further 8,954 participants) have pledged to contribute data and materials upon completion.

2.1.4 Governance structure

The TOPCHILD Collaboration's governance structure is shown in Figure 1 as of 7 February 2024. The below sections are taken from the collaboration governance plan.

Figure 1. Governance structure of the TOPCHILD Collaboration

TOPCHILD Steering Group

The Steering Group comprises the chair (Anna Lene Seidler) and deputy chairs (Kylie Hunter and Brittany Johnson)—who lead the day-to-day research activities involved in the collaboration, and are each responsible for leading a component of the TOPCHILD project. It also includes three senior researchers (Rebecca Golley, Lisa Askie, Louise Baur) who provide expertise and advice on a regular basis, the data/coding managers (Sol Libesman, Mason Aberoumand, Nipun Shrestha, Samantha Pryde) and project managers (Angie Barba, Jonathan Williams, Jannik Aagerup), who are responsible for managing the individual participant data sets, intervention coding and communication with the Trial Representatives, respectively. Steering Group members will be responsible for promoting and advocating for the TOPCHILD Collaboration. The Steering Group meets fortnightly, until completion of the first cycle of analysis, when meeting frequency may be revised.

TOPCHILD Advisory Group

The Advisory Group is comprised of experts identified to bring unique skills to the Collaboration and two consumer representatives (Figure 1). The Advisory Group provides expert guidance and strategic oversight through regular advisory group meetings (held every two months or as needed) and through answering questions based on area of expertise. Advisory Group members are also responsible for promoting and advocating for the TOPCHILD Collaboration. This may include sharing information and links to the TOPCHILD website through email signatures, research profiles, slides in presentations, speaking to colleagues about the Collaboration and more.

TOPCHILD Trial Representatives

The Trial Representatives are the individuals who are nominated to represent each trial that has joined the TOPCHILD collaboration. The primary function of the Trial Representatives is to

ensure their trial is appropriately represented in the TOPCHILD Collaboration. Trial Representatives share their de-identified individual participant data with the TOPCHILD data management team, but they remain the custodians of their own data, which are de-identified before being shared with the TOPCHILD Collaboration data management team. Data are transferred and stored securely in accordance with the University of Sydney Data Management policies and ethics approval. Trial representatives are also asked to share their unpublished intervention materials, which are kept strictly confidential and are only accessible to members of the research team responsible for deconstructing the interventions. Trial Representatives have the opportunity to contribute their expert knowledge to the TOPCHILD Collaboration, including the protocols, statistical analysis plans and final manuscripts. There will usually be only one Representative per trial, but in certain instances two Representatives are permissible. Trial Representatives that are too busy to give much input are not required to do so, this is an opportunity not a requirement. Meetings with the Trial Representatives occur annually in the first instance and are usually online (with two options provided to accommodate for time zones), with additional face-to-face meetings held before, during or after relevant conferences where possible.

2.2 General principles for the statistical analysis plan

2.2.1 Data processing, cleaning and analysis principles

This statistical analysis plan applies to all studies eligible for inclusion in TOPCHILD, including all trials that have contributed individual participant data and those for which aggregate data can be extracted from publications. The analyses will be completed using the free statistical software R version 4 and results will be reported using the PRISMA IPD extension.[6]

The data processing and cleaning approach involves re-coding by one data officer, checking of recoding by a second data officer, cleaning by one data officer, checking of cleaning by a second data officer, duplicate independent data integrity checks, and clarifying any issues with trial

representatives, prior to integration with the complete TOPCHILD dataset. Details of these processes can be found in sections 2.1 and 2.2.

Unless explicitly stated otherwise, the analysis of outcomes encompasses all infants evaluated for a specific outcome. Infants who are confirmed not to have undergone assessment for a particular outcome, and thus have missing data, will be excluded from the analysis.

Unless otherwise specified, analysis of outcomes includes all infants that are assessed for that particular outcome. Infants who are known not to have undergone assessment for an outcome, and therefore have missing data, will not be included in the analysis. If it is not known if the data are missing or simply not available, then that data are included if it is considered pragmatic to do so. Where possible, an intention-to-treat analysis will be completed using data from all randomised infants including data from those excluded post-randomisation. If there are insufficient data for a particular outcome, then the outcome will not be analysed. For the first cycle of analysis, outcomes and covariates/subgroups that are not able to be analysed due to insufficient data have been documented in Appendix A. Further detailed definitions of outcomes can be found in Section 3.3.3.

2.2.2 Future cycles of analysis

Future cycles of analysis will be considered biennially. If sufficient funding is available, the Steering Group, in consultation with the Advisory Group, will decide whether to conduct additional analyses based on the currency of the completed analysis, potential importance and impact of the update, and need for the update. These will be assessed using the framework described by Garner at al.[7] A nested prospective meta-analysis will be performed for future cycles.[2] Future analyses answering additional research questions with the TOPCHILD dataset are possible if trial investigators approve.

2.3 Changes from protocol

The protocol was published in January 2022,[8] with this statistical analysis plan being finalised in February 2024. We have made a few pragmatic decisions that deviate from the original protocol based on knowledge about variable availability in the included trials or new best-practice methods, with all decisions made prior to analysis (a priori).

2.3.1 Changes to analysis

Inclusion of aggregate data

The protocol had previously stated that aggregate data will be included for the primary analysis where IPD are unavailable. Due to concerns raised on possible issues with data integrity for aggregate data and the potential for systematic differences between the IPD and aggregate data,[9] [10] we plan to investigate any potential bias in the non-available data (see section 4.3 for details on prespecified decision criteria). This might result in exclusion of aggregate data from the primary analysis. This change was made after consultation with the TOPCHILD Steering Group and additional external statisticians, but prior to any analyses.

Meta-analysis

After consultation with TOPCHILD Advisors and additional external statisticians, the following change has been made:

> The protocol had previously stated that the primary analysis would use a one-stage approach combining all available IPD and aggregate data where available. Now, we will plan for two possible scenarios for the analysis instead:
>
> ○ Scenario 1 – a two-stage approach combining both IPD and aggregate data (AD) ○ Scenario 2 – a one-stage approach using IPD only.

The decision to use the aggregate data is as described in section 4.3, with further details on these scenarios available in section 4.4.

For scenario 1, we will be calculating 2-stage models to combine IPD and AD, since a 1 stage model with hierarchical related regression (originally proposed for this analysis) does not allow adjustment for continuous covariates, and complicates imputation for missing data. In the first stage, a generalised mixed effects model (GLMM) will be employed (rather than generalised estimating equations (GEE) as stated in protocol) with a nested random effect within each trial to take into account the correlation between outcomes resulting from cluster randomisation.

2.3.2 Changes to secondary outcomes

The protocol listed several secondary outcomes. We have since decided to select some key secondary outcomes (one per domain) to aid interpretation. Further details are available in section

3.3.2.

Abdominal circumference

The protocol had previously stated that we may assess abdominal circumference as another weightrelated measure. However, based on expert advice about clinical relevance and data availability, we have decided to assess waist circumference instead. This change has been made prior to any analyses.

2.3.3 Changes to subgroups/covariates

The protocol listed several proposed subgroups and covariates. This list has since been refined based on advisor feedback. For detailed definitions of all subgroups and covariates please see sections 3.4 and 3.5.

3 Methods

3.1 Data collection, processing, and cleaning

We will request individual participant data (IPD) for all eligible trials. Trial representatives may provide IPD in TOPCHILD format (Appendix B: Data coding form), or as raw data to be re-coded into TOPCHILD format by the TOPCHILD data management team. For studies where IPD are unavailable, aggregate data will be extracted and included, as outlined in section 3.3.

IPD received from each trial will be processed as follows:

For data that are not supplied in TOPCHILD format:

1. Data recoded into TOPCHILD format by one coder
2. Data recoding checked by a second coder
3. Re-coding cross-checked between coders, and discrepancies resolved, where possible
4. Remaining queries clarified with TOPCHILD data management team, Trial Representatives and/or TOPCHILD Steering Group, as needed

For all IPD datasets:

1. Data cleaned by one data officer: all available variables checked against published results and plausible ranges (refer to Table 1 for data cleaning checks, and Appendix C for specific validation/logic rules)
2. Cleaning checked by a second data officer
3. Integrity and risk of bias (ROB) checks[11] undertaken by one data officer (see section 3.2 for integrity checks)
4. Integrity and ROB checked by a second data officer
5. Any issues resolved within TOPCHILD data management team, where possible 6. Remaining queries clarified with Trial Representatives and/or TOPCHILD Steering Group.
7. Final trial dataset for TOPCHILD analysis produced
8. Trial datasets merged into one combined TOPCHILD dataset

It is expected that most issues identified will be simple data transcription errors that can easily be resolved with trial representatives. However, if trial representatives do not respond to queries, or their responses are unsatisfactory to address the issue(s), the TOPCHILD data management team in consultation with the TOPCHILD Steering Group will determine whether to set a particular value to missing or to exclude a study until further information becomes available.

This extensive process ensures high-quality datasets.

Table 1. Individual participant data cleaning checks and actions if issues are identified

Item	Checks & methods	Issues / action
Consistency cross-checks between IPD and associated publications +/- registration records *(including appendices, supplemental materials and other available attachments)*		
Recruitment dates	• Conduct manual check for inconsistencies in: - date of first participant enrolment; and/or - date of last participant enrolment	• Contact trial representatives* for clarification if: - inconsistencies in recruitment dates are identified
Study setting/ location	• Conduct manual check for inconsistencies in: - country/ies in which study was conducted	• Contact trial investigators* for clarification if: - inconsistencies in study locations are identified
Eligibility criteria	• Conduct manual check for inconsistencies in: - IPD provided and eligibility criteria specified in publication(s) and/or registration record(s)	• Contact trial representatives* for clarification if: - inconsistencies are identified between IPD and eligibility criteria
Baseline characteristics	• Conduct manual check for inconsistencies in: - distribution of baseline characteristics between IPD and publication(s)	• Contact trial representatives* for clarification if: - inconsistencies are identified in the distribution of baseline characteristics between publication and IPD
Sample size	• Conduct manual check for inconsistencies in: - participant numbers overall - participant numbers per group In particular, check CONSORT flow diagram and tables in publication(s), where available	• Contact trial representatives* for clarification if: - inconsistencies are identified between CONSORT diagram, publication text/tables, and IPD, which cannot be explained by post-randomisation exclusions or loss to follow-up
Outcomes collected	• Conduct manual check for TOPCHILD relevant variables that were: - reported in publication(s) or listed in registration record, but for which IPD were not provided (in particular, check any available publication appendices and/or supplementary materials)	• Contact trial representatives* to request additional data or provide clarification if: - there are TOPCHILD relevant variables reported in publication(s) or listed in registration record, for which IPD were not provided
Outcome data	• For each outcome, use IPD to calculate appropriate summary statistics, e.g. median (IQR), mean (SD), and compare against publication(s)	• Contact trial representatives* for clarification if: - inconsistencies are identified in outcome results that cannot be reasonably explained (e.g. due to rounding)
Randomisation & baseline characteristics *Use IPD to complete each check in this section*		
Sequence generation	• Check for randomness of sequence generation using: - appropriate statistical tests (e.g. runs test or tests within the R package 'randtests') - visual inspection for obvious nonrandom allocation patterns, e.g. alternating allocation (A,B,A,B,A,B) or	• If non-random allocation patterns are identified: - consider whether minimisation, blocked or cluster randomisation methods may reasonably explain the pattern - check registration records, publications and/or contact trial representatives* for clarification of sequence generation and allocation concealment methods

Item	Checks & methods	Issues / action
	grouped allocation (A,A,A,A,A,A,B,B,B,B,B,B,B)	• If the methods described are not random, and/or there is strong evidence of nonrandomness without justifiable reason, study should be excluded from TOPCHILD due to incorrect study design
Baseline characteristics	• Check for imbalances in baseline characteristics between groups	• Contact trial representatives* for clarification if: - baseline characteristics (particularly prognostic factors) are excessively different between groups beyond what is expected by chance • If randomisation methods are adequate, include study in TOPCHILD but account for potential biases arising from baseline imbalances • If randomisation methods are inadequate and there are significant baseline imbalances, study should be excluded from TOPCHILD due to incorrect study design
Data Pattern *Use IPD to complete each check in this section*		
Variable distributions	• Check distributions of continuous and categorical variables, e.g. using descriptive statistics, frequency histograms • Cross-check dependant or correlated variables, e.g. using cross-tabulation, scatter plots	• Contact trial representatives* for clarification if: - values are unlikely to have arisen by chance - illogical values are identified
Outliers	• Check for outliers using graphical methods (e.g. boxplot) and descriptive statistics	• If any outliers are identified: - discuss among TOPCHILD data management team and/or TOPCHILD Steering Group to determine whether values are clinically feasible - compare against reference values, where available (e.g. from dietary guidelines) - contact trial representatives* to check for potential data entry errors
Missing data *Use IPD to complete each check in this section*		
Missing data	• Inspect data for missing participant IDs (if sequential)	• Contact trial representatives* for clarification if: - missing data cannot be accounted for - there are highly unusual numbers and types of participants with missing values and imbalances across groups • Check that data have been provided for all randomised participants

Dates *Use IPD to complete each check in this section*

Item	Checks & methods	Issues / action
Order of dates	• Check that dates occur in a logical order and are feasible	• Contact trial representatives* for clarification if: > impossible order of dates, e.g. outcome assessment occurs before randomisation, > dates are not feasible, e.g. all 100 participants were randomised on the same date

*If trial representatives cannot be contacted or do not provide sufficient clarification to address the issue(s), the TOPCHILD data management team in consultation with the TOPCHILD Steering Group will determine whether to set a particular value to missing or to exclude a study until further information becomes available.

3.2 Integrity checks

In addition to the data processing and cleaning checks listed above, the overall integrity of studies will be assessed by two independent reviewers using the IPD Integrity Tool[12] (Table 2). All studies will undergo the 'Summary/aggregate/publication-level data' checks, while only those providing IPD will undergo the additional 'Individual participant data' checks. If any issues are identified, they will first be discussed among the TOPCHILD data management team and, if necessary, with the TOPCHILD Steering Group. If they cannot be resolved, trial representatives will be contacted for further information. If trial representatives cannot be contacted or do not provide sufficient clarification to address the issue(s), the study will be excluded from analyses and classified as 'Awaiting classification' until further information becomes available. If no further information becomes available, the study will be excluded.

Table 2. Decision table to guide assessment of each item of the IPD Integrity Tool[13] (note this is a generic table for assessing integrity of trials and their data, and therefore not all examples are relevant to TOPCHILD)

Publication-level / aggregate data checks

Integrity domain and items	How to assess	No issues	Some/minor issue(s)	Many/major issue(s)	Exceptions: may downgrade severity of issue(s)
1. Retraction notices and expressions of concern					
1.1 Retraction notice – study of interest	Check for retraction notice in journal where study was published and search Retraction Watch http://retractiondatabase.org/	- No retraction notice published for study of interest		- Study has been retracted	- Retraction is due to error by journal or publisher; OR - Retraction is instigated by authors due to inadvertent error in publication; AND - Validity of data is not affected
1.2 Retraction notice(s) – other study/ies by same authors	Search Retraction Watch http://retractiondatabase.org/	- No retraction notices published for other studies by same authors	- >1 retraction for other authors (not first or last)	- >1 retraction for first or last author	- Retraction is due to error by journal or publisher; OR - Retraction is instigated by authors due to inadvertent error in publication; AND - Validity of data is not affected
1.3 Expression of concern (EOC) – study of interest	Check for EoC in journal where study was published, search Retraction Watch http://retractiondatabase.org/, search PubPeer https://pubpeer.com/	- No EoC published for study of interest		- EoC raises serious concerns about validity of data	- EoC describes issues not related to validity of data, e.g. authorship disputes; OR - Concerns are adequately addressed in consultation with journal and/or trialist
1.4 Expression of concern – other study/ies by same authors	Search Retraction Watch http://retractiondatabase.org/, search PubPeer https://pubpeer.com/	- No EoC published for other studies by same authors	- >1 EoC for other authors (not first or last)	- >1 EoC for first or last author	- EoC describes issues not related to validity of data, e.g. authorship disputes; OR - Concerns are adequately addressed in consultation with journal and/or trialist

2. Provision of individual participant data (IPD)					
2.1 IPD not available or not provided on request	Request IPD from primary investigator/corresponding author, e.g. via email (including	- IPD for all participants and codebook are provided		- Trialist does not share IPD; AND	- Study is ongoing; trialist pledges to share IPD after

Integrity domain and items	**How to assess**	**No issues**	**Some/minor issue(s)**	**Many/major issue(s)**	**Exceptions: may downgrade severity of issue(s)**
	reminders), phone, a mutual connection, at a conference. If no response, attempt to contact all other authors. Look for current email addresses if messages bounce; check if IPD are available elsewhere, e.g. journal supplement, data repository. If IPD are provided, check whether data for all eligible participants are provided using trial CONSORT diagram or registration record			- IPD are not publicly available elsewhere, e.g. journal supplement, data repository; OR - IPD only provided for subset of participants (without reasonable explanation), e.g. 40/120 participants; OR - IPD not suitable for use due to uncertainties about variables and their coding stemming from the absence of a codebook or inadequate explanations, e.g. unclear whether 1=intervention and 2=control	their main results are published; OR - Other plausible explanation, e.g. data are lost or data custodian cannot be contacted because trial was conducted many years ago - Subset of IPD provided because remainder of participants do not meet eligibility criteria for IPD-MA - Ethics approval to share IPD was denied - Under-resourced to prepare and share IPD
3. Communication					
3.1 Lack of trialist engagement in communication (see also domain 2: Provision of IPD)	Attempt to contact trial investigators by email, phone, through peers, and in their native language if possible. Collate queries where possible to avoid inundating trialists with too many emails. Record any responses	- Trialist responds to communication within a reasonable timeframe	- Initial eagerness from trialist to share IPD, but no further communication - No response to any queries about trial	- No response to queries about major integrity issues	- Trialist does not speak English - Old study, where trialists may have retired or passed away - Unable to identify current contact details of any authors - Trialist busy with other commitments, e.g. clinical work during COVID pandemic

4. Ethics approval					
4.1 Absent or inadequate ethics approval	Seek ethics approval letter or details by direct contact with trialist, or by checking trial registration record, publication(s), or study website	- Ethics approval letter available for study; OR - Ethics approval ID and name of committee are available and there is evidence that the named committee exists		- No evidence of ethics approval; OR - Retrospective ethics approval, i.e. approval obtained after study commencement - Ethics approval ID also used for another (unrelated) study	- Trial is registered on ClinicalTrials.gov and is ongoing or complete (since provision of ethics approval number and board details are required for registration)

Integrity domain and items	**How to assess**	**No issues**	**Some/minor issue(s)**	**Many/major issue(s)**	**Exceptions: may downgrade severity of issue(s)**
5. Trial registration / protocol					
5.1 Absent or retrospective trial registration +/- publicly available protocol	Look for trial registration ID in any study publication(s), search WHO ICTRP, ClinicalTrials.gov and other relevant registers in WHO Registry Network; and/or directly seek registration details from trialist, e.g. via email. Note registration ID, registration date, dates of first & last participant enrolment and date of main results publication (if applicable). The proportion of participants enrolled at time of registration could be noted, but this may be out-of-date	- Trial is prospectively registered, i.e. registration date is before or on date of first participant enrolment - Month of registration same as month of first participant enrolment (where exact dates are not provided; and enrolment was not completed in same month) - Full study protocol published prior to study start date, regardless of registration status (open platforms like OSF are acceptable)	- Retrospectively registered before recruitment completion, i.e. trial registration was approved after participant enrolment commenced but before enrolment of final participant. Consider how many days retrospective relative to trial duration, and proportion of participants enrolled at time or registration (but may not be up-to-date)	- Retrospectively registered after recruitment completion, i.e. date of registration occurred after date of final participant enrolment. Consider especially whether registration occurred near date of publication - No evidence of trial registration	- Trial commenced prior to July 1, 2005 (ICMJE registration cut-off); though some leniency is allowed for studies commencing prior to 2010 - If there is uncertainty, reviewers can investigate whether there are any major discrepancies between a trial's registration record and publication(s), in particular regarding study design, sample size and time. They could also consider changes to registration record over time, currency of the most recent version and whether any changes are adequately documented and explained.

6. Randomisation					
6.1 Randomisation – balance/imbalance across groups	Examine the number of participants randomised to each group. Review consort diagram or publication text and consider whether reasons given for exclusion are plausible	- Similar numbers randomised to each group (for 1:1 allocation)	- Exactly equal numbers across groups and block randomisation is not used - Numbers randomised to each group and/or baseline characteristics are imbalanced		- Randomisation methods (e.g. block allocation) account for equal numbers across groups
7. Plausibility					
7.1 Implausible recruitment rate	Check enrolment period against sample size. Assess plausibility in context of facilities available at recruitment centre(s),	- Recruitment rate seems feasible based on enrolment period, sample size, resources, rarity of eligibility criteria	- Recruitment rate appears implausible based on enrolment period, sample	- Recruitment rate is impossible based on enrolment period, sample size, resources, rarity of eligibility criteria	- Reasonable explanation for rapid recruitment rate, e.g. multiple recruitment sites in areas where prevalence of
Integrity domain and items	**How to assess**	**No issues**	**Some/minor issue(s)**	**Many/major issue(s)**	**Exceptions: may downgrade severity of issue(s)**
	prevalence of disease/condition in population, resources/ funding, eligibility criteria, number of collaborators, etc.		size, resources, rarity of eligibility criteria		disease/condition of interest is very high
7.2 Implausible follow-up	Check rates of follow-up across timepoints, and whether any reasons are given for dropouts. Consider plausibility in the context of length of follow-up, target population (disease/ condition, age), setting, sample size, variable and assessment method. It may be useful to establish some general plausibility guidelines.	- Follow-up rates are as expected or plausible	- Identical drop-out rates across groups or rounded numbers that appear too perfect	- No loss to follow-up	- Reasonable explanation, e.g. 100% completion may be plausible for a single intervention with immediate assessment, but extremely unlikely for 5 year follow-up in severely ill or elderly patients

7.3 Implausible results	Assess magnitude of results for some key pre-specified variables in comparison to similar trials on the same topic and consider biological mechanisms underlying results. Consult relevant literature, and seek advice from clinical or topic experts if needed.	- Results do not deviate substantially from similar trials that have no integrity issues	- Very large differences among studies with similar participants (based on literature and/or clinical expertise) - Highly significant risk reduction with small sample size - Highly unusual frequency of rare outcomes	- Extremely implausible results not supported by biological mechanisms, i.e. extreme differences compared to similar studies, extreme risk reduction, extreme outcome frequency	- Different results to similar studies may be justified by differences in population characteristics, or if strongly supported by biological mechanisms
7.4 Implausible author group	Note the number of authors and consider plausibility relative to study size	- At least 3 authors for RCT or adequate author / study size ratio	- 2-3 authors or low author/ study size ratio (particularly for multi-centre trials) - Excessive productivity, e.g. more than 3 RCTs published per year as first author - Implausible time from study completion to article submission.	- Single author RCT publication	- Student theses may list themselves as sole author (with supervisor acknowledgement)

Individual participant data level integrity checks

Note: ***(R) denotes assessments that may be semi-automated using the R markdown template***

Integrity domain and items	**How to assess**	**Response options**			**Exceptions: may downgrade severity of issue(s)**
		No issues	**Some/minor issue(s)**	**Many/major issue(s)**	
1. Unusual or repeated data patterns					
1.1 Repeating patterns *within* baseline variables	Sort and visually assess the data for repeating patterns within baseline variables. Assess in dataset order, randomisation order, and also separately for study groups	- No repeating data patterns identified	- Some repeating data patterns identified, but may be consistent with chance	- Repeating data patterns identified that are extremely unlikely to have occurred by chance, e.g. trialist copy and pasted every 10 rows	- Poor granularity of measures and rounding may lead to repetition of values, e.g. age rounded to years with narrow eligibility range

1.2 Repeating data patterns *across* baseline variables	Sort each baseline variable from smallest to largest, and look for patterns across variables ***R markdown***	- No repeating data patterns identified	- Some repeating data patterns identified, but may be consistent with chance or plausible correlation between variables	- Repeating data patterns identified that are extremely unlikely to have occurred by chance, e.g. all newborns with a length of 30cm have identical birthweight	- Poor granularity of measures and rounding may lead to repetition of values, e.g. when gestational age at birth is rounded to weeks, and birthweight is rounded to the nearest 500g
1.3 Repeating data patterns across baseline variables *and rare variables*	As above, but focus on repetition across any rare variables present in dataset ***R markdown***	- No repeating data patterns identified	- Some repeating data patterns identified, but may be consistent with chance	- Repeating data patterns identified that are extremely unlikely to have occurred by chance, e.g. all children who suffer an adverse event have the same sex, birthweight and age at enrolment	
1.4 Bias in the terminal (rightmost) digits	Plot and examine bar charts of the terminal digit for select continuous variables (avoid variables that tend to be rounded or that lack precision) ***R markdown***	- Terminal digits follow a uniform or expected distribution	- Biased or non-uniform distribution of terminal digits	- Extremely biased or unexpected distribution of terminal digits - Conspicuous absence of a single digit across a large number of observations	- Poor granularity of measures, e.g. broad categorisation of continuous measures or use of less precise measurement instruments
2. Baseline characteristics					

Integrity domain and items	**How to assess**	**Response options**			**Exceptions: may downgrade severity of issue(s)**
		No issues	**Some/minor issue(s)**	**Many/major issue(s)**	

2.1 Excessively homogeneous distribution of binary baseline variables, i.e. loss of independence or serial correlation across consecutive observations	Use the runs test to examine whether binary baseline data occurs in a random manner Note: if row order is not organised chronologically by randomisation date and time, this test may be invalid. This test is most suited to larger datasets, and variables for which the rate of occurrence is not rare ***R markdown***	- No significant p values, i.e. all ≥0.05	- One significant p value (i.e. <0.05)	- Multiple significant p values (i.e. <0.05)	- Variable(s) with significant p values have a low rate of occurrence, i.e. are rare
2.2 Excessive imbalances between groups in continuous baseline variables	Use IPD to tabulate the mean and standard deviation for continuous baseline variables ***R markdown***	- No excessive imbalances	- Some imbalances between groups	- Excessive imbalances between groups (particularly for prognostic factors), i.e. beyond what is expected by chance or that excludes the possibility of random allocation	
2.3 Excessive imbalances in baseline categorical variables between groups	Use Chi squared test (or Fisher's Exact if this fails) to generate p values comparing proportions of categorical variables between groups ***R markdown***	- No significant p values, i.e. all ≥0.05	- Any significant p values (i.e. <0.05)		
2.4 Significant difference in variance of continuous baseline variables between groups	Apply Levene's test to continuous baseline variables ***R markdown***	- No significant p values, i.e. all ≥0.05	- Any significant p values (i.e. <0.05)		
3. Correlations					
3.1 No association between variables	Select participant-level variables which are known to be highly correlated. Generate scatter	- Correlation between variables is as expected	- Correlations appear too weak or too strong, or are in the wrong direction	- No association between variables known to be highly correlated	

Integrity domain and items	How to assess	Response options			Exceptions: may downgrade severity of issue(s)
		No issues	**Some/minor issue(s)**	**Many/major issue(s)**	
known to be highly correlated	plots for visual assessment and calculate Pearson correlation coefficient. Consult topic experts to generate acceptable thresholds or for guidance on interpretation if needed. ***R markdown***				
4. Date violations					
4.1 Individual enrolment dates do not fit within study start and end dates	Compare the start and end date of each study with individual enrolment/ randomisation dates, if available. Start and end dates may be obtained from publications, trial registration records, or by direct contact with trialists. ***R markdown***	- All individual enrolment/randomisation dates occur between study start and end dates	- Some individual enrolment dates do not fit within study start and end dates	- Many individual enrolment dates fall well outside of the study start and end dates	- Trialist provides plausible reason, e.g. inadvertent data entry error, incorrect date format, etc.
4.2 Dates (or visits) are not in logical order	Where repeated measures are taken across timepoints check if these occur in logical order	- All dates occur in logical order	- Impossible dates, e.g. a participant's third visit cannot occur before their first visit.	- Many illogical or impossible visit dates	- Trialist provides plausible reason, e.g. data entry error, incorrect date format, etc.
5. Patterns of allocation					
5.1 Non-random allocation patterns - plot	If date of randomisation is provided, plot cumulative number of participants allocated to each group over time. ***R markdown***	- Similar numbers in each group and plotted curves do not deviate from each other drastically (1:1 allocation). - If allocation is not 1:1, we would expect curves to track one another but not cross.	-	- Plotted curves deviate drastically from each other	- Smaller trials may have greater separation in curves and less crossing over - Minimisation, blocked or cluster randomisation methods may explain the pattern of sequence generation

5.2 Non-random allocation patterns – statistical test	Use *Wald-Wolfowitz runs test* (or other appropriate statistical test) to evaluate randomness of allocation using date of	- Result not statistically significant (p>0.05)	-	- Statistically significant result (p<0.05)	- Consider whether there may be alternative explanations for significance, e.g. multiples/ twins randomised together,

Integrity domain and items	**How to assess**	**Response options**			**Exceptions: may downgrade severity of issue(s)**
		No issues	**Some/minor issue(s)**	**Many/major issue(s)**	
	randomisation or other indicator of randomisation sequence. ***R markdown***				minimisation, blocked or cluster randomisation
5.3 Unexpected imbalance in randomisation day of week	Create and review bar graphs showing the day of week on which each participant was randomised. ***R markdown***	- Uniform distribution across groups for each week day, and fewer enrolments on weekends for non-urgent interventions	- Obvious deviations from what is expected, e.g. no participants enrolled on Wednesdays		- For urgent interventions, enrolments on weekends may be expected - Trial staff only available on certain days
6. Internal inconsistencies					
6.1 Inconsistent or illogical values across variables within individual participants	Derive logic rules for each variable to be collected, e.g. *date of hospital discharge* = *date of admission* + *days in hospital*; if *number of transfusions* ≥1, then *any transfusion* = yes. Incorporate these rules into an R-Markdown (or similar) so that any breaches are displayed in the output.	- No/few/minor inconsistencies that can often be resolved with trialist	- Several inconsistencies that can be amended with plausible explanation from the trialist	- Several major inconsistencies, no response from trialist, or trialist corrects most/all of these without adequate explanation	- Consider whether it may be appropriate to exclude only a problematic variable from the analyses, rather than excluding the whole study (if there are no other major integrity issues)
7. External inconsistencies					

7.1 IPD do not correspond to publications or reports	Plot all variables provided in the IPD dataset and tabulate summary statistics for each, e.g. mean, median, range, etc. Cross-check these against any published trial reports, including appendices and supplements. Record any inconsistencies identified, e.g. discrepancies in summary variable values between IPD and publication, inclusion of participants in IPD	- No/few/minor inconsistencies that can often be resolved with trialist	- Several inconsistencies that can be amended with plausible explanation from the trialist	- Several major inconsistencies, no response from trialist, or over willingness to correct corrects most/all of the inconsistencies without adequate explanation	- Consider whether it may be appropriate to exclude only a problematic variable from the analyses, rather than excluding the whole study (if there are no other major integrity issues) - Inconsistencies can be adequately explained, e.g. variables are defined differently, honest error, etc.

Integrity domain and items	**How to assess**	**Response options**			**Exceptions: may downgrade severity of issue(s)**
		No issues	**Some/minor issue(s)**	**Many/major issue(s)**	

	that do not meet eligibility criteria in publication, published variables that are missing from IPD dataset. If data are provided for excluded participants, check whether reasons for exclusion are consistent with publication. Tally and rate severity of inconsistencies. Once informed of inconsistencies, note how many are corrected by trialist and whether an adequate explanation is given. If the trialist has re-coded their data into the IPD-MA format, request the raw data to investigate whether any discrepancies may be due to errors in re-coding or misunderstandings, e.g. due to language barriers.				
8. Plausibility of data					
8.1 Too few missing data or missing data are overly similar between groups	Use the IPD to tabulate missing data by group for key variables. Examine these tables to determine whether missing data appear too perfect across groups or are implausibly few.	- No/few/minor inconsistencies that can often be resolved with trialist	- Implausibly few missing data compared to expected - Identical missing values across groups	- No missing data	- (Close to) 100% follow-up may be achieved for outcomes assessed immediately after intervention delivery
8.2 Implausible event rates – outcomes and demographics	Tabulate event rates for key outcomes and demographic variables. Compare with expected event rates, based on literature, biological mechanisms, and expert advice.	- Event rates are within a plausible range	- Events rates do not fall within expected range	- Event rates are extremely implausible, i.e. extremely high (e.g. 80% of healthy infants die) or extremely low (e.g. 1% of acutely ill patients die over 5 years)	

Overall assessment

	How to assess	No concerns	Some concerns	Major concerns
OVERALL ASSESSMENT	Provide an overall rating based on all items	No issues identified, OR any issues adequately resolved or had a reasonable explanation **The study may be considered sufficiently trustworthy to contribute to the evidence base, i.e.. to include in metaanalysis, or to be considered for publication**	≥1 minor issue identified that could not be adequately resolved and had no reasonable explanation **Decision on how to proceed should be based on circumstantial evidence or pending further information**	≥1 major issue identified that cannot be adequately resolved or had a reasonable explanation **The study should NOT be considered trustworthy enough to contribute to the evidence base, i.e. do NOT include in meta-analysis or consider for publication**

3.3 Outcomes

Variables were only considered outcomes if measured *after* the intervention commenced. As trials commenced interventions at different timepoints (some antenatally and others within the first year after birth), whether a variable is an outcome or a baseline characteristic will vary across trials.

Data for all outcomes were collected for all trials, where available, with consensus on final outcomes and timepoints determined via the data harmonisation process as described below in section 3.3.1. Final outcome definitions are available in section 3.3.3.

3.3.1 Outcome harmonisation process

TOPCHILD outcomes were collected by trialists using a variety of definitions and measures, and at various timepoints. We sought to harmonise these and derive standardised definitions of outcomes to facilitate data synthesis and improve statistical power for analyses.

To achieve this, a retrospective harmonisation process was completed as follows:

1. Target variables and suggested coding were defined in a data dictionary developed by the steering group in consultation with advisors.
2. After receipt of a dataset, the following information was extracted from each trial by one reviewer (and checked by another reviewer) into a single variable map:
    a. Variable name, e.g. hypertension
    b. Dataset where variable is available (if there are multiple)
    c. Variable definition, e.g. defined as blood pressure >140/90 mmHg
    d. Description of measure, instrument or tool used, e.g. measured 3 times using automatic sphygmomanometer (average measure recorded)
    e. Whether variable was self-reported or objectively measured, e.g. by trained researcher
    f. Coding for categorical variables, e.g. 0=no, 1=yes
    g. Units of measurement, e.g. kg, cm, grams/day
    h. Timepoints, e.g. baseline and 6 months post intervention
    i. Other relevant details pertaining to variable collection, e.g. how a score was calculated
3. Next, we tallied how many trials had (i) collected the target outcome, or (ii) collected a similar or equivalent outcome that may be transformed to match the target outcome.
4. Consensus meetings were held with subject area experts to assess equivalence and potential for harmonisation of outcomes. This involved careful consideration and discussion of whether:
    - varying definitions may be considered sufficiently equivalent to combine
    - conversion to the common definition was possible
    - different coding categories across trials could be merged into common categories
    - timepoints were sufficiently equivalent to be appropriately combined

    Common harmonisation methods discussed included algorithmic transformations (e.g. recoding of categories), calibration to common units (e.g. conversion of pounds to kg), and re-scaling different scores and questionnaires measuring the same thing.

5. All decisions made were clearly documented and used to refine outcome definitions and recoding of datasets in preparation for analyses.
    Detailed notes from consensus meetings and the decision-making process are available upon request. We also plan to publish a full manuscript describing these methodologies in detail.

Throughout the process, we carefully considered the balance between maintaining the clinical content of an outcome for meaningful analyses, and maximising use of information across trials. If measures across trials had low compatibility or required too much modification to harmonise, precision would be lost, and analyses would be less informative and meaningful. Conversely, if outcome definitions were too strict, few studies will be able to contribute to the meta-analyses. On some occasions, there were insufficient data available to undertake harmonisation that was valid and worthwhile.

Details of harmonised outcomes were shared with planned or ongoing trials to enable prospective harmonisation.

3.3.2 Primary and secondary Outcomes

Primary outcome

BMI z-score at age 24 months (±6 months)

Child body mass index z-score (BMI-z) at age 24 months (± 6 months). Refer to section 3.3.3 for definition.

Secondary outcomes

Table 3 lists all secondary outcomes that were included in the published protocol,[8] and indicates which of these will be assessed in the first cycle of TOPCHILD analyses. For those outcomes that will not be assessed (grey text), reasons are provided.

Given the large number of secondary outcomes, we decided to select some key secondary outcomes a priori. This will not change analyses, but will assist in interpretation of results by directing readers' attention to particular outcomes of interest. Key secondary outcomes are bolded in Table 3 and were chosen based on i) data availability; and ii) relative importance of the outcome to child health, as judged by our expert Advisory Group. There is one key secondary outcome per domain, except for anthropometry (since our primary outcome is within this domain) and adverse events.

More detailed information on each of these outcomes is available in section 3.3.3.

Table 3. Secondary outcomes[1]

Outcome and assessment timepoint(s)	**Assessed in first cycle?**
DOMAIN: Anthropometry / weight-related measures	
BMI z-score at age 12 months (±3 months)	Yes
BMI z-score at age 48 months (±12 months)	No (follow-up outcome to be assessed in subsequent cycles)
BMI z-score beyond 60 months of age	No (follow-up outcome to be assessed in subsequent cycles)
Weight z-score at age 12 months (±3 months)	Yes
Weight z-score at age 24 months (±6 months)	Yes
Overweight at age 24 months (±6 months)	Yes
Obesity at age 24 months (±6 months)	Yes

Percent fat content/adiposity/skinfold thickness at age 24 months (±6 months)	No (insufficient data)
Abdominal circumference	No (a priori decision to assess waist circumference instead – see below)
Waist circumference at age 24 months (±6 months)	Yes
Waist-to-height ratio at age 24 months (±6 months)	Yes
Velocity of weight gain at age 24 months (±6 months)	No (insufficient data)
Weight-for-length	No (a priori decision not to analyse due to little added value)
Per cent excess BMI >95th percentile	No (a priori decision not to analyse due to little added value)
Adiposity rebound at age 24 months (±6 months)	No (insufficient data)
DOMAIN: Infant feeding	
Any breastfeeding	Yes
Duration of any breastfeeding assessed at age 24 months (±6 months)	Yes
Duration of exclusive breastfeeding assessed at 6 months (±2 months)	Yes
Age at introduction of solid foods	Yes
DOMAIN: Dietary intake	
Energy intake per day at age 24 months (±6 months)	Yes
Fruit consumed per day at age 24 months (±6 months)	Yes
Vegetables consumed per day at age 24 months (±6 months)	Yes
Combined fruit and vegetables consumed per day at age 24 months (±6 months)	No (outcome is redundant since we have fruit intake & vegetable intake data available separately)
Intake of energy-dense-nutrient poor foods per day at age 24 months (±6 months)	Yes
Intake of sugar-sweetened beverages per day at age 24 months (±6 months)	Yes
DOMAIN: Sedentary behaviours	
Average time per day in sedentary behaviour in front of a screen at age 24 months (±6 months)	Yes
Average time per day restrained while awake at age 24 months (±6 months)	Yes
DOMAIN: Physical activity	
Tummy time at 6 months (±1 month)	Yes
Self-reported physical activity at age 24 months (±6 months)	Yes

Outcome and assessment timepoint(s)	Assessed in first cycle?
Device assessed physical activity at age 24 months (±6 months)	No (insufficient data)
DOMAIN: Sleep	
Sleep duration per night at age 24 months (±6 months)	Yes
Sleep duration per day at age 24 months (±6 months)	Yes
Combined sleep duration per night and day at age 24 months (±6 months)	Yes
Sleep quality – frequency of waking during the night at age 24 months (±6 months)	Yes
Sleep quality – duration of disrupted sleep episodes at age 24 months (±6 months)	Yes
DOMAIN: Parental/caregiver outcomes	
Parenting self-efficacy at age 24 months (±6 months)	Yes
Parenting styles	Yes
Parent feeding practices – Control (Restriction) at age 24 months (±6 months)	Yes
Parent feeding practices – Control (Pressure to eat) at age 24 months (±6 months)	Yes
Parent feeding practices – Control (Food as a reward) at age 24 months (±6 months)	Yes
Parent feeding practices – Structure (Monitoring and rules) at age 24 months (±6 months)	Yes
Parent physical activity practices	No (not targeted by most interventions, heterogeneity in assessment method)
Parent sleep practices	No (not targeted by most interventions, heterogeneity in assessment method)
Parent stress	No (not targeted by most interventions, heterogeneity in assessment method)
DOMAIN: Adverse events	
Severe underweight at age 24 months (±6 months)	Yes
Adverse events (qualitative) at age 24 months (±6 months)	Yes

[1] *Note: outcomes that will not be assessed in the first cycle (but were included in the published protocol) are in grey text. The bolded text indicates key secondary outcomes within each domain. All outcomes are infant outcomes except when specified, i.e. the domain 'Parental/caregiver outcomes'.*

3.3.3 Definitions of outcomes

This section provides definitions of all outcomes. Note that all outcomes are assessed at 24 months of infant age ± 6 months unless specified otherwise, where alternative timepoints are more developmentally appropriate (e.g. exclusive breastfeeding, tummy time).

The denominator refers to the population or sample included in analysis for each outcome. It includes participants for whom the outcome was collected directly by the trial, or those for whom the outcome could be derived from the available data. Those with missing data are excluded.

For those outcomes that will not be assessed (grey text), reasons are provided.

Domain: Anthropometry / weight-related measures

BMI z-score

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> Primary: 24 months (±6 months) of age

> Secondary: 12 months (±3 months) of age

> (Subsequent analyses cycles: 48 months (±12 months), beyond 60 months of age)

Definition:

Child body mass index z-score determined in accordance with 2006 WHO growth standards.[14] Calculated using length and weight up to <24 months of age, and height and weight from 24 months of age onwards.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Weight z-score

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 12 months (±3 months) of age

> 24 months (±6 months) of age

Definition:

Child weight z-score determined in accordance with 2006 WHO growth standards.[14]

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Overweight

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

BMI z-score of at least 2 SD above the WHO reference.[15]

Denominator:

All: The total number of children randomised to the study for whom the trial collected this outcome.

Obesity

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

BMI z-score of at least 3 SD above the WHO reference.[15]

Denominator:

All: The total number of children randomised to the study for whom the trial collected this outcome.

Per cent fat content/adiposity/skinfold thickness

Not analysed as the majority of included trials did not collect this outcome. This decision was made prior to any analyses.

Abdominal circumference

Waist circumference to be analysed instead based on data availability and expert advice. This decision was made prior to any analyses.

Waist circumference

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Child waist circumference (in cm), as determined using trial protocol.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Waist-to-height ratio

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Child waist-to-height ratio determined using waist circumference in cm and height in cm, as collected using trial protocol.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Velocity of weight gain
Not analysed due to insufficient data. This decision was made prior to any analyses.

Weight-for-length
Not analysed based on expert advice that this would add little or no value. This decision was made prior to any analyses.

Per cent excess BMI >95th percentile
Not analysed based on expert advice that this would add little or no value. This decision was made prior to any analyses.

Adiposity rebound
Not collected by any trials, and therefore not analysed. This decision was made prior to any analyses.

Domain: Infant feeding

Any breastfeeding

Data type:
- Binary (yes/no)

Unit of analysis:
- Child

Timepoint(s):
- Any

Definition:
Number of infants who received any breast milk. Includes breast milk administered via maternal breastfeeding, expressed breast milk and breast milk sourced from milk bank.

Denominator:
All: The total number of infants randomised to the study for whom the trial collected this outcome.

Duration of any breastfeeding

Data type:
- Continuous

Unit of analysis:
- Child

Timepoint(s):
- From birth until 24 months (±6 months) of age

Definition:
Duration of any breastfeeding in weeks.

Denominator:
All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:
If data collection was censored at earlier timepoints, we will report this and take it into account in our analyses.
Where a trial provided age stopped breastfeeding, this was used as a proxy for breastfeeding duration.
Where duration was assessed categorically, it was transformed to a continuous variable (where possible), by setting all values to the lowest point of the category, e.g. if category is 3-6 months, 3 months was used. The lower point was considered most appropriate since the data for this outcome are expected to be positively skewed. Additionally, if a trial collected breastfeeding at multiple timepoints as yes/no, the final timepoint where 'yes' was indicated was used as duration.

Duration of exclusive breastfeeding

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> From birth until 6 months (±2 months) of age

Definition:

Duration of exclusive breastfeeding in weeks assessed from birth until 6 months of age. Exclusive breastfeeding defined (by WHO) as giving no other food or drink, not even water, except breast milk.[16] Oral rehydration salts, drops and syrups (vitamins, minerals and medicines) are permitted. If WHO definition is not available, the trial definition will be used.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial provided age stopped exclusive breastfeeding, this was used as a proxy for exclusive breastfeeding duration. Where duration was assessed categorically, it was transformed to a continuous variable (where possible), by setting all values to the lowest point of the category, e.g. if category is 3-6 months, 3 months was used. Additionally, if a trial collected exclusive breastfeeding at multiple timepoints as yes/no, the final timepoint where 'yes' was indicated was used as duration.

Age at introduction of solid foods

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> Censored at 6 months of age

Definition:

Age at introduction of solid foods in months, as defined by the trialist, censored at 6 months of age (the recommended age of introduction)[17]

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Domain: Dietary intake

Energy intake per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months)

Definition:

Energy intake per day in kilojoules (if in calories multiply by 4.184 to convert to kJ)

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Fruit intake per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definitions:

Fruit intake in grams per day, as defined by the trial (this may or may not include 100% fruit juice).

For trials that report frequency of fruit intake in times per day, country specific conversion factors will be applied based on standardised portion estimates in grams (see Appendix D). Standardised portion estimates will be derived from available population intake data for children around 24 months of age. Noting there is likely a difference in year that population data and trial data were collected. When there are multiple portion size options a minimum or average will be derived.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Vegetable intake per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definitions:

Vegetable intake in grams per day, as defined by the trial. For trials that report frequency of vegetable intake in times per day, country specific conversion factors will be applied based on standardised portion estimates in grams (see Appendix D). Standardised portion estimates will be derived from available population intake data for children around 24 months of age. Noting there is likely a difference in year that population data and trial data were collected. When there are multiple portion size options an average will be derived.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Sensitivity analyses:

1) according to dietary assessment method (e.g. food diary, 24 hour recall, FFQ)
2) if grams of intake were calculated/reported in the trial data, versus calculated by the TOPCHILD team using country specific standardised portion estimates, also described in section 4.6.

Combined fruit and vegetable intake per day

Not analysed because outcome is redundant as we have fruit intake and vegetable intake data available separately. This decision was made prior to any analyses.

Intake of energy dense nutrient poor foods per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Intake of energy dense nutrient poor foods in grams per day, as defined by the trial. Energy dense nutrient poor foods are foods with little nutritional value that are high in energy, e.g. cakes, confectionary, fast food, pre-sugared cereals, etc.

For trials that report frequency of energy dense nutrient poor intake in times per day, country specific conversion factors could not be derived due to heterogeneity in definitions. Therefore, categorical data will not be converted to a continuous measure.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Intake of sugar-sweetened beverages per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Intake of sugar-sweetened beverages consumed in ml per day as defined by the trial.
Examples of sugar-sweetened beverages include: cordial, squash, soda, fizzy or soft drinks, sports drinks, flavoured milk, fruit juice drinks (excl 100% fruit juice), etc. For trials that report frequency of sugarsweetened beverage intake in times per day, country specific conversion factors will be applied based on standardised portion estimates in mls (see Appendix D). Standardised portion estimates will be derived from available population intake data for children around 24 months of age. Noting there is likely a difference in year that population data and trial data were collected. When there are multiple portion size options an average will be derived.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Domain: Sedentary behaviours

Screen time

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Average minutes per day in sedentary behaviour in front of a screen, as defined by the trial. May include: TV, DVDs, computer games, video games, smartphones, tablets, etc. Where possible, movement console games such as Wii™, Eyetoy and Xbox Kinect will be excluded.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this outcome categorically, it was transformed to a continuous variable (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was 'between 1 and 2 hours per day', this was converted to 1.5 hours
- For peripheral or fringe categories that stated 'less than' or 'more than' values, 30 minutes was subtracted or added as appropriate. For example, if the lowest category was 'less than 1 hour' it was converted to 0.5 hours, and if the highest category was 'more than 8 hours' it was converted to 8.5 hours.

Restrained time while awake

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Average minutes per day restrained while awake, as defined by the trial. May include: in a stroller or pram, in a car seat or capsule, in a cot or bed during the day, in a highchair or other chair, in infant seat, in a baby carrier or sling, etc.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this outcome categorically, they were transformed to continuous variables (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was 'at least 2 hours but less than 4 hours', this was converted to 3 hours. Or if a category was <2 hours, this was converted to 1 hour (assuming 0 is the lower cut-off and therefore 1 is the midpoint).
- For peripheral or fringe categories that stated 'more than' values, 30 minutes was subtracted or added as appropriate. For example, if the highest category was 'more than 8 hours' it was converted to 8.5 hours.

If a trial collected both average time on weekday and average time on weekend day, then the daily average was calculated as follows: [(Weekday hrs x 5) + (Weekend hrs x 2)] ÷7

Domain: Physical activity

Tummy time

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 6 months (±2 months) of age

Definition:

Tummy time/prone play per day in minutes, as defined and measured by the trialist.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Self-reported physical activity

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Self-reported physical activity/play time per day in minutes, as defined by the trialist.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Device assessed physical activity

Will not be analysed due to insufficient data at 24 months (±6 months) of age. This decision was made prior to any analyses.

Domain: Sleep

Sleep duration per night

Data type:

> Continuous

Unit of analysis:

> Child Timepoint(s):

> 24 months (±6 months) of age

Definition:

Child sleep duration in hours per night (i.e. between 7pm-7am, or as defined and measured by the trial). Does not include wakings during the night.

Denominator:

All: The total number of children randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this outcome categorically, they were transformed to continuous variables (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was '8-10 hours', this was converted to 9 hours. Or if a category was <2 hours, this was converted to 1 hour (assuming 0 is the lower cut-off and therefore 1 is the midpoint).
- For peripheral or fringe categories that stated 'more than' values, 30 minutes was added. For example, if the highest category was 'more than 8 hours' it was converted to 8.5 hours.

Sleep duration per day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Child sleep duration in hours per day (i.e. between 7am-7pm, or as defined and measured by the trial)

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this oucome categorically, they were transformed to continuous variables (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was '8-10 hours', this was converted to 9 hours. Or if a category was <2 hours, this was converted to 1 hour (assuming 0 is the lower cut-off and therefore 1 is the midpoint).
- For peripheral or fringe categories that stated 'more than' values, 30 minutes was added. For example, if the highest category was 'more than 8 hours' it was converted to 8.5 hours.

Combined sleep duration per night and day

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Child combined duration of day and night sleep in hours per day.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Sensitivity analyses:

Only including data provided as a continuous outcome (i.e. excluding continuous estimates derived from categorical outcomes)

Sleep quality – frequency of waking during the night

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Frequency of waking during the night.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this outcome categorically, they were transformed to continuous variables (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was '2-4 times', this was converted to 3 times, and where a category was '0-2 times' this was converted to 1 time.
- For peripheral or fringe categories that stated 'more than' values, 0.5 was added. For example, if the highest category was '>10' it was converted to 10.5.

Sleep quality – duration of disrupted sleep episodes

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Duration of disrupted sleep episodes in minutes.

Denominator:

All: The total number of infants randomised to the study for whom the trial collected this outcome.

Notes:

Where a trial assessed this outcome categorically, they were transformed to continuous variables (where possible), as follows:

- Where categories were provided in ranges, the midpoint of the category was used. For example, where a category was '6-10 minutes', this was converted to 8 minutes, and for the category 'up to 5 minutes' this was converted to 2.5 minutes.
- For peripheral or fringe categories that stated 'more than' values, the upper bound was used. For example, if the highest category was '>45 minutes' it was converted to 45 minutes.

Domain: Parental/caregiver outcomes

Parenting self-efficacy

Data type:

> Continuous

Unit of analysis:

> Parent/caregiver

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Any measure of parenting self-efficacy as defined/assessed by the trialist, e.g. 5 point Likert scale used in the Longitudinal Study of Australian Children (LSAC)[18]

Denominator:

All: The total number of parents/caregivers randomised to the study for whom the trial collected this outcome.

Parenting styles

Not analysed, since interventions did not target this. This decision was made prior to any analyses.

Parent feeding practices – Control (Restriction)

Data type:

> Continuous

Unit of analysis:

> Parent/caregiver

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Parent feeding practices – Domain of control, construct of restriction: Eight items (18, 27, 29, 33, 34, 35, 41, and 45) of restriction for weight control from the Comprehensive Feeding Practices Questionnaire (CFPQ),[19] defined as "Parents control the child's food intake with the purpose of decreasing or maintaining the child's weight". Variable aligns with the domain 'control' and category 'restriction' of the O'Connor Food Parenting Practices framework.[20] The specific items are:

18. I have to be sure that my child does not eat too many high-fat foods.
27. I encourage my child to eat less so he/she won't get fat.
29. I give my child small helpings at meals to control his/her weight.
33. If my child eats more than usual at one meal, I try to restrict his/her eating at the next meal.
34. I restrict the food my child eats that might make him/her fat.
35. There are certain foods my child shouldn't eat because they will make him/her fat.
41. I don't allow my child to eat between meals because I don't want him/her to get fat.
45. I often put my child on a diet to control his/her weight.

Items are measured on a 5-point Likert scale (disagree, slightly disagree, neutral, slightly agree, agree).

Denominator:

All: The total number of parents/caregivers randomised to the study for whom the trial collected this outcome.

Parent feeding practices – Control (Pressure to eat)

Data type:

> Continuous

Unit of analysis:

> Parent/caregiver

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Parent feeding practices – Domain of control, construct of pressure to eat: Two items of pressure to eat from the Comprehensive Feeding Practices Questionnaire[19] (CFPQ, items 17 and 30) measuring parents pressure the child to consume more at meals' and Child Feeding Questionnaire (CFQ, items 25 and 27) assessing parent's tendency to pressure their children to eat more food, typically at mealtimes. Variable aligns with the domain 'control' and category 'pressure to eat' of the O'Connor Food Parenting Practices framework.

The specific items are:

CFPQ 17/CFQ 25. My child should always eat all of the food on her plate

CFPQ 30/CFQ 27. If my child says "I'm not hungry" I try to get her to eat anyway

Items are measured on a 5-point Likert scale (disagree, slightly disagree, neutral, slightly agree, agree)

Denominator:

All: The total number of parents/caregivers randomised to the study for whom the trial collected this outcome.

Parent feeding practices – Control (Food as a reward)

Data type:

> Continuous

Unit of analysis:

> Parent/caregiver

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Parent feeding practices – Domain of control, construct of food as a reward: Three items of food as a reward from the Comprehensive Feeding Practices Questionnaire[19] (CFPQ, items 19, 23, 36), measuring parents use food as a reward for child's behaviour. Variable aligns with the domain 'control' and category 'food as a reward' of the O'Connor Food Parenting Practices framework.

The specific items are:

19. I offer my child his/her favorite foods in exchange for good behavior.

23. I offer sweets (candy, ice cream, cake, pastries) to my child as a reward for good behavior.

36. I withhold sweets/dessert from my child in response to bad behavior.

Items are measured on a 5-point Likert scale (disagree, slightly disagree, neutral, slightly agree, agree)

Denominator:

All: The total number of parents/caregivers randomised to the study for whom the trial collected this outcome.

Parent feeding practices – Structure (Monitoring and rules)

Data type:

> Continuous

Unit of analysis:

> Parent/caregiver

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Feeding practices - Domain of structure, construct of monitoring: Three items of monitoring from the Comprehensive Feeding Practices Questionnaire (CFPQ) and Child Feeding Questionnaire (CFQ), measuring extend to which parents oversee/keep track of their child's intake of less healthy foods. Variable aligns with the domain 'structure' and category 'rules and limits' of the O'Connor Food Parenting Practices framework. Both questionnaires measure the same 3 items, as follows:

1. How much do you keep track of the sweets (candy, ice cream, cake, pies, pastries) that your child eats?
2. How much do you keep track of the snack food (potato chips, Doritos, cheese puffs) that your child eats?
3. How much do you keep track of the high-fat foods that your child eats?

Items are measured on a 5-point Likert scale (disagree, slightly disagree, neutral, slightly agree, agree)

Denominator:

All: The total number of parents/caregivers randomised to the study for whom the trial collected this outcome.

Parent physical activity practices

Not analysed, because it was not targeted by most interventions and there was heterogeneity in assessment. This decision was made prior to any analyses.

Parent sleep practices

Not analysed, because it was not targeted by most interventions and there was heterogeneity in assessment. This decision was made prior to any analyses.

Parent stress

Not analysed, because it was not targeted by most interventions and there was heterogeneity in assessment. This decision was made prior to any analyses.

Adverse events

Severe underweight

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoint(s):

> 24 months (±6 months) of age

Definition:

Weight-for-age at least 3 SD below the WHO reference.[15]

Denominator:

All: The total number of children randomised to the study for whom the trial collected this outcome.

Adverse events: qualitative analysis

Qualitative synthesis will be undertaken of any adverse events that are reported across trials. These will be categorised as appropriate and presented descriptively as frequencies and proportions.

3.4 Subgroups

Table 4 lists all subgroups that were included in the published protocol,[8] and indicates which of these will be assessed in the first cycle of TOPCHILD analyses. For those subgroups that will not be assessed (grey text), reasons are provided.

More detailed information on each of these subgroups is available in sections 3.4.1 and 3.4.2.

Table 4. Subgroups[1]

Subgroup	Analysed in first cycle
Individual-level	
Birth weight	Yes
Any formal childcare attendance	Yes
Gestational age at birth	Yes
Partner status	Yes
Household composition	No (insufficient data)
Maternal/birthing parent weight status	Yes
Parity/first-time parent	Yes
Race/ethnicity	No (data too heterogenous to harmonise; added immigration status instead)
Parent/carer immigration status	Yes
Sex	Yes
Socioeconomic position – household income	Yes
Socioeconomic position – carer education	Yes
Socioeconomic position – carer employment status	Yes
Intervention/trial-level	
Intervention delivery mode (individual vs group)	Yes
Intervention delivery mode (any face-to-face component)	Yes
Intervention setting	Yes
Intervention dose/intensity	Yes
Fidelity	No (not enough variation in data)
Timing of intervention onset	Yes
Timing of intervention completion	Yes
Current level of background care in the community	Yes (will analyse Human Development Index as a proxy)
Country	Yes (will analyse Human Development Index as a proxy)
Behavioural ± other intervention type	No (insufficient data; only one trial had an additional non-behavioural intervention component)

[1] *Note: subgroups that will not be assessed in the first cycle (but were included in the published protocol) are in grey text.*

3.4.1 Definitions of individual-level subgroups

Birth weight

Data type:

> Continuous

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

Birth weight in grams

Included trials:

All that started after birth

Any formal childcare attendance

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoints:

> 0-12 months of age

> >12-24 months of age

Definition:

Attendance at any type of formal childcare on a regular basis. Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool, etc.

Gestational age at birth

Data type:

> Continuous

Unit of analysis:

> Child

Timepoint:

> Birth

Definition:

Gestational age at the time of birth in weeks as assessed by the trialist.

Included trials:

All that started after birth

Partner status

Data type:

> Categorical

Unit of analysis:

> Parent/caregiver

Timepoint:

> At baseline/enrolment in trial

Definition:

Partner or relationship status, categorised as:
1 = in a partnership (married, de facto, living with partner)
2 = single (single, divorced, widowed)

Maternal/birthing parent weight status

Data type:

> Continuous

Unit of analysis:

> Mother/birthing parent

Timepoint:

> Pre-pregnancy

Definition:

The pre-pregnancy body mass index of the mother/birthing parent.

Parity/first-time parent

Data type:

> Binary

Unit of analysis:

> Mother/birthing parent

Timepoint:

> At baseline/enrolment in trial

Definition:

Whether the mother/birthing parent is a first-time parent or has other children, where:
1=first-time parent,
2=already has at least 1 other child

Race/ethnicity

Due to data unavailability and substantial variability in the definitions of 'race' and 'ethnicity' in the eligible trials, it is not possible to establish common categories. Therefore, race and ethnicity will not be analysed in the first cycle of TOPCHILD. As an alternative similar measure, we will assess parent/carer immigration status (see below). This decision was made prior to any analyses.

Parent/carer Immigration status

Data type:

> Categorical

Unit of analysis:

> Carers (all)

Timepoint:

> At baseline/enrolment in trial

Definition:

Birthplace of main carer, categorised as:
1 = primary parent/carer born in study country
2 = primary parent/carer born outside study country

Sex

Data type:

> Categorical

Unit of analysis:

> Infant

Timepoint:

> At birth

Definition:

Sex of infant at birth, where:
1 = male
2 = female
3 = ambiguous/other

Socioeconomic position: weighted standardised household income

Data type:

> Continuous

Unit of analysis:

> Household

Timepoint:

> At baseline/enrolment in trial

Definition:

Calculated as follows:

$$\frac{\text{(annual median country \& year specific household income) – (total household income per year at baseline)}}{\text{annual median country \& year specific household income}}$$

Notes:

If total household income is provided as a category, use the midpoint, e.g. for category $15 001 - $20,000, midpoint = ($15,001 + $20,000) / 2 = $17,500.50
Annual median country and year specific household income is sourced from government/census records where available, e.g. Australia: ABS Survey of Income and Housing, various years https://www.abs.gov.au/statistics/economy/finance/household-income-and-wealth-australia/latestrelease, New Zealand: Stats NZ https://www.stats.govt.nz/information-releases/household-income-and-housing-cost-statistics-yearended-june-2022/

Socioeconomic position: Carer education

Data type:

> Categorical

Unit of analysis:

> Parent/carer

Timepoint:

> At baseline/enrolment in trial

Definition:

Carer's highest education level at baseline/enrolment in trial, categorised as:
1 = low education (little/no formal education, or some school but did not finish high school),
2 = high school graduate,
3 = non-university tertiary education or qualification or incomplete university,
4 = university graduate or postgraduate.

Socioeconomic position: Carer employment status

Data type:

> Categorical

Unit of analysis:

> Parents

Timepoint:

> At baseline/enrolment in trial

Definition:

Carer employment status at baseline/enrolment in trial, categorised as:
1 = any employment (including paid leave)*
3 = unemployed (includes returned, student without employment, unpaid leave, home duties, charity work).
*Note: full time employment and part time employment have been collapsed into one category (any employment), therefore there is no longer a category 2.

3.4.2 Definitions of intervention/trial-level characteristics

For all intervention/trial-level subgroups, the reference group will be the largest group (by number of trials), except where categories are combined.

Intervention category codes were determined as part of the TOPCHILD Intervention Coding Project,[3] based on published and unpublished intervention materials and validation meetings with trial representatives.

Intervention delivery mode (individual vs group)

Data type:

> Categorical

Definition:

Whether the intervention delivery is to a participant as individual-based mode, group-based mode, or both group and individual components. Mode of delivery coded to the Human Behaviour Change Project Mode of Delivery Ontology.
Mode of delivery will be categorised as:
1 = Individual
2 = Group
3 = Both Individual and Group

Intervention delivery mode (any face-to-face component)

Data type:

> Categorical

Definition:

Whether the intervention included any face-to-face component, categorised as:
1 = face-to-face (yes)
2 = no face-to-face (no)

Intervention setting

Data type:

> Categorical

Definition:

The broad category of settings where the intervention is delivered. Settings coded to the Human Behaviour Change Project Intervention Setting Ontology (sub-level 3 codes). Settings will be categorised as:
1 = at home, i.e. residential only
2 = out of home, i.e. healthcare facility, educational facility, community facility, or research facility
3 = both at home and out of home

Intervention dose/intensity

Data type:

> Continuous

Definition:

Estimate of the total minutes of intervention delivery intended to be received by participants. This estimate does not include time for data collection or factor in intervention adherence.

Notes:

If a range is provided, the middle point of the range will be used.

Fidelity

Not assessed due to insufficient variation in data (all but one trial had a fidelity protocol planned and/or implemented). This decision was made prior to any analyses.

Timing of intervention onset

Data type:

> Categorical

Definition:

Whether the intervention commenced preconception, antenatally (during pregnancy) or postnatally (after birth), categorised as:
1 = preconception
2 = antenatal
3 = postnatal

Timing of intervention completion

Data type:

> Continuous

Definition:

Intended age that last intervention received (calculated from age of enrolment (IPD) and intervention duration (coding)

Country / Current level of background care in the community: Human Development Index

Data type:

> Continuous

Definition:

Country in which the carers were recruited and current level of background care in the community are captured by this comprehensive measure that allows continuous data to be incorporated into analysis. Human Development Index (HDI) - https://hdr.undp.org/data-center/human-developmentindex#/indicies/HDI. Note that for multinational trials this will be a site-level characteristic, not trial-level.

Behavioural ± other intervention type

Not assessed due to insufficient data; only one trial had an additional non-behavioural intervention component. This decision was made prior to any analyses.

3.5 Covariates

Table 5 lists covariates/prognostic factors that may potentially be used for descriptive or post-hoc analyses. They may also be used to assess and potentially control for confounding factors within and between trials, but they will not be used to assess treatment differences by subgroups.

Table 5. Covariates[1]

Covariates	Analysed in first cycle
Individual-level	
Birth length	Yes
Child's age at final assessment	No (not a baseline variable)
Any childcare attendance	Yes
Any informal childcare attendance	Yes
Infant's age at enrolment	Yes
Maternal age	Yes
Maternal diabetes (type 1, type 2, gestational)	Yes
Maternal gestational weight gain	Yes
Mode of delivery at birth	Yes
Smoking during pregnancy	Yes
Multiple pregnancy	Yes
Small for gestational age	Yes
Appropriate for gestational age	Yes
Large for gestational age	Yes
Intervention adherence	No (insufficient data available; available data very heterogeneous)

[1] *Note: covariates that will not be assessed in the first cycle (but were included in the published protocol) are in grey text.*

3.5.1 Definitions of individual-level covariates

Birth length

Data type:

> Continuous

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

Infant length at birth in centimetres.

Included trials:

Analysed in all that started after birth (i.e. excluding those that commenced pre-conception or antenatally (during pregnancy).

Any childcare attendance

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoints:

> 0-12 months of age
> >12 months to 24 months of age

Definition:

Any childcare: Attendance at any type of formal or informal childcare on a regular basis

Any formal childcare attendance

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoints:

> 0-12 months of age
> >12 months to 24 months of age

Definition:

Formal childcare: Attendance at any type of formal childcare on a regular basis. Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool, etc.

Any informal childcare attendance

Data type:

> Binary (yes/no)

Unit of analysis:

> Child

Timepoints:

> 0-12 months of age

> >12 months to 24 months of age

Definition:

Informal childcare: Attendance at any type of informal childcare on a regular basis. Informal childcare includes non-centre-based care, e.g. grandparents, other relatives, friends, neighbours, nanny, babysitter, etc.

Infant's age at enrolment

Data type:

> Continuous

Unit of analysis:

> Infant

Timepoint:

> Enrolment

Definition:

Infant age in weeks at point of enrolment into original study; NA if during pregnancy.

Maternal/birthing parent age

Data type:

> Continuous

Unit of analysis:

> Mother/birthing parent

Timepoint:

> At birth of child

Definition:

Age of mother/birthing parent in years at birth of child.

Maternal/birthing parent type 1 diabetes

Data type:

> Binary (yes/no)

Unit of analysis:

> Mother/birthing parent

Timepoint:

> Baseline

Definition:

Whether the birthing parent had type 1 diabetes at baseline

Maternal/birthing parent type 2 diabetes

Data type:

> Binary (yes/no)

Unit of analysis:

> Mother/birthing parent

Timepoint:

> Baseline

Definition:

Whether the birthing parent had type 2 diabetes at baseline

Maternal/birthing parent gestational diabetes

Data type:

> Binary (yes/no)

Unit of analysis:

> Mother/birthing parent

Timepoint:

> During pregnancy

Definition:

Whether the birthing parent experienced gestational diabetes (during pregnancy)

Maternal/birthing parent gestational weight gain

Data type:

> Continuous

Unit of analysis:

> Mother/birthing parent

Timepoint:

> From conception to birth

Definition:

Difference between weight at conception and weight at birth in kilograms.

Mode of delivery at birth

Data type:

> Categorical

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

1 = Vaginal

2 = Caesarean

Smoking during pregnancy

Data type:

> Binary (yes/no)

Unit of analysis:

> Mother/birthing parent

Timepoint:

> Pregnancy

Definition:

Whether the mother ever smoked during pregnancy.

Multiple pregnancy

Data type:

> Binary (yes/no)

Unit of analysis:

> Infant

Timepoint:

> Pregnancy

Definition:

As recorded by trials, categorised as:
1 = yes, multiple pregnancy
2 = no, singleton pregnancy

Small for gestational age

Data type:

> Binary (yes/no)

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

Infant <10th percentile, based on weight in grams at birth and gestational age, calculated using Intergrowth charts.[21]

Included trials:

All that started after birth

Appropriate for gestational age

Data type:

> Binary (yes/no)

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

Infant ≥10th percentile or ≤90th percentile, based on weight in grams at birth and gestational age, calculated using Intergrowth charts.[21]

Included trials:

All that started after birth

Large for gestational age

Data type:

> Binary (yes/no)

Unit of analysis:

> Infant

Timepoint:

> Birth

Definition:

Infant >90th percentile, based on weight in grams at birth and gestational age, calculated using Intergrowth charts.[21]

Included trials:

All that started after birth

Child's age at final assessment

Not assessed given lack of clinical interpretation (not a baseline variable). This decision was made prior to any analyses.

Intervention adherence

Not analysed as the majority of included trials did not collect this outcome. For those that did, data collection was very heterogeneous. This decision was made prior to any analyses.

4 Data analysis

4.1 Analysis population

Analyses of each outcome will follow the intention-to-treat principle and include all randomised infant-parent/caregiver dyads for which data are available, including those that were excluded from the original study analysis. Only trials that commenced prior to outcome collection will be included in each outcome analysis (e.g. trials commencing after 6 months of age will not be included in the 'breastfeeding at 6 months' analysis since this variable constitutes a baseline variable in these specific trials and not an outcome).

4.2 Descriptive analysis

We will plot and tabulate the following:

- Baseline characteristics of infants and parent/caregivers
- Distribution of primary outcome
- Relationship between primary outcome and key covariates

4.3 Decision on whether to include aggregate data

For some trials, individual participant data will not be available. This will apply to investigators who do not respond to or decline our requests for data sharing, or (particularly for older studies) where data are no longer available. For these trials only published aggregate data will be available. Unfortunately, aggregate data limits the capacity to perform more complex analyses (e.g. adjust for covariates and examine effect modification). Furthermore, previous studies suggest that trials for which IPD are not shared tend to be of lower quality, have a higher risk of bias, have compromised data integrity, and employ less appropriate analysis procedures compared to those that do share their IPD.[9 10] As per our published protocol,[8] we plan to combine IPD and aggregate data (AD) from publications in the meta-analysis, where possible, unless there are indications of systematic differences between the provided IPD and the extracted AD, pointing toward bias/ lower quality of AD. We will assess whether there are systematic differences between IPD and AD considering multiple domains[9] as follows:

Firstly, we will consider the proportion of data omitted if AD data are excluded from analyses, and the types of analyses not possible with the extracted AD. We will conduct a power analysis to evaluate whether extracting the additional AD may be impactful. Here we will also consider the trade-off between the inclusion of AD limiting the ability to conduct subgroup analyses and adjust for covariates vs the additional data gained. Next, we will compare the baseline and study characteristics of IPD and AD to assess whether they differ systematically. The baseline variables examined will be maternal baseline (pre-pregnancy) BMI, time of intervention onset (preconception, during pregnancy, infant baseline age (before or after age 6 months)), carer age, and education status. The study characteristics examined will be sample size and year. Both baseline and study characteristics will be compared using descriptive statistics, e.g. the appropriate measure of central tendency and variability, proportions and number. These checks will ensure that IPD and AD are representing comparable populations. In addition, we will compare risk of bias across IPD and AD studies, and potential integrity issues that were insufficient to exclude a trial completely.

We will compare treatment effect estimates across IPD and AD for the intervention groupings assessed in the meta-analysis for the primary outcome BMI z-score at age 24 months (±6 months) using meta-analysis and forest plots with no adjustment for prognostic factors. We will conduct subgroup analyses on whether IPD are available or not. Outcome estimates will be calculated, and split based on the dummy coded variable IPD supplied (yes/no), pooled in a two-stage common effect meta-analysis. Pooled estimates and heterogeneity will be compared graphically by examining forest plots and statistically by applying interaction terms. Due to low power of such subgroup analyses, a significance threshold of $p<0.1$ will be regarded as evidence for systematic differences between IPD and AD.

In addition, we will examine the key outcome BMI z-score at age 24 months (±6 months) for systematic differences between IPD and AD using contour-enhanced funnel plots. For this outcome we will produce two separate funnel plots, one for trials that provided IPD and one for trials for which AD were extracted. Differences in asymmetry will be visually evaluated using the funnel plots. They will be further quantified by dummy coding the data as IPD supplied (yes/no) and comparing whether the regression estimates taken from Egger's test (effect estimate as predicted by standard error

weighted by the inverse variance) significantly differ when introducing IPD supplied as an extra predictor. A significant main effect (intercept difference between groups) or interaction effect (slope difference between groups) indicates systematic differences between IPD and AD.

The final decision about whether to include AD or not is a multi-factor decision based on the items outlined in table 6, with particular emphasis put on systematic bias.

Table 6. Checklist of pre-specified criteria to compare studies with IPD and with only AD based on Seidler et al (2023)[9]

Checklist		
Item	**Description**	**Explanation**
Data availability	Proportion of missing values for primary outcome if only IPD are included.	Number of trials or overall sample size often misleading, since not all trials have primary outcome data available.
Statistical methods	Statistical methods used to derive AD sufficiently comparable to IPD	E.g. controlling for same covariates/ confounders, linear or logistical regression methods
Baseline characteristics	Differences between key baseline characteristics IPD vs AD	Identify whether IPD and AD studies assessed comparable populations
Study characteristics	Differences between key study characteristics	Systematic differences between the types of studies providing data (e.g. study year, size)
Effect size	Differences in effect size for key prespecified outcome (meta-regression, visual inspection of forest plots & contourenhanced funnel plots)	Major differences in effect sizes may point toward bias or different underlying populations
Risk of bias	Differences in risk of bias IPD vs AD	Assess and compare risk of bias for primary outcome, applying standard risk of bias tool (e.g. Cochrane ROB 2 for RCTs)
Trustworthiness	Differences in trustworthiness assessments IPD vs AD	Perform integrity checks to compare trustworthiness of included studies
Overall decision	**Do concerns about AD outweigh data availability concerns?**	**Overall assessment across categories, and severity of concerns**

4.4 Meta-analysis

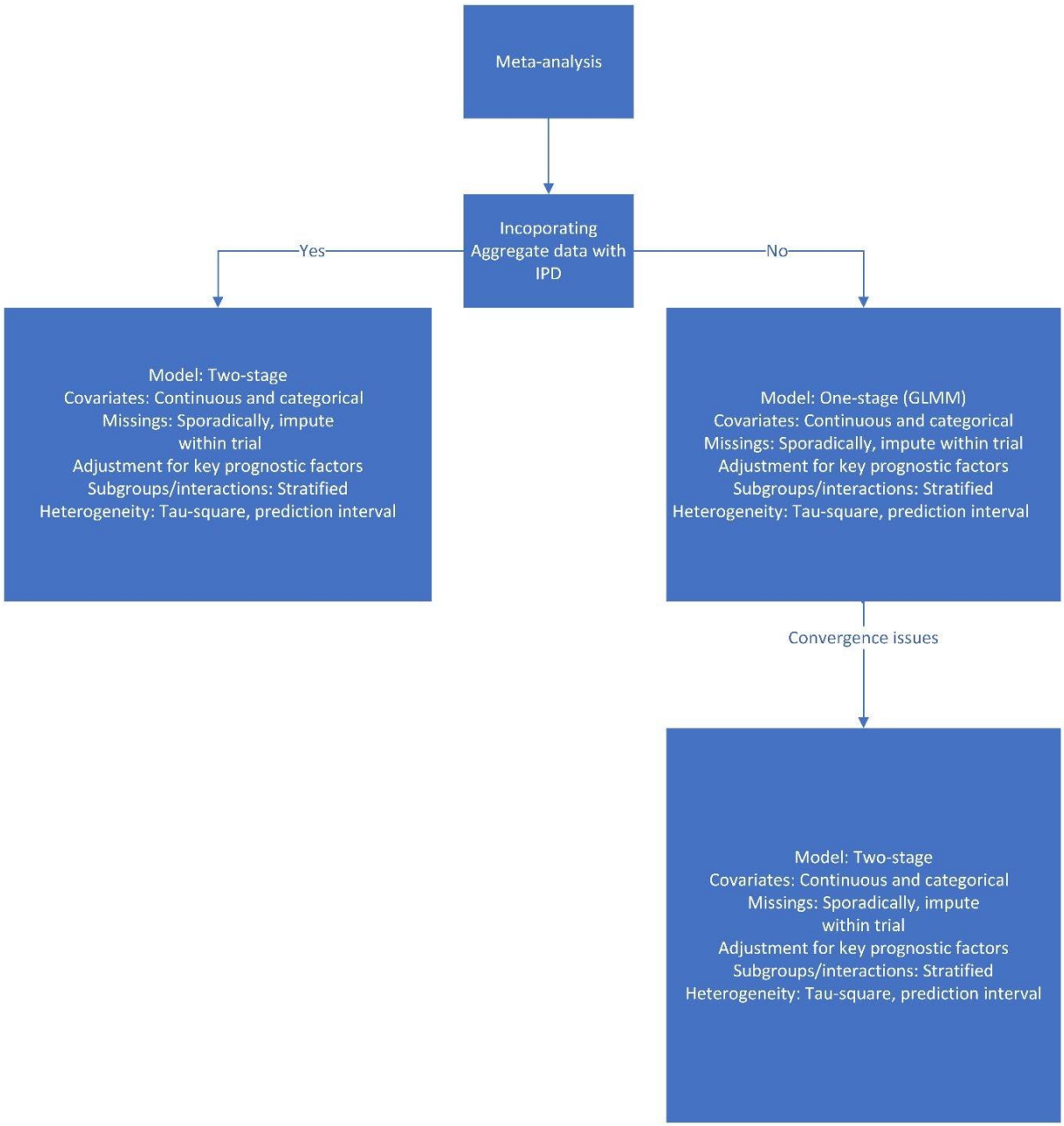


Figure 2. Model choice depending on inclusion of aggregate data and convergence issues.

Analyses will include all randomised participants for which data are available (including post-randomisation exclusions, where possible), and the primary analyses will be based on intention-to-treat. For child outcomes including the primary outcome, the unit of analysis will be the individual child; for carer outcomes, the unit of analysis will be the carer. We will perform different types of analyses depending on whether AD are included (see decision criteria above) or not, and whether convergence issues arise or not as illustrated in Figure 2 and described below.

4.4.1 Scenario 1 – analyses with IPD and AD combined

We will be calculating 2-stage models to combine IPD and AD, since a 1 stage model with hierarchical related regression (originally proposed for this analysis) does not allow adjustment for continuous covariates, and complicates imputation for missing data as outlined below. In the first stage a generalised mixed effect model (GLMM) will be employed with a nested random effect within each trial to take into account the correlation between outcomes resulting from cluster randomisation. If there are substantial numbers of multiple births (e.g. twin pregnancies) for which both children were included (>10%), we will adjust for clustering among multiple births by fitting a random intercept for each multiple cluster. We will consider the treatment effect as random effects in our main meta-analysis models.

4.4.2 Scenario 2 – analyses only including IPD

For each outcome, a one-stage approach to analysis will be employed to include IPD from all eligible trials in a generalised linear mixed model (GLMM). The key prognostic factors sex and maternal weight status (pre-pregnancy BMI) will be adjusted for as stratified effects as recommended by Riley & Debray, [22] or if there are convergence issues they will be adjusted for as random effects. Variation across trials will be accounted for within the model by including a stratified trial intercept, other non-treatment variables such as prognostic factors and residual variances will also be stratified by trial. If convergence issues arise, the treatment intercept and other non-treatment variables will be made random to reduce model complexity. For continuous outcomes Residual Maximum Likelihood (REML) estimation will be applied; for binary, ordinal and count outcomes Maximum Likelihood (ML) estimation will be applied (instead of pseudo-REML since small trials in terms of participants and outcome events are anticipated). As recommended by Riley et al,[22] trial-specific centring of the treatment variable and any covariates/prognostic variables will be applied, when using ML estimation. Nested random intercepts within trials will be added to take into account correlations between outcomes resulting from cluster randomisation. If there are substantial numbers of multiple births (e.g. twin pregnancies) for which both children were included (>10%), we will adjust for clustering among multiple births by fitting nested random intercepts for each multiple cluster. If no events are recorded in a trial for either control or treatment group for an outcome, data will not be included for this study for this outcome as recommended by Riley et al.[22] If our model does not converge, we will resort to a 2-stage approach as discussed in Scenario 1, but still only including IPD.

4.4.3 Treatment effect estimates, both scenarios

Appropriate outcome distributions and link functions will be chosen dependent on outcome type. For example, binomial with log link will be used to estimate risk ratios for binary outcomes (if risk ratios don't converge, odds ratios with logit link will be considered), and Gaussian with identity link for mean differences, and count outcomes will be analysed using a Poisson distribution and log link. The results of all comparative analyses will be presented using appropriate estimates of treatment effect along with 95% CIs and two-sided p values. Due to potential multiplicity issues, we will assess and interpret any emphatic evidence for systematic differences instead of single significant results.

4.4.4 Heterogeneity

Heterogeneity will be explored through examining Tau^2, the variance between studies. It will also be examined through 95% prediction intervals which indicate the interval in which an *individual* future trial mean will likely occur given the heterogeneity. If excessive statistical heterogeneity across treatment effects is detected, then the rationale for combining trials will be questioned and the source of heterogeneity explored. The common effect model will be considered as a nested model

without a heterogeneity parameter, in a sensitivity analysIs. Forest plots will be presented by trial for the primary outcome, and for any secondary outcomes where there is evidence of heterogeneity across trials. We will explore possible sources of heterogeneity, see Section 4.5 below.

4.4.5 Missing data

Primary outcome

To understand the patterns of missing data, baseline data for participants with BMI z-score at age 24 months (±6 months) (primary outcome) available, will be compared to baseline data for participants for whom the primary outcome is not available across trials, by looking at mean, median and standard deviation for continuous baseline variables, and percentages for binary baseline variables.

For the primary outcome, BMI z-score at age 24 months (±6 months), if we have greater than 5% missing, or a covariate-treatment interaction, we will use the principles of Jakobsen et al.[23] to determine whether we will apply complete case analysis (CCA) or multiple imputation. If multiple imputation is the most appropriate approach, we will assume missing at random (MAR) and we will apply a fully conditional specification (FCS) approach, also known as multiple imputation by chained equations (MICE). We will define one regression model that will be applied to each trial and treatment group separately.

Beyond this, care will be taken to ensure congeniality between the analysis model and the imputation model (e.g., clustering, non-linear effects etc). Missing values for variables are initially imputed by using a random sample from the observed data. The imputed values are imputed over themselves multiple times (10-20 cycles) until the results have converged to a stable estimate. If we have less than 20% missing data we will make 20 imputed dataset copies, if we have more than 20% missing data, the number of dataset copies will be the same as the percentage of missing participants. FCS will be applied with the *mice* package within the R computing environment.

Analyses will be applied to each imputed dataset, and the parameter estimates combined using Rubin's rules. If we revert to a two-stage model due to convergence issues, we will pool the imputed datasets with Rubin's rule and then combine estimates in the second stage. If we cannot get the MICE model to converge, we will use joint imputation and the *jomo* package to perform multiple imputation. If large proportions (>40%) of data are missing within a trial, this trial will be excluded from the primary analysis and included in a sensitivity analysis with complete case analysis to probe whether trials with high missingness influence our estimates.

Covariates

For case-wise missing covariates, where possible, we will perform mean imputation to any relevant pre-randomisation covariate data when there are no theoretical grounds to believe the variable interacts with treatments, and it is not being investigated in an interaction analysis. When applied to missing randomised controlled trial data, mean imputation can be a valid approach for baseline covariates that are used for adjustment.[24-26] In these instances, mean imputation is recommended due to being computationally more efficient than multiple imputation. Because mean imputation reduces the variance of the covariate, any descriptive reporting of the covariate distribution will be based on the original data without mean imputation.

For any follow-up variables, we will examine what proportion of infants for whom a follow-up assessment was planned were missing (since some trials only planned to follow-up some of their participants e.g. only certain centres). We will examine the baseline patterns of infants for whom follow up data were collected by looking at mean, median and standard deviation for continuous baseline

variables, and percentages for binary baseline variables. Significance tests between baseline variables across treatment categories will be performed. We will also use any imputed follow-up

data in sensitivity analyses to examine whether we have an indication the data may be 'missing not at random' (MNAR).

4.5 Subgroup analyses

The size of the treatment effect may differ by certain characteristics of either the individual (i.e. the infant, parent or caregiver) or the way the intervention was delivered. This will be explored by subgroup analyses of the following characteristics.

Individual-level characteristics:

- Birth weight
- Any formal childcare attendance
- Gestational age at birth
- Partner status
- Maternal/birthing parent weight status
- Parity/first-time parent
- Parent/carer immigration status
- Sex
- Socioeconomic position – household income
- Socioeconomic position – carer education
- Socio-economic position – carer employment status

Intervention/trial-level characteristics:

- Intervention delivery mode (individual vs group)
- Intervention delivery mode (any face-to-face component)
- Intervention setting
- Intervention dose/intensity
- Timing of intervention onset
- Timing of intervention completion
- Country / Current level of background care in the community

Subgroup analyses will only be undertaken on the primary outcome using trials with individual participant data available (regardless of whether AD are included in the main analyses). Any differences in treatment effect between pre-specified subgroups will be assessed by testing a treatment-by-covariate interaction term within the model. To avoid aggregation bias, models will be stratified by trial, with common effects placed on the within trial interaction. To visualize the data, we will summarise the treatment effects in the form of a meta-analysis for each subgroup (subject to aggregation bias) in forest plots. This will be accompanied with the estimate of the interaction, pooled in a random effects model based on each within trial interaction as described above. Again, if models do not converge we will revert to a two-stage model. Meta-regression will be employed to examine intervention/trial-level characteristics, if possible.

4.6 Sensitivity analyses

The following sensitivity analyses will be performed for the primary outcome, where possible:

- Two-stage approach

- Including IPD only, if AD included in the main analysis, or combining IPD and AD if only IPD are included in the main analysis
- Excluding trials with a high risk of bias for sequence generation and/or allocation concealment and/or loss to follow-up
- Excluding trials with some integrity concerns, but where these concerns are not sufficient to warrant exclusion from the meta-analysis entirely
- 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 (i.e. aims and objectives, hypotheses, eligibility criteria, main outcomes, subgroup and sensitivity analyses) were initially agreed in December 2020
- Excluding trials with a significant conflict of interest (e.g. funded by industry)
- The impact of missing data on conclusions about the intervention effect (if appropriate)
- Excluding trials with low levels of intervention adherence/attendance (trial-level)

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.

Additionally, the following sensitivity analyses will be performed for key secondary outcomes, as indicated, where possible:

- Excluding data from trials where continuous estimates have been converted from categorical data; will be considered where >40% were converted from categorical data, for the following key secondary outcomes: duration of exclusive breastfeeding, vegetable intake per day, self-reported physical activity, screen time, combined sleep duration

4.7 Additional analyses

All outcomes listed in section 3, to be assessed at the following timepoints, where data are available, and where considered relevant by the collaboration:

1. 6 months of age ± 1 months
2. 12 months of age ± 3 months
3. 48 months of age ± 12 months
4. 60 months of age or beyond

There are a range of additional analyses we are looking to answer using the TOPCHILD dataset. Some of these include:

- Examining associations between intervention components and effectiveness
- Analysis of primary outcomes based on an as treated analysis
- Causal mediation model exploring some selected variables, e.g. household composition, socioeconomic position

Some of these analyses may only be feasible to undertake after the publication of primary results (i.e.

they may be performed and published at a later stage).

4.8 Statistical inference

Statistical tests will be two-sided and performed using a 5% level of significance, unless otherwise specified. There will be no adjustment for multiple comparisons. Due to potential multiplicity issues, we

will assess and interpret any emphatic evidence for systematic differences instead of single significant results. The primary analyses will use the intention-to-treat population.

Appendix A. Outcomes, subgroups, and covariates that will not be analysed in cycle 1

Outcomes

The following pre-specified outcomes will not be reported on as insufficient data are available to perform analyses, or the outcome(s) are no longer applicable. These decisions were made prospectively prior to data analysis.

Outcome	Comment
BMI z-score (child) at age 48 months (±12 months) and beyond 60 months of age	follow-up outcomes to be assessed in subsequent cycles
Percent fat content/adiposity/skinfold thickness at age 24 months (±6 months)	insufficient data at this timepoint
Abdominal circumference	a priori decision to use waist circumference instead
Velocity of weight gain at age 24 months (±6 months)	insufficient data
Weight-for-length	a priori decision not to analyse due to little added value
Per cent excess BMI >95th percentile	a priori decision not to analyse due to little added value
Adiposity rebound at age 24 months (±6 months)	insufficient data
Combined fruit and vegetables consumed per day at age 24 months (±6 months)	outcome is redundant since we have fruit intake and vegetable intake data available separately
Device assessed physical activity at age 24 months (±6 months)	insufficient data
Parent physical activity practices	not targeted by most interventions
Parent sleep practices	not targeted by most interventions
Parent stress	not targeted by most interventions, heterogeneity

Covariates and Subgroups

The following covariates/subgroups will not be assessed as insufficient data are available to perform analyses or for other reasons as specified. These decisions were made prospectively prior to data analysis.

Individual-level	Comment
Household composition	Not enough trials collected this information to perform analyses.
Race/ethnicity	Data are too heterogenous to harmonise
Intervention/trial-level	**Comment**
Fidelity (protocols)	not enough variation in data
Intervention adherence	insufficient data available; available data very heterogeneous

Behavioural ± other intervention type	insufficient data; only one trial had an additional non-behavioural intervention component

Appendix B. Data Coding Form

TOPCHILD

Transforming Obesity Prevention for CHILDren

Data coding form

Instructions

1. If possible, please use the suggested coding below when submitting your trial data.
2. Please provide data for EVERY participant randomised, including those excluded after randomisation.
3. If you cannot provide data for a variable in the format suggested, please provide data for that variable in whatever format you have available, AND make sure you provide your coding/data dictionary/case report forms (CRFs)/ questionnaire(s) so it is clear what it means.
4. Note that you do not need to have collected every variable in this form. Please simply provide data for all variables that you have collected in this form.
5. Where applicable, or for variables marked with an asterisk (*), please provide the definition, measure and/or coding used in your trial in the accompanying 'Data provision form', which includes illustrative examples.
6. Datasets can be provided in long or wide format, depending on your preference.

STUDY LEVEL DATASET		
Variable name	**Description**	**Suggested coding**
rand_unit	Unit of randomisation used *If 'other', provide information in rand_unit_other variable below*	1=individual/family, or carer/child dyad 2=cluster (e.g. health centre) 3=other
rand_unit_other	Brief description of the unit of randomisation used	Free text
country1	Country/ies of recruitment *If >1 country, provide as separate variables, i.e. country2, country3, etc.*	Free text
mult_eligible	Were multiples (e.g. twins or triplets) eligible for your study?	1=yes, multiples were eligible 2=no, only singletons were eligible
n_families	Number of families or carer/child dyads included in your study	Number (integer)
n_child	Number of children included in your study *Only required if multiples were eligible, or if different to number of families*	Number (integer)
mult_carers	Did your study allow more than 1 carer to be enrolled per child? *If yes, provide mult_carers_n variable below*	0=no; 1=yes
mult_carers_n	Maximum number of carers that could be enrolled per child	Number (integer)
enrol_start	Date of first participant enrolment	dd/mm/yyyy
enrol_end	Date of last participant enrolment	dd/mm/yyyy
consent	Describe consent/assent procedures, e.g. informed consent, waiver of consent	Free text
group1	Provide your trial's classification or brief description of intervention group 1, e.g. Breastfeeding advice, sleep advice, etc. *If > 1 intervention group, describe under variables group2, group3, etc.*	Trialist classification* (if available) or free text
control	Provide your trial's classification or brief description of control group, e.g. usual care	Trialist classification* (if available) or free text
background_care	Describe level of background care in the community at the time the trial was conducted, e.g. expected number of health contacts between birth and 1 year, expectation of attending prenatal programs (yes/no), etc. *If >1 recruitment community, provide separate descriptions for each and label accordingly, e.g. background_care_Aus, background_care_UK, etc.*	Free text
fund_ind	Has your trial received any commercial/industry funding? *If 'yes', specify in fund_ind_name variable below*	0=no; 1=yes
fund_ind_name	Specify the name(s) of the commercial/industry funding source(s)	Free text
fund_gov	Has your trial received any government funding? *If 'yes', specify in fund_gov_name variable below*	0=no; 1=yes
fund_gov_name	Specify the name(s) of the government funding source(s)	Free text

fund_hosp	Has your trial received any hospital funding? *If 'yes', specify in fund_hosp_name variable below*	0=no; 1=yes
fund_hosp_name	Specify the name(s) of the hospital funding source(s)	Free text
fund_char	Has your trial received any charitable funding? *If 'yes', specify in fund_char_name variable below*	0=no; 1=yes
fund_char_name	Specify the name(s) of the charitable funding source(s)	Free text
fund_uni	Has your trial received any university funding? *If 'yes', specify in fund_uni_name variable below*	0=no; 1=yes
fund_uni_name	Specify the name(s) of the university funding source(s)	Free text
fund_other_name	Specify any other funding sources not mentioned above	Free text
int_lang1	Indicate the language(s) the intervention is delivered in for group 1 *If >1 intervention group, provide as separate variables, e.g. int_lang2, etc.*	Free text
COVID_timing	Indicate when your trial was conducted relative to onset of the COVID-19 pandemic (declared by WHO in March 2020) *If 'other', provide information in COVID_timing_other variable below*	1=recruitment, intervention delivery, and follow-up completed prior to pandemic 2=intervention delivery (but not followup) completed prior to pandemic 3=intervention delivered partly before and partly during pandemic 4=intervention delivered entirely during pandemic 5=other, please specify
COVID_timing_other	Brief description of timing of your trial relative to the pandemic	Free text
COVID_int	Did you need to modify your trial's intervention due to the COVID-19 pandemic? *If yes, provide information in COVID_int_text variable below*	0=no; 1=yes
COVID_int_text	Brief description of how the intervention was modified	Free text
COVID_other	Brief description of any other impacts of the COVID-19 pandemic on your trial, e.g. due to lockdown, food insecurity, etc.	Free text

CHILD DATASET

Variable name	**Description**	**Suggested coding**
family_ID	Unique family identifier used within your trial	Anonymised, can be character or number format
child_ID	Unique child identifier used within your trial	Anonymised, can be character or number format
child_carer	How many carers were enrolled in the trial for this child?	Number (integer)
centre	Unique identifier for study centre in which randomisation occurred *If there was only 1 study centre in your trial, code all participants the same*	Trialist classification* (if available) or free text
enrol_cat	At which stage did participant enrolment occur?	1=pre-conception 2=antenatal/during pregnancy 3=postnatal/after birth
child_dob	Child date of birth	dd/mm/yyyy
GA_weeks	Gestation at birth, using best estimate (weeks) *Enter completed weeks here and additional days in the next variable GA_days, (e.g. if born at 36^{4} weeks, enter 36 here and 4 for GA_days)*	completed weeks
GA_days	Gestation at birth, using best estimate (days)	additional days
GA_term	Was the baby born at or beyond term, i.e. ≥37 weeks' gestation? *Only required if GA_weeks & GA_days variables are unknown/not provided*	0=no; 1=yes
child_age_enrol	Child's age at enrolment *If enrolment occurred pre-conception, enter 'NA'* *If enrolment occurred during pregnancy, enter 'NA' and complete GA_enrol below*	in weeks
GA_enrol	If enrolled during pregnancy, provide gestational age at enrolment	in weeks
sex	Infant sex	1=male; 2=female; 3=ambiguous/other
ethnicity	Ethnicity/race of child (or parents if not available for child)	Trialist classification* (if available) or free text
birthweight	Infant weight at birth	in grams
birthlength	Infant length at birth	in cm
SGA	Was the infant small for gestational age? (*As defined in your trial**)	0=no; 1=yes

LGA	Was the infant large for gestational age (*As defined in your trial**)	0=no; 1=yes
child_devel	Does the child have any development delay, congenital anomaly or physical impairment? e.g. cerebral palsy, deafness, club foot. *If 'yes', specify condition below*	0=no; 1=yes
child_devel_type	Provide name(s) of development delay, congenital anomaly, physical impairment	Free text
group	Indicate to which group the participant was allocated	group1; group2; control; etc.
child_age_final	Child's age at final assessment	in months
care_infant	Did the child attend any type of formal or informal childcare on a regular basis between **age 0-12 months?**	0=no; 1=yes
care_child	Did the child attend any type of formal or informal childcare on a regular basis between **age >12 months to 5 years**?	0=no; 1=yes

care_infant_formal	Did the infant attend any type of **formal** childcare on a regular basis between age **0-12 months?** Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool	0=no; 1=yes
care_child_formal	Did the child attend any type of **formal** childcare on a regular basis between **age 12-24 months?** Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool	0=no; 1=yes
care_infant_informal	Did the infant attend any type of **informal** childcare on a regular basis between **age 0-12 months?** Informal childcare includes non-centre based care, e.g. grandparents, other relatives, friends, neighbours, nanny, babysitter	0=no; 1=yes
care_child_informal	Did the child attend any type of **informal** childcare on a regular basis between **age 12-24 months?**. Informal childcare includes non-centre based care, e.g. grandparents, other relatives, friends, neighbours, nanny, babysitter	0=no; 1=yes
OUTCOMES		
Please provide outcomes at <u>any timepoints</u> you have collected them. Indicate multiple measurements/timepoints by numbering the variables, e.g. weight1, weight2, etc. For each outcome, please also indicate age/timepoint of collection as a separate variable, e.g. weight1_age, weight2_age, etc.		
weight	Child weight	in kilograms
weight_age	Age at measurement of above variable weight	in months
weight_method	Type of method used to collect weight-related outcome data	1=clinic/research-based measures 2=parent/carer self-reported
weight_text	Description of methods used to collect weight-related outcomes	Free text and/or excerpt from publication
length	Child length (up to <24 months of age)	in cm
length_age	Age at measurement of above variable length	in months (should be <24)
height	Child height (≥24 months of age)	in cm
height_age	Age at measurement of above variable height	in months (should be ≥24)
ZBMI	Child body mass index z-score (also known as weight-for-length/height zscore) *Using 2006 WHO growth standards*	numeric (decimal)
ZBMI_age	Age at measurement of above variable ZBMI	in months
BMI	Child body mass index	in kg/m^2
BMI_age	Age at measurement of above variable BMI	in months
waist	Child waist circumference	in cm
waist_age	Age at measurement of above variable waist	in months
WHR	Child waist-to-height ratio (waist circumference divided by height)	numeric (decimal)
WHR_age	Age at measurement of above variable WHR	in months
adiposity	Child body fat percentage (*As defined/measured in your trial**)	%
adiposity_age	Age at measurement of above variable adiposity	in months
overweight	Child overweight *For children <5 years of age: defined as body mass index z-score of > 2 standard deviations above the WHO reference* *For children aged 5-19 years: defined as BMI-for-age > 1 standard deviations above the WHO Growth Reference median*	0=no; 1=yes
overweight_age	Age at measurement of above variable overweight	in months

obesity	Child obesity *For children <5 years of age: defined as body mass index z-score of > 3 standard deviations above the WHO reference* *For children aged 5-19 years: defined as BMI-for-age > 2 standard deviations above the WHO Growth Reference median*	0=no; 1=yes
obesity_age	Age at measurement of above variable obesity	in months
bf_any	Has the infant ever received breast milk? Definition includes expressed milk and milk sourced from Milk Bank. We are interested in whether infant ever received any breast milk (not whether the mother breastfed) If responded no to 'ever breastfed' at 1 month onwards, it is safe to assume the baby will most likely never be breastfed. Note: binary data (1=yes, 0 = no) provided under the previous definition is acceptable, no transformation is needed	0=no; 1=yes
bf_any_age	Age at measurement of above variable bf_any	in months
bf_duration	Duration of any breastfeeding Note: age stopped breastfeeding can be used as a proxy for breastfeeding duration, i.e. assume bf started at (or close to) birth and that it occurs continuously.	in weeks
bf_duration_age	Age at measurement of above variable bf_duration	in months
bf_exclusive	Duration of exclusive breastfeeding (*As defined in your trial**) Use WHO definition of exclusive breastfeeding: Exclusive breastfeeding is defined as giving no other food or drink – not even water – except breast milk. It does, however, allow the infant to receive oral rehydration salts (ORS), drops and syrups (vitamins, minerals and medicines). OR trial definition where WHO is not available	in days If trial collected this outcome at multiple timepoints, go with the last time they say 'yes'

bf_exclusive_age	Age at measurement of above variable bf_exclusive	in months
diet_method	Method used to assess dietary intake of fruit, vegetables, EDNP and SSB	1=Food Frequency Questionnaire (FFQ) 2=24-hr recall 3=Food diary 4=Other
energy_kj	Energy intake per day in kilojoules (*As defined/measured in your trial*) Not required if energy_calorie is provided below*	in kj/day
energy_kj_age	Age at measurement of above variable energy_kj	in months
energy_cal	Energy intake per day in calories (*As defined/measured in your trial*) Not required if energy_kj is provided above*	in calories/day
energy_cal_age	Age at measurement of above variable energy_cal	in months
fruit	Fruit consumed per day (*As defined/measured in your trial**) Typically includes 100% fruit juice	in grams/day
fruit_cat	Serves of fruit consumed per day (*As defined/measured in your trial**)	0=no serving 1=1 serving 2=2 servings 3=3 servings 4=4 servings 5=5 servings 6=6 servings 7=7 or more servings
fruit_age	Age at measurement of above variable fruit	in months
veg	Vegetables consumed per day (*As defined/measured in your trial**)	in grams/day
veg_age	Age at measurement of above variable veg	in months
fruit_veg	Combined fruit and vegetables consumed per day (*As defined/measured in your trial*) Not required if fruit and veg variables are provided above*	in grams/day
fruit_veg_ age	Age at measurement of above variable fruit_veg	in months

EDNP	Intake of energy dense nutrient poor foods per day (*As defined/measured in your trial*) If this information is collected across multiple variables, please provide all with appropriate labels (e.g. cake, cookies, pastry, etc.) and coding* Includes: foods high in saturated fats, trans-fatty acids, free sugars and/or salt, non-core foods, potato crisps or other salty snacks (such as Twisties or corn chips), savoury snacks (e.g. Jatz, Shapes), cakes, donuts, muffins, sweet biscuits, fruit pies, scones, waffles, pastries, muesli or fruit bars, confectionary such as lollies/sweets/candy, chocolate (bar/block/coated biscuits), ice cream or ice blocks, Pie, pasty or sausage roll, Hot chips or French fries, Takeaway (e.g. McDonalds, KFC, Fish & Chips/Chicken shop), Pre-sugared cereals (e.g. Coco Pops, Fruit Loops) or sugar added to cereal, Cheese and/or cheese spreads, Hot dog/Fritz/Devon/processed meats, Sugar, jam, honey, syrups, Butter or dairy spreads, Margarine "collective name for products that have little nutritional value, but are high in energy, e.g. savoury snacks, sugared drinks, sweets, chocolate, pastries, cakes and ice cream"	in grams/day
EDNP_age	Age at measurement of above variable EDNP	in months
SSB	Intake of sugar-sweetened beverages per day (*As defined/measured in your trial**) *If this information is collected across multiple variables, please provide all with appropriate labels (e.g. juice, squash, etc.) and coding* Includes: fruit juice, cordial, squash, soda, fizzy or soft drinks, sports drinks, flavoured milk, squash, etc.	in ml/day
SSB_age	Age at measurement of above variable SSB	in months
screen	Average time per day in sedentary behaviour in front of a screen *(As defined/measured in your trial*)* May be defined as TV only +/- DVDs, Videos, Games that hook up to TV, Computer games, video games, Computer for other, Handheld console games, e.g. Gameboy, Standard console games, Mobile, smartphone, ipad/tablets, internet, portable and non-portable devices If possible, exclude Movement console games (e.g. WiiTM/Eye Toy/X-Box Kinect)	in minutes/day
screen_age	Age at measurement of above variable screen	in months
restrained	Average time per day restrained while awake (*As defined/measured in your trial**) May include any of the following: in a stroller or pram, In a car seat or capsule, In a cot or bed during the day, In a highchair or other chair, In infant seat, In a baby carrier or sling	in minutes/day
restrained_age	Age at measurement of above variable restrained	in months
PA_report	Self-reported physical activity/play time per day (*As defined/measured in your trial**)	in minutes/day
	Depending on age, may include playing games (peek-a-boo, block building), Being physically active with you (helping them roll, kick legs, move on floor, chasing, crawling, playing ball, dancing, flying & lowering your baby), tummy time, Free to move about, Playing outside or at the park, In a playpen, Walking, Pushing bike, Swimming, light activities (standing up, moving around), more vigorous activities (running, jumping, skipping, hopping, climbing) 'playing time outdoors' should NOT be used as a proxy for PA Similarly, 'time unconfined' should not be used as proxy for PA	
PA_report_age	Age at measurement of above variable PA_report	in months
PA_device	Device assessed physical activity/play time per day (*As defined/measured in your trial**)	in minutes/day
PA_device_age	Age at measurement of above variable PA_device	in months
tummy	Prone play ('tummy time') per day (*As defined/measured in your trial**)	in minutes/day
tummy_age	Age at measurement of above variable tummy	in months
sleep_method	Method used to assess sleep duration	1=questionnaire 2=sleep diary 3=accelerometery 4=other
sleep_day	Sleep duration per day *(i.e. between 7am-7pm or as defined/measured in your trial*)* Include both self-reported and device collected data according to availability	in hours/day

sleep_day_age	Age at measurement of above variable sleep_day	in months
sleep_night	Sleep duration per *night (i.e. between 7pm-7am or as defined/measured in your trial*).* Include both self-reported and device collected data according to availability Can be calculated from time child went to sleep and time they woke, though note limitation: does not include wakings during the night, which are common in young children. Note: 'longest baby has slept in the night without waking' is a different measure and cannot be used for this variable	In hours/night
sleep_night_age	Age at measurement of above variable sleep_night	in months
sleep_combined	Combined duration of day and night sleep, i.e. total sleep per 24 hours	in hours/day
sleep_combined_age	Age at measurement of above variable sleep_combined	in months
wake_night	Frequency of waking during the night (measure of sleep quality)	Number (integer)
wake_duration	Duration of disrupted sleep episodes (measure of sleep quality)	in minutes
wake_age	Age at measurement of above sleep quality variables (wake_night, wake_duration)	in months
solids	Age at introduction of solid foods	in months
adverse_events	Adverse events, e.g. injuries, underweight, infection	Trialist classification* (if available) or free text

PARENT/CARER DATASET

Variable name	**Description**	**Suggested coding**
family_ID	Unique family identifier used within your trial	Anonymised, can be character or number format
rand_date	Date of randomisation	dd/mm/yyyy
carer_ID	Unique parent/caregiver identifier used within your trial	Anonymised, no participant names, can be character or number format
carer_enrolled	Was the carer enrolled as a participant in your trial, or did they only have data collected for some variables, such as demographic information?	0=no, not enrolled, but had data collected for some variables 1=yes, enrolled
primary_carer	Was/is the person the child's primary carer?	0=no; 1=yes
carer_type	Indicate the carer relationship to child *If 'other' is selected, specify the type below in variable 'carer_type_other'*	1=mother 2=father 3=grandparent 4=other
carer_type_other	Specify the type of carer, e.g. step-father, auntie	Free text
carer_dob	Carer's date of birth	dd/mm/yyyy
carer_age_birth	Carer's age at birth of child *Not required if carer_dob & child_dob provided*	in whole years
prev_child	Indicate the number of previous children of the carer	Numeric (integer)
prev_child_cat	Indicate whether the carer is a first time-parent or has other children *Not required if prev_child variable above is provided*	1=first-time parent 2=already has at least 1 other child
multiple	Is/was the current pregnancy a multiple pregnancy?	0=no (singleton); 1=yes (multiple)
GWG	Maternal gestational weight gain (*As defined/measured in your trial**)	in kilograms
T1D	Type 1 diabetes	0=no; 1=yes
T2D	Type 2 diabetes	0=no; 1=yes
GD	Gestational diabetes	0=no; 1=yes
carer_weight	Pre-pregnancy weight	in kg
carer_height	Pre-pregnancy height	in cm
carer_BMI	Pre-pregnancy body mass index *Not required if carer_weight & carer_height variables are provided above*	in kg/m^2
carer_smoking	Any smoking during pregnancy	0=no; 1=yes
income	Total household income per year at baseline/enrolment in trial	(annual median country & year specific household income) – (total household income per year at baseline) ÷ annual median country & year specific household income

household_adults	Number of adults currently living in household *(As defined/measured in your trial*)*	Number
household_children	Number of children currently living in household (including the enrolled child/children) *(As defined/measured in your trial*)*	Number
HIED	Equivalised household income, derived by dividing total household income by an equivalence factor (e.g. the 'modified OECD' equivalence scale, which equals the sum of those in the household, whereby first adult=1 point, each additional person ≥15 years =0.5 points, and each child <15 =0.3 points) *Not required if income, household_adults & household_children variables are provided*	Amount in $AUD, OR using trialist classification* (if available)
partner_status	Partner or relationship status at baseline/enrolment in trial	1 = in a partnership (married, de facto, living with partner) 2 = single (single, divorced and widowed)
carer_education	Carer's highest education level at baseline/enrolment in trial Note: create new numbered variables if this information is available for >1 carer, e.g. carer1_education, carer2_education, etc.	1=Low education (little/no formal education, or some school – but didn't finish high school) 2=High school graduate 3=Non-university tertiary education or qualification or incomplete university 4=University graduate or postgraduate
carer_employment	Carer employment status at baseline/enrolment in trial Note: create new numbered variables if this information is available for >1 carer, e.g. carer1_employment, carer2_employment, etc.	1=Full time employment (including paid leave) 2=Part time employment (including paid leave) 3=Unemployed (includes retired, student without employment, unpaid leave, home duties, charity work)
carer_occupation	Level of carer's most recent occupation, e.g. manager, professional, admin, never employed (*As defined/measured in your trial**)	Using coding below OR trialist classification* OR free text 1=Manager 2=Professional/associate 3=Tradesperson/farmer 4=Clerical, sales and services 5=Labourer 6=Homemaker/housewife 7=Other (including unemployed)
SEP	Any composite or summary measure of socio-economic position/status (*As defined/measured in your trial**) Note: decisions to be made on a case-by-case basis regarding appropriate categorisation. Examples include: Social class Brazil: D-E (low), C (middle), A-B (high) NZ Deprivation Index: 8-10 = Low, 4-7 = Middle, 1-3 = High UK Index of Multiple Deprivation: Deciles 1-3 = Low, 4-7 = Middle, 8-10 = High USA WIC participants = Low	1=Low 2=Medium 3=High
SEI_area	Socio-economic index of area where participant lives, e.g. SEIFA code (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
immigration_status	Was parent/carer born in study country or outside study country? Note: create new numbered variables if this information is available for >1 carer, e.g. Immigration_status_carer1, immigration_status_carer2, etc.	1=parent/carer born in study country 2=parent/carer born outside study country
home_lang	Primary language spoken at home	Free text
lang_prof	Carer language proficiency in national or nationally dominant language, e.g. how well carer in Australia speaks English (*As defined/measured in your trial**)	Using coding below OR trialist classification* OR free text 1=very well 2=well 3=not very well 4=not at all
health_literacy	Carer health literacy (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
SEP_other	Any other measures of socioeconomic position (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
carer_PA	Any measure of carer physical activity in your trial, e.g. average duration of moderate physical activity per week (*As defined/measured in your trial**)	Trialist classification* (if available) or free text

carer_diet	Any measure of carer dietary intake in your trial, e.g. daily energy intake (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
carer_sleep	Any measure of carer sleep practices in your trial, e.g. average sleep duration per night (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
carer_stress	Any measure of carer stress & wellbeing in your trial (*As defined/measured in your trial**)	Trialist classification* (if available) or free text
birth_mode	Mode of delivery at birth of infant enrolled in this trial	1=vaginal 2=Caesarean
contacts_actual	Actual number of intervention contacts/visits	Number (integer)
time_actual	Actual total duration of intervention contacts/visits	in hours
duration_actual	Actual duration over which intervention was delivered	in days
compliance	Other measures of compliance with allocated intervention (*As defined/ measured in your trial**)	Trialist classification* (if available) or free text
restriction	Any measure of restriction as feeding practice	5-point scale
restriction_age	Child age at measurement of above variable restriction	In months
pressure_to_eat	Any measure of pressure to eat as feeding practice	5-point scale
pressure_to_eat_age	Child age at measurement of above variable pressure_to_eat	In months
Food_as_reward	Any measure of food as reward as feeding practice	5-point scale
Food_as_reward_age	Child age at measurement of above variable Food_as_reward	In months
rules_and_limits	Any measure of rules and limits as feeding practice	5-point scale
rules_and_limits_age	Child age at measurement of above variable rules_and_limits	In months
self_efficacy	Parenting self-efficacy	5-point scale
self_efficacy_age	Child age at measurement of above variable self_efficacy	In months
excluded	Was the participant excluded from your analyses? *If yes, please state reason below.*	0=no; 1=yes
reason_excluded	Reason participant excluded	Trialist classification* (if available) or free text

Appendix C. Data validation/logic rules for data processing and cleaning

STUDY-LEVEL VARIABLES				
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**
rand_unit	Unit of randomisation used *If 'other', provide information in rand_unit_other variable below*	1=individual/family, or carer/child dyad 2=cluster (e.g. health centre) 3=other	1 2 3	
rand_unit_other	Brief description of the unit of randomisation used	Free text	Free text	
country1	Country/ies of recruitment If >1 country, provide all variables, i.e. country2, country3, etc.	Free text	Free text	should align with country listed at https://www.iso.org/obp/ui/#search/code/
mult_eligible	Were multiples (e.g. twins or triplets) eligible for your study?	1=yes, multiples were eligible 2=no, only singletons were eligible	1 2	if mult_eligible=2, check that there is no more than one child_ID for each family_ID
n_families	Number of families or carer/child dyads included in your study	Number (integer)	1-20,000	check against n_child, mult_carers and mult_carers_n
n_child	Number of children included in your study Only required if multiples were eligible, or if different to number of families	Number (integer)	1-20,000	check against n_families, mult_carers and mult_carers_n
mult_carers	Did your study allow more than 1 carer to be enrolled per child? If yes, provide mult_carers_n in the next variable	0=no; 1=yes	0 1	If mult_carers_n >1, then mult_carers should =1
mult_carers_n	Maximum number of carers that could be enrolled per child	Number (integer)	2-3	Check corresponds to mult_carers above
enrol_start	Date of first participant enrolment	dd/mm/yyyy	01/01/1996 - xx/xx/2023 (adjust latter depending on cleaning date)	Check correct date format and corresponds to publication/registration record enrol_start should be before enrol_end

enrol_end	Date of last participant enrolment	dd/mm/yyyy	01/01/1996 - xx/xx/2023 (adjust latter depending on cleaning date)	Check correct date format and corresponds to publication/registration record enrol_end should be after enrol_start

STUDY-LEVEL VARIABLES				
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**
consent	Describe consent/assent procedures, e.g. informed consent, waiver of consent, deferred consent	Free text	Free text	
group1	Provide your trial's classification or brief text description of intervention group 1, e.g. Breastfeeding advice, sleep advice, etc. If > 1 intervention group, also describe variables group2, group3, etc.	Trialist classification* (if available) or free text	Free text	if >1 group, each should be clearly distinguishable
control	Provide your trial's classification or brief text description of control group, e.g. usual care	Trialist classification* (if available) or free text	Free text	should be clearly distinguishable from groups
background_care	Describe level of background care in the community at the time the trial was conducted, e.g. expected number of health contacts between birth and 1 year, expectation of attending prenatal programs (yes/no), etc. If >1 recruitment community, provide separate descriptions for each and label accordingly, e.g. background_care_Aus, background_care_UK, etc.	Free text	Free text	if multiple countries of recruitment, ensure a description of background care is available for each
fund_ind	Has your trial received any commercial/industry funding? If 'yes', specify in fund_ind_name variable below	0=no; 1=yes	0 1	Check corresponds to fund_ind_name
fund_ind_name	Specify the name(s) of the commercial/industry funding source(s)	Free text	Free text	only applicable if fund_ind=1

fund_gov	Has your trial received any government funding? If 'yes', specify in fund_gov_name variable below	0=no; 1=yes	0 1	Check corresponds to fund_gov_name
fund_gov_name	Specify the name(s) of the government funding source(s)	Free text	Free text	only applicable if fund_gov=1
fund_hosp	Has your trial received any hospital funding? If 'yes', specify in fund_hosp_name variable below	0=no; 1=yes	0 1	Check corresponds to fund_hosp_name

STUDY-LEVEL VARIABLES				
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**
fund_hosp_name	Specify the name(s) of the hospital funding source(s)	Free text	Free text	only applicable if fund_hosp=1
fund_char	Has your trial received any charitable funding? If 'yes', specify in fund_char_name variable below	0=no; 1=yes	0 1	Check corresponds to fund_char_name
fund_char_name	Specify the name(s) of the charitable funding source(s)	Free text	Free text	only applicable if fund_char=1
fund_uni	Has your trial received any university funding? If 'yes', specify in fund_uni_name variable below	0=no; 1=yes	0 1	Check corresponds to fund_uni_name
fund_uni_name	Specify the name(s) of the university funding source(s)	Free text	Free text	only applicable if fund_uni=1
fund_other_name	Specify any other funding sources not mentioned above	Free text	Free text	check that name provided does not fit in any of the previous categories (industry, government, hospital, charity, uni)
int_lang1	Indicate the language(s) the intervention is delivered in for group 1 If >1 intervention group, provide as separate variables, e.g. int_lang2, etc.	Free text	Free text	

COVID_timing	Indicate when your trial was conducted relative to onset of the COVID-19 pandemic (declared by WHO in March 2020) If 'other', provide information in COVID_timing_other variable below	1=recruitment, intervention delivery, and follow-up completed prior to pandemic 2=intervention delivery (but not follow-up) completed prior to pandemic 3=intervention delivered partly before and partly during pandemic 4=intervention delivered entirely during pandemic 5=other, please specify	1 2 3 4 5	check corresponds to enrol_start and enrol_end CoVID_timing = 1or 2 then enrol_end occur prioir to March 2020 COVID_timing = 3 then enrol_start is prioir to march 2020 Manual check for the fourth level
COVID_timing_other	Brief description of timing of your trial relative to the pandemic	Free text	Free text	check corresponds to enrol_start and enrol_end
COVID_int	Did you need to modify your trial's intervention due to the COVID-19 pandemic? If yes, provide information in COVID_int_text variable below	0=no; 1=yes	0 1	
STUDY-LEVEL VARIABLES				
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**
COVID_int_text	Brief description of how the intervention was modified	Free text	Free text	only applicable if COVID_int=1
COVID_other	Brief description of any other impacts of the COVID-19 pandemic on your trial, e.g. due to lockdown, food insecurity, etc.	Free text	Free text	check corresponds to enrol_start and enrol_end

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**

family_ID	Unique family identifier used within your trial	Anonymised, no participant names, can be character or number format		check for duplicates - there may be some if >1 child is enrolled per family check for missing IDs if sequential	Check that the number of unique family_ID matches n_families	
child_ID	Unique child identifier used within your trial	Anonymised, no participant names, can be character or number format		Check for duplicates (should be none). Each child should have a unique child_ID check for missing IDs if sequential	Check that the number of unique child_ID matches n_child	
child_carer	How many carers were enrolled in the trial for this child?	Number (integer)	1-3			check that the number of unique carer_ID corresponding to a child or family's ID matches the number provided for this variable
centre	Unique identifier for study centre in which randomisation occurred If there was only 1 study centre in your trial, code all participants the same	Trialist classification* (if available) or free text			check corresponds to country variable	If multiple=1, centre should generally be the same for child_ID within a multiple (i.e. with same family_ID) Check that values for this variable are unique for each trial

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
enrol_cat	At which stage did participant enrolment occur?	1=pre-conception 2=antenatal/during pregnancy 3=postnatal/after birth	1 2 3			if enrol_cat=1, then child_dob should be **later** than rand_date if enrol_cat=2, then child_dob should be **later** than rand_date if enrol_cat=3, then child_dob should be **earlier** than rand_date

child_dob	Child date of birth	dd/mm/yyyy	01/01/1996 - 1/03/2022 (adjust latter depending on cleaning date)		check dates against enrol_start and enrol_end	child_dob should be later than rand_date if enrol_cat=1 or 2 child_dob should be earlier than rand_date if enrol_cat=3
GA_weeks	Gestation at birth, using best estimate (weeks) Enter completed weeks here and additional days in the next variable GA_days, (e.g. if born at 364 weeks, enter 36 here and 4 for GA_days)	completed weeks	20-45	Use text to columns to split at decimal place to give GA_weeks and proportion for GA_days Check against eligibility criteria and check for balance across groups		If multiple=1, GA_weeks should be the same for all child_ID within the multiple (i.e. with same family_ID or carer_ID) - except in rare circumstances
GA_days	Gestation at birth, using best estimate (days) Enter additional days here and completed weeks in the previous variable GA_weeks (e.g. if born at 364 weeks, enter 36 for GA_weeks and 4 here)	additional days	0-6	Use text to columns to split at decimal place to give GA_weeks and proportion for GA_days; multiply this proportion by 7 to give GA_days		If multiple=1, GA_days should be similar for all child_ID within the multiple (i.e. with same family_ID or carer_ID) - except in rare circumstances
GA_term	Was the baby born at or beyond term, i.e. ≥37 weeks' gestation? Only required if GA_weeks & GA_days variables are unknown/not provided	0=no; 1=yes	0 1	check corresponds to GA_weeks and GA_term	Check against study eligibility criteria	

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**

child_age_enrol	Child's age at enrolment If enrolment occurred preconception, enter 'NA' If enrolment occurred during pregnancy, enter 'NA' and complete the GA_enrolment variable below	in months	0-12	should be NA if enrol_cat=1 or 2 should be >/=0 if enrol_cat=3	check occurs between enrol_start and enrol_end	
GA_enrol	If enrolled during pregnancy, provide gestational age at enrolment	in weeks	12-42	only applicable if enrol_cat=2		
sex	Infant sex	1=male; 2=female; 3=ambiguous/other	1 2 3	Expect ambiguous gender to be quite low		
ethnicity	Ethnicity/race of child (or parents if not available for child)	Trialist classification* (if available) or free text				If multiple=1, ethnicity should be the same as for other child_ID within the multiple (i.e. with same family_ID)
birthweight	Infant weight at birth	in grams	500-6000	Check against GA (derive range by GA)		
birthlength	Infant length at birth	in cm	43-57		Check against study eligibility criteria	
SGA	Was the infant small for gestational age? (As defined in your trial*)	0=no; 1=yes	0 1	Check against sex, birthweight, GA and trial definition	Check against study eligibility criteria	
LGA	Was the infant large for gestational age (As defined in your trial*)	0=no; 1=yes	0 1	Check against sex, birthweight, GA and trial definition	Check against study eligibility criteria	
child_devel	Does the child have any development delay, congenital anomaly or physical impairment? e.g. cerebral palsy, deafness, club foot If 'yes', specify condition below	0=no; 1=yes	0 1			

child_devel_type	Provide name(s) of development delay, congenital	Free text	Free text	NA if child_devel=0		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
	anomaly and/or physical impairment					
group	Indicate to which group the participant was allocated	group1; group2; control; etc.	group1 group2 group3 control	or trialist classification may also be used	check consistency with number of groups indicated at study level	If multiple=1, group should most likely be the same as for other child_ID within the multiple (i.e. with same family_ID)
child_age_final	Child's age at final assessment	in months	1-60	should be >/= weight_age	should occur >/= enrol_end	
care_infant	Did the child attend any type of formal or informal childcare on a regular basis between age 012 months?	0=no; 1=yes	0 1	should be 1 if care_infant_formal=1 and/or care_infant_informal=1		
care_child	Did the child attend any type of formal or informal childcare on a regular basis between age >12 months to 5 years?	0=no; 1=yes	0 1	should be 1 if care_child_formal=1 and/or care_child_informal=1		
care_infant_formal	Did the infant attend any type of formal childcare on a regular basis between age 0-12 months? Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool	0=no; 1=yes	0 1	should not be 1 if care_infant=0		

care_child_formal	Did the child attend any type of formal childcare on a regular basis between age 12-24 months? Formal childcare includes centre-based care with some level of regulation, e.g. day care centre, preschool	0=no; 1=yes	0 1	should not be 1 if care_child=0		
care_infant_informal	Did the infant attend any type of informal childcare on a regular basis between age 0-12 months? Informal childcare includes non-centre based care,	0=no; 1=yes	0 1	should not be 1 if care_infant=0		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
	e.g. grandparents, other relatives, friends, neighbours, nanny, babysitter					
care_child_informal	Did the child attend any type of informal childcare on a regular basis between age 12-24 months?. Informal childcare includes non-centre based care, e.g. grandparents, other relatives, friends, neighbours, nanny, babysitter	0=no; 1=yes	0 1	should not be 1 if care_child=0		
Outcomes						
weight	Child weight	in kilograms	Based on WHO Child Growth Charts: 9-15 months: 5.6-14.4 18-30 months: 719.2	check plausibility against weight_age and length/height if assessed at multiple timepoints, weight should not decrease for an individual participant, i.e. weight2 should be >weight1		
weight_age	Age at measurement of above variable weight	in months	0-60	should occur </=child_age_final		
weight_method	Type of method used to collect weight-related outcome data	1=clinic/research-based measures 2=parent/carer selfreported	1 2	check corresponds to weight_text below		

weight_text	Description of methods used to collect weight-related outcomes	Free text and/or excerpt from publication		check corresponds to weight_method above		
length	Child length (up to <24 months of age)	in cm	Based on WHO Child Growth Charts: 9-15 months: 62-88	if assessed at multiple timepoints, length should not decrease for an individual		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
			18-30 months: 71-103	participant, i.e. length2 should be >length1		
length_age	Age at measurement of above variable length	in months	1-<24	should occur </=child_age_final		
height	Child height (≥24 months of age)	in cm	24-30 months: 7-19.2	check plausibility against height_age if assessed at multiple timepoints, height should not decrease for an individual participant, i.e. height2 should be >height1		
height_age	Age at measurement of above variable height	in months	24-30	should occur </=child_age_final		
	Child body mass index z-score (also known as weight-forlength/height z-score) Using 2006 WHO growth standards	numeric (decimal)	-3-3	calculate using weight, length/height, sex and WHO growth charts and check against value provided (and definition used by trial)		
ZBMI_age	Age at measurement of above variable BMIz-score	in months	0-60	should occur </=child_age_final		
BMI	Child body mass index	in kg/m^2	10-22	check plausibility against BMI_age and sex valid range based on WHO growth standards (https://www.who.int/tools/child-growth-standards/standards)		

BMI_age	Age at measurement of above variable BMI	in months	0-60	should occur </=child_age_final		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
waist	Child waist circumference	in cm	40-120	check plausibility against waist_age valid range from 0-2 years difficult to find valid range for >2 years based on CDC data (https://www.cdc.gov/nchs/data/series/sr_03/sr03_039.pdf)		
waist_age	Age at measurement of above variable waist	in months	0-60	should occur </=child_age_final		
WHR	Child waist-to-height ratio (waist circumference divided by height)	numeric (decimal)	0.35-0.7	if value is provided, calculate from waist and height to check can't find reliable estimates for young children; valid range for children 5+ years is based on Canadian data: https://cpeggcep.net/content/waistcircumference-and-waistheight-ratio-charts		
WHR_age	Age at measurement of above variable WHR	in months	0-60	should occur </=child_age_final		

adiposity	Child body fat percentage (As defined/measured in your trial*)	%	1-40	check plausibility against adiposity_age infant reference values: https://doi.org/10.1093/ajcn/nqy377 child reference values: https://www.cooperinstitute.org/vault/2440/web/files/787.pdf		
adiposity_age	Age at measurement of above variable adiposity	in months	0-60	should occur </=child_age_final		
overweight	Child overweight Defined as body mass index zscore of > 2 standard deviations above the WHO reference	0=no; 1=yes	0 1	check consistent with ZBMI		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
overweight_age	Age at measurement of above variable overweight	in months	1-30	should occur </=child_age_final		
obesity	Child obesity Defined as body mass index zscore of > 3 standard deviations above the WHO reference	0=no; 1=yes	0 1	check consistent with ZBMI		
obesity_age	Age at measurement of above variable obesity	in months	1-30	should occur </=child_age_final		

bf_any	Has the infant ever received breast milk? Definition includes expressed milk and milk sourced from Milk Bank. We are interested in whether infant ever received any breast milk (not whether the mother breastfed) If responded no to 'ever breastfed' at 1 month onwards, it is safe to assume the baby will most likely never be breastfed. Note: binary data (1=yes, 0 = no) provided under the previous definition is acceptable, no transformation is needed	0=no; 1=yes	0 1	If trial collected this outcome categorically, can assume: 'Never/rarer than once a week' = 0 (no). Are you currently breastfeeding? Yes = yes No – stopped = yes No – never started = 0 Also check other trial-specific breastfeeding questionnaire items for more information (e.g. timepoint of assessment) to inform coding		
bf_any_age	Age at measurement of above variable bf_any	in months		if bf_any=1, bf_any_age should be >0		
bf_duration	Duration of any breastfeeding Note: age stopped breastfeeding can be used as a proxy for breastfeeding duration, i.e. assume bf started at (or close to) birth and that it occurs continuously.	in weeks	0-156	if bf_any=1, bf_duration should be >/=1 bf_duration should be >/= bf_exclusive (though note different units - weeks vs days) If trial collected this outcome categorically, generate 2 different variables: 1. bf_duration_conservative = use the lowest version of the category 2. bf_duration_mid = use the mid=point of the category		
bf_duration_age	Age at measurement of above variable bf_duration	in months	0-36	should occur </=child_age_final		

bf_exclusive	Duration of exclusive breastfeeding (As defined in your trial*) Use WHO definition of exclusive breastfeeding: Exclusive breastfeeding is defined as giving no other food or drink – not even water – except breast milk. It does, however, allow the infant to receive oral rehydration salts (ORS), drops and syrups (vitamins, minerals and medicines). OR trial definition where WHO is not available	in days	0-185	if bf_exclusive=1, bf_duration should be >/=1 If trial collected this outcome at multiple timepoints, go with the last time they say 'yes' (ALSPAC data, only 0.1% exclusive bf at 7 months; 0.4% at 6 months; Reference: Pontin et al. Patterns of breastfeeding in a UK longitudinal cohort study. Matern Child Nutr. 2007 doi: 10.1111/j.17408709.2007.0006)		
bf_exclusive_age	Age at measurement of above variable bf_exclusive	in months	0-6	should occur </=child_age_final		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
diet_method	Method used to assess dietary intake of fruit, vegetables, EDNP and SSB	1=Food Frequency Questionnaire (FFQ) 2=24-hr recall 3=Food diary 4=Other				
energy_kj	Energy intake per day in kilojoules (As defined/measured in your trial*) Not required if energy_calorie is provided below	in kj/day	1000-6300	check plausibility against energy_kj_age valid range estimated from https://www.nrv.gov.au/dietary-energy		
energy_kj_age	Age at measurement of above variable energy_kj	in months	0-60	should occur </=child_age_final		

energy_cal	Energy intake per day in calories (As defined/measured in your trial*) Not required if energy_kj is provided above	in calories/day	240-1500	check plausibility against energy_cal_age valid range estimated from https://www.nrv.gov.au/dietary-energy		
energy_cal_age	Age at measurement of above variable energy_cal	in months	0-60	should occur </=child_age_final		
fruit	Fruit consumed per day (As defined/measured in your trial*) Typically includes 100% fruit juice	in grams/day	0-600	check plausibility against fruit_age		
fruit_cat	Serves of fruit consumed per day (As defined/measured in your trial*)	0=no serving 1=1 serving 2=2 servings 3=3 servings 4=4 servings 5=5 servings 6=6 servings 7=7 or more servings	0-7	check against fruit		
fruit_age	Age at measurement of above variable fruit	in months	0-60	should occur </=child_age_final		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
veg	Vegetables consumed per day (As defined/measured in your trial*)	in grams/day	0-400	check plausibility against veg_age range ref: https://doi.org/10.1017/S136898001900209X		
veg_age	Age at measurement of above variable veg	in months	0-60	should occur </=child_age_final		

fruit_veg	Combined fruit and vegetables consumed per day (As defined/measured in your trial*) Not required if fruit and veg variables are provided above	in grams/day	0-1000	check plausibility against fruit_veg_age should equal veg+fruit (if provided)		
fruit_veg_age	Age at measurement of above variable fruit_veg	in months	0-60	should occur </=child_age_final		
EDNP	Intake of energy dense nutrient poor foods per day (As defined/measured in your trial*) If this information is collected across multiple variables, please provide all with appropriate labels (e.g. cake, cookies, pastry, etc.) and coding	in grams/day	0-700	check plausibility against EDNP_age ref: https://www.nature.com/articles/1602720		
EDNP_age	Age at measurement of above variable EDNP	in months	0-60	should occur </=child_age_final		
SSB	Intake of sugar-sweetened beverages per day (As defined/measured in your trial*) If this information is collected across multiple variables, please provide all with	in ml/day	0-500	check plausibility against SSB_age ref: https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-950		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**

	appropriate labels (e.g. juice, squash, etc.) and coding					
SSB_age	Age at measurement of above variable SSB	in months	0-60	should occur </=child_age_final		
screen	Average time per day in sedentary behaviour in front of a screen (As defined/measured in your trial*)	in minutes/day	0-360	ref: http://dx.doi.org/10.1136/bmjopen-2016-012342		
screen_age	Age at measurement of above variable screen	in months	0-60	should occur </=child_age_final		
restrained	Average time per day restrained while awake (As defined/measured in your trial*)	in minutes/day	0-360	check plausibility against restrained_age		
restrained_age	Age at measurement of above variable restrained	in months	0-60	should occur </=child_age_final		
PA_report	Self-reported physical activity/play time per day (As defined/measured in your trial*)	in minutes/day	0-500	check plausibility against PA_report_age ref: https://doi.org/10.1186/s12966-020-0912-4 PA_report + screen should not be > 840		
PA_report_age	Age at measurement of above variable PA_report	in months	0-60	should occur </=child_age_final		
PA_device	Device assessed physical activity/play time per day (As defined/measured in your trial*)	in minutes/day	0-500	check against PA_report (should be similar) check plausibility against PA_device_age ref: https://doi.org/10.1186/s1296		

CHILD VARIABLES						
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**	**Relationship to parent/caregiver variables**
				6-020-0912-4 PA_device + screen should not be > 840		
PA_device_age	Age at measurement of above variable PA_device	in months	0-60	should occur </=child_age_final		
tummy	Prone play ('tummy time') per day (As defined/measured in your trial*)	in minutes	0-60	only valid up to ~6months of age ref using InFANT raw data		
tummy_age	Age at measurement of above variable tummy	in months	0-6	should occur </=child_age_final		
sleep_method	Method used to assess sleep duration	1=questionnaire 2=sleep diary 3=accelerometery 4=other	1-4			
sleep_day	Sleep duration per day (i.e. between 7am-7pm or as defined/measured in your trial*) Include both self-reported and device collected data according to availability	in hours/day	0-13	check plausibility against sleep_day_age and PA variables, i.e. PA_report or PA_device should not be greater than wake time, i.e. (24-(sleep_day + sleep_night)) sleep_day + sleep_night should be <23 ref using infant raw data		
sleep_day_age	Age at measurement of above variable sleep_day	in months	0-60	should occur </=child_age_final		

CHILD VARIABLES

Variable name	Description	Coding	Valid input/range	Notes	Relationship to study level variables	Relationship to parent/caregiver variables
sleep_night	Sleep duration per night (i.e. between 7pm-7am or as defined/measured in your trial*). Include both self-reported and device collected data according to availability Can be calculated from time child went to sleep and time they woke, though note limitation: does not include wakings during the night, which are common in young children. Note: 'longest baby has slept in the night without waking' is a different measure and cannot be used for this variable	In hours/night	4-14	check plausibility against sleep_night_age sleep_day + sleep_night should be <23 ref using infant raw data		
sleep_night_age	Age at measurement of above variable sleep_night	in months	0-60	should occur </=child_age_final		
sleep_combined	Combined duration of day and night sleep, i.e. total sleep per 24 hours	in hours/day	4-24	should equal sleep_day + sleep_night and be <24 hours		
wake_night	Frequency of waking during the night (measure of sleep quality)	Number (integer)	0-10			
wake_duration	Duration of disrupted sleep episodes (measure of sleep quality)	in minutes	0-240			
wake_age	Age at measurement of above sleep quality variables (wake_night, wake_duration)	in months	0-60	should occur </=child_age_final		

solids	Age at introduction of solid foods	in months	1-12	ref: https://www.liebertpub.com/doi/full/10.1089/chi.2016.0021 should be > bf_exclusive		
adverse_events	Adverse events, e.g. injuries, underweight, infection	Trialist classification* (if available) or free text		for underweight, check against antropometric measures		

PARENT/CARER VARIABLES					
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**
family_ID	Unique family identifier used within your trial	Anonymised, can be character or number format			
rand_date	Date of randomisation	dd/mm/yyyy	01/01/1996 - 1/03/2022 (adjust latter depending on cleaning date)	Check correct date format and corresponds to publication/registration record	
carer_ID	Unique parent/caregiver identifier used within your trial	Anonymised, no participant names, can be character or number format		Check for duplicates (should be none). Each carer should have a unique carer_ID check for missing IDs if sequential	
carer_enrolled	Was the carer enrolled as a participant in your trial, or did they only have data collected for some variables, such as demographic information?	0=no, not enrolled, but had data collected for some variables 1=yes, enrolled	0 1		
primary_carer	Was/is the person the child's primary carer?	0=no; 1=yes	0 1	check only one primary carer per child	

carer_type	Indicate the carer relationship to child If 'other' is selected, specify the type below in variable 'carer_type_other'	1=mother 2=father 3=grandparent 4=other	1-4		
carer_type_other	Specify the type of carer, e.g. step-father, auntie	Free text	Free text	text entered here should not match options 1-3 for carer_type	
carer_dob	Carer's date of birth	dd/mm/yyyy		should be at least 16 years earlier than child_dob carer_dob should roughly equal rand_date - carer_age_birth	
carer_age_birth	Carer's age at enrolment/randomisation Only required if carer_dob & rand_date not provided	Carer's age at enrolment/randomisation in whole years	16-50	child_dob - carer_dob = carer_age_birth	
prev_child	Indicate the number of previous children of the carer	Numeric (integer)	0-6		
prev_child_cat	Indicate whether the carer is a first timeparent or has other children Not required if prev_child variable above is provided	1=first-time parent 2=already has at least 1 other child	1 2	if prev_child=0, prev_child_cat should=1 if prev_child >/=1, prev_child_cat should=2	
multiple	Is/was the current pregnancy a multiple pregnancy?	0=no (singleton); 1=yes (multiple)	0 1		multiple should=0 if mult_eligible=2

GWG	Maternal gestational weight gain	in kilograms	-5-27.5	only applicable if carer_type=1 check against maternal BMI (i.e. carer_BMI for carer_type=1): weight loss should only occur if carer_BMI for carer_type=1 is in obese range (i.e. >/=30) P50 for mothers with normal BMI (18.5-24.9) is~15kg ref: https://doi.org/10.1186/s12916 -018-1189-1	
T1D	Type 1 diabetes	0=no; 1=yes	0 1		
T2D	Type 2 diabetes	0=no; 1=yes	0 1	more likely if carer_BMI >/=25	

PARENT/CARER VARIABLES					
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**
GD	Gestational diabetes	0=no; 1=yes	0 1	only applicable if carer_type=1 more likely if carer_BMI >/=25 (though can occur even in underweight women) ref: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866592/	

carer_weight	Pre-pregnancy weight	in kg	40-140	ref: https://dqydj.com/weight -percentile-calculatormen-women/	
carer_height	Pre-pregnancy height	in cm	145-180	ref: https://dqydj.com/height - percentile-calculator-formen-and-women/	
carer_BMI	Pre-pregnancy body mass index Not required if mat_weight & mat_height variables are provided above	in kg/m2	17-50	ref: https://dqydj.com/bmipercentile-calculatormen-women-unitedstates/ check against carer_weight and carer_height	
carer_smoking	Any smoking during pregnancy	0=no; 1=yes	0 1		
income	Total household income per year at baseline/enrolment in trial	(annual median country & year specific household income) – (total household income per year at baseline) ÷ annual median country & year specific household income	0-1		check against country and locate relevant median household income for randomisation year

PARENT/CARER VARIABLES					
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**
household_adults	Number of adults currently living in the household (As defined/measured in your trial*)	Number	1-8	check against partner status, e.g. if partner_status=1, assume household_adults >/=2 if partner_status=2, assume household_adults =1	

household_children	Number of children currently living in the household (including the enrolled child/children) (As defined/measured in your trial*)	Number	1-8	check against prev_child, e.g. if prev_child >/=1, it would be more likely (though not definite) that household_children >/=1	
partner_status	Partner or relationship status at baseline/enrolment in trial	1 = in a partnership (married, de facto, living with partner) 2 = single (single , divorced and widowed)	1 2		
carer_education	Carer's highest education level at baseline/enrolment in trial Note: create new numbered variables if this information is available for >1 carer, e.g. carer1_education, carer2_education, etc.	1=Low education (little/no formal education, or some school – but didn't finish high school) 2=High school graduate 3=Non-university tertiary education or qualification or incomplete university 4=University graduate or postgraduate	1-Apr	check against carer_age_birth, e.g. if carer_age_birth </=20 then carer_education=4 is unlikely	
carer_employment	Carer employment status at baseline/enrolment in trial Note: create new numbered variables if this information is available for >1 carer, e.g. carer1_employment, carer2_employment, etc .	1=Full time employment (including paid leave) 2=Part time employment (including paid leave) 3=Unemployed (includes retired, student without employment, unpaid leave, home duties, charity work)	1-3		

PARENT/CARER VARIABLES					
Variable name	**Description**	**Coding**	**Valid input/range**	**Notes**	**Relationship to study level variables**

carer_occupation	Level of carer's most recent occupation, e.g. manager, professional, admin, never employed (As defined/measured in your trial*)	Using coding below OR trialist classification* OR free text 1=Manager 2=Professional/associate 3=Tradesperson/farmer 4=Clerical, sales and services 5=Labourer 6=Homemaker/housewife 7=Other (including unemployed)			
SEP	Any composite or summary measure of socio-economic position/status (As defined/measured in your trial*) Note: decisions to be made on a case-bycase basis regarding appropriate categorisation. Examples include: Social class Brazil: D-E (low), C (middle), A-B (high) NZ Deprivation Index: 8-10 = Low, 4-7 = Middle, 1-3 = High UK Index of Multiple Deprivation: Deciles 1-3 = Low, 4-7 = Middle, 8-10 = High USA WIC participants = Low	1=Low 2=Medium 3=High		check against income and HIED, i.e. if these are high, then would expect other SEP variables to also be high	
SEI_area	Socio-economic index of area where participant lives, e.g. SEIFA code (As defined/measured in your trial*)	Trialist classification* (if available) or free text		ref: https://www.abs.gov.au/websitedbs/censushome.nsf/home/seifa	only applicable if country=Australia
immigration_status	Was parent/carer born in study country or outside study country? Note: create new numbered variables if this information is available for >1 carer, e.g. Immigration_status_carer1, immigration_status_carer2, etc.	1=parent/carer born in study country 2=parent/carer born outside study country	1 2		
home_lang	Primary language spoken at home	Free text		check home_lang against this list: https://www.dss.gov.au/sites/default/files/files/foi	

				_disclosure_log/12-12-13/language-list.pdf	
lang_prof	Carer language proficiency in national or nationally dominant language, e.g. how well carer in Australia speaks English (As defined/measured in your trial*)	Using coding below OR trialist classification* OR free text 1=very well 2=well 3=not very well 4=not at all	1-4	this may be correlated with home_lang (if different vs the same as int_lang), i.e. if home_lang is the same as int_lang, would expect lang_prof =1 or 2?	
SEP_other	Any other measures of socioeconomic position (As defined/measured in your trial*)	Trialist classification* (if available) or free text		check against SEP, income and HIED, i.e. if these are high, then would expect SEP_other to also be high	
carer_PA	Any measure of carer physical activity in your trial, e.g. average duration of moderate physical activity per week (As defined/measured in your trial*)	Trialist classification* (if available) or free text		potentially useful ref: https://www.abs.gov.au/statistics/health/healthconditions-andrisks/physicalactivity/latest-release	
carer_diet	Any measure of carer dietary intake in your trial, e.g. daily energy intake (As defined/measured in your trial*)	Trialist classification* (if available) or free text		potentially useful ref: https://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Dietary&Cycle=2017-2020	
carer_sleep	Any measure of carer sleep practices in your trial, e.g. average sleep duration per night (As defined/measured in your trial*)	Trialist classification* (if available) or free text		ref: https://www.nature.com/articles/s41562-020-00965 -x/figures/1	
birth_mode	Mode of delivery at birth of infant enrolled in this trial	1=vaginal 2=Caesarean	1 2		
contacts_actual	Actual number of intervention contacts/visits	Number (integer)	1-50		check against contacts

time_actual	Actual total duration of intervention contacts/visits	in hours	1-50		check against freq and time
duration_actual	Actual duration over which intervention was delivered	in days	1-365		check against duration
compliance	Other measures of compliance with allocated intervention (As defined/ measured in your trial*)	Trialist classification* (if available) or free text			
parent_feeding	Parent/caregiver feeding practices/styles (As defined/measured in your trial*)	Trialist classification* (if available) or free text			
self_efficacy	Parenting self-efficacy (As defined/measured in your trial*)	Trialist classification* (if available) or free text			
excluded	Was the participant excluded from your analyses? If yes, please state reason below.	0=no; 1=yes	0 1		
reason_excluded	Reason participant excluded	Trialist classification* (if available) or free text	Free text		check against study eligibility criteria

Appendix D. TOPCHILD Dietary Intake Additional Harmonisation Summary and Conversion Factors

Preferred outcome variable as grams / millilitres for all food group dietary intake variables. For cycle 1 analysis, studies with data available at the 24 months of age timepoint primarily report in grams or frequency of times intake.

There are planned sensitivity analyses to compare dietary intake variables as reported by trialist vs calculated to harmonise (noting there will be a difference in data structure from applying a conversion factor to count data), as well as to compare dietary assessment method (e.g. 24hr recall, diet record, Food Frequency Questionnaire (FFQ)).

Considered a range of analysis options to use serving size recommendations or portion size estimates to calculate g/ml of intake, as well as whether to use country specific conversation factors or international averaged conversion factors.

Summary of process undertaken to harmonise frequency of diet variables into grams:

- Looked at FFQs used for item wording and any estimated portion sizes, and if not available, looked for data sources/questionnaires that they were based on
- Looked for country specific papers that report average portion size per eating occasion for approximately 24 months of age (only found for USA), and if not available used minimum intake assuming minimum was only one portion
- Confirmed feasibility of portion sizes by comparing against total day population intake and thinking about the size of that portion in food items
- Compared conversation factors across countries as a sense check that they weren't drastically different or there were country specific rationales for differences

Assumptions made:

- One time in an FFQ is a portion of food group (rather than serving size from dietary guidelines), based on dietetic knowledge and given assumption made with one included study reporting grams that were converted from FFQ based on portion size. Tried to follow consistent approaches.
- USA data in cups: searched for country specific conversion and looked at US Dietary Guidelines for definition of 1 cup=1 cup raw or cooked vegetable or fruit; 1 cup vegetable or fruit juice; 2 cups leafy salad greens; ½ cup dried fruit or vegetable. Therefore assumed 1 cup=150g
- Australia data: Data in serves per day and converted to grams according to AGHE definitions for grams per serve

Decisions:

- Use country specific average portion size conversion factors as preferred option to reduce some of the assumptions of using average international estimates, as per outcome harmonisation decisions. See table 1 for estimates. When circulating statistical analysis plan to collaboration ask trial representatives from the named countries to confirm suitability. Need frequency converted to times per day, then multiply by the conversion factors.

- Unable to reliability estimate average portion conversion factors for energy dense nutrient poor foods given the heterogeneity of food items within group and mixed reporting of population intake including SSB, as well as variations in what is defined by trials.
- If using 'fruit and veg combined' as an outcome variable add the 'fruit' and 'vegetable' conversion factors together.
- Based on cycle 1 data analysis variable mapping, there is 1 trial (Netherlands_Karssen_2017) with intake reported in pieces/spoons which can be calculated from the gram estimates provided from the trial.

Table 1: Average portion sizes and population intake for food group categories

	Conversion factors (g/portion)				Population intake (g/day)			
Country	**Reference source and year of data**	**Fruit (g)**	**Veg (g)**	**SSB (ml)**	**Reference source**	**Fruit (g)**	**Veg (g)**	**SSB (ml)**
Norway	Øverby_2017 6 month questionnaire[a]	60	60	150ml[b] or 60ml	Wright 2023 (based on national survey 2019)	129g Juice (30g) and smoothies (58g) Total: 217g (including juice)	71g (potato separate, 14g)	42g Artificially sweetened beverages 32g
USA[c]	FITS 2002: Average portion size per eating occasion (1924m):	90	50	150 mls	FITS 2016 (SSB), NHANES 2007-1016	1.25 cups (188g)	0.5 Cups (75g)	290ml
Australia	OzFITS 2021 – per day (18-24 months)	78	41	152mls	OzFITS 2021– per day (1824 months)	168 (range 78260)	89 (range 41182)	152mls

[a] Assuming portion sizes for 6 month questionnaire are the same as for the 24 month questionnaire [b] If taking the average portion size option within FFQ 150ml or if taking the smallest portion size option 60ml.
[c] Assuming 1 cup = 150g
Assumption that only consuming 1 (Norway and AUS) to 2 (USA) portion/s of SSB per day.

References:

USA:
FITS 2002: https://www.sciencedirect.com/science/article/pii/S000282230501727X
FITS 2016: https://www.mdpi.com/2072-6643/10/7/825
Average Intakes: Analysis of What We Eat in America, NHANES 2007-2016, day 1 dietary intake data, weighted. Recommended Intake Ranges: Healthy U.S.-Style Dietary Patterns

https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans2020-2025.pdf

Norway:
Øverby 2017: https://pubmed.ncbi.nlm.nih.gov/29162136/
Wright 2023: https://link.springer.com/article/10.1007/s00394-023-03243-4

Australia:
OzFITS: https://www.mdpi.com/2072-6643/14/14/2890

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C: PRISMA Checklists

PRISMA 2020 checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	p1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	p3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p6
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p7
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	pp6-7, Appendix
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	pp6-7, Appendix
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	p7, Table 2
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p7

Section and Topic	Item #	Checklist item	Location where item is reported
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	pp7-8, Appendix
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Appendix
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	pp7-8, Appendix
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	p8
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	p8, Appendix
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	IPD available, reporting biases NA
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	p7
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p8, Figure 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Appendix
Study characteristics	17	Cite each included study and present its characteristics.	Table 1
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Appendix
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Figure 2, Appendix
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	pp8-9
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	pp8-9, Appendix, Figure 2, Tables 2-5
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Table 2
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Appendix
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	IPD

Section and Topic	Item #	Checklist item	Location where item is reported
			available, reporting biases NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Table 2
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	pp10-11
	23b	Discuss any limitations of the evidence included in the review.	pp9-10
	23c	Discuss any limitations of the review processes used.	pp9-10
	23d	Discuss implications of the results for practice, policy, and future research.	pp11
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	pp3,6
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	p6
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	p6
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p8, pp12-13
Competing interests	26	Declare any competing interests of review authors.	pp12-13
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	p12, Appendix

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

PRISMA IPD Checklist

PRISMA-IPD Checklist of items to include when reporting a systematic review and meta-analysis of individual participant data (IPD)

PRISMA-IPD Section/topic	Item No	Checklist item	Reported on page
Title			
Title	1	Identify the report as a systematic review and meta-analysis of individual participant data.	1
Abstract			
Structured summary	2	Provide a structured summary including as applicable:	3
		Background: state research question and main objectives, with information on participants, interventions, comparators and outcomes.	
		Methods: report eligibility criteria; data sources including dates of last bibliographic search or elicitation, noting that IPD were sought; methods of assessing risk of bias.	
		Results: provide number and type of studies and participants identified and number (%) obtained; summary effect estimates for main outcomes (benefits and harms) with confidence intervals and measures of statistical heterogeneity. Describe the direction and size of summary effects in terms meaningful to those who would put findings into practice.	
		Discussion: state main strengths and limitations of the evidence, general interpretation of the results and any important implications.	
		Other: report primary funding source, registration number and registry name for the systematic review and IPD meta-analysis.	
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of the questions being addressed with reference, as applicable, to participants, interventions, comparisons, outcomes and study design (PICOS). Include any hypotheses that relate to particular types of participant-level subgroups.	6
Methods			
Protocol and registration	5	Indicate if a protocol exists and where it can be accessed. If available, provide registration information including registration number and registry name. Provide publication details, if applicable.	6

Eligibility criteria	6	Specify inclusion and exclusion criteria including those relating to participants, interventions, comparisons, outcomes, study design and characteristics (e.g. years when conducted, required minimum follow-up). Note whether these were applied at the study or individual level i.e. whether eligible participants were included (and ineligible participants excluded) from a study that included a wider population than specified by the review inclusion criteria. The rationale for criteria should be stated.	6
Identifying studies - information sources	7	Describe all methods of identifying published and unpublished studies including, as applicable: which bibliographic databases were searched with dates of coverage; details of any hand searching including of conference proceedings; use of study registers and agency or company databases; contact with the original research team and experts in the field; open adverts and surveys. Give the date of last search or elicitation.	6
Identifying studies - search	8	Present the full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix
Study selection processes	9	State the process for determining which studies were eligible for inclusion.	6
Data collection processes	10	Describe how IPD were requested, collected and managed, including any processes for querying and confirming data with investigators. If IPD were not sought from any eligible study, the reason for this should be stated (for each such study).	7
		If applicable, describe how any studies for which IPD were not available were dealt with. This should include whether, how and what aggregate data were sought or extracted from study reports and publications (such as extracting data independently in duplicate) and any processes for obtaining and confirming these data with investigators.	
Data items	11	Describe how the information and variables to be collected were chosen. List and define all study level and participant level data that were sought, including baseline and follow-up information. If applicable, describe methods of standardising or translating variables within the IPD datasets to ensure common scales or measurements across studies.	6-7
IPD integrity	A1	Describe what aspects of IPD were subject to data checking (such as sequence generation, data consistency and completeness, baseline imbalance) and how this was done.	7
Risk of bias assessment in individual studies.	12	Describe methods used to assess risk of bias in the individual studies and whether this was applied separately for each outcome. If applicable, describe how findings of IPD checking were used to inform the assessment. Report if and how risk of bias assessment was used in any data synthesis.	7
Specification of outcomes and effect measures	13	State all treatment comparisons of interests. State all outcomes addressed and define them in detail. State whether they were pre-specified for the review and, if applicable, whether they were primary/main or secondary/additional outcomes. Give the principal measures of effect (such as risk ratio, hazard ratio, difference in means) used for each outcome.	7, Appendix

Synthesis methods	14	Describe the meta-analysis methods used to synthesise IPD. Specify any statistical methods and models used. Issues should include (but are not restricted to): • Use of a one-stage or two-stage approach. • How effect estimates were generated separately within each study and combined across studies (where applicable). • Specification of one-stage models (where applicable) including how clustering of patients within studies was accounted for. • Use of fixed or random effects models and any other model assumptions, such as proportional hazards. • How (summary) survival curves were generated (where applicable). • Methods for quantifying statistical heterogeneity (such as I^2 and τ^2). • How studies providing IPD and not providing IPD were analysed together (where applicable). • How missing data within the IPD were dealt with (where applicable).	7-8, Appendix
Exploration of variation in effects	A2	If applicable, describe any methods used to explore variation in effects by study or participant level characteristics (such as estimation of interactions between effect and covariates). State all participant-level characteristics that were analysed as potential effect modifiers, and whether these were pre-specified.	7, Appendix
Risk of bias across studies	15	Specify any assessment of risk of bias relating to the accumulated body of evidence, including any pertaining to not obtaining IPD for particular studies, outcomes or other variables.	7
Additional analyses	16	Describe methods of any additional analyses, including sensitivity analyses. State which of these were pre-specified.	7-8
Results			
Study selection and IPD obtained	17	Give numbers of studies screened, assessed for eligibility, and included in the systematic review with reasons for exclusions at each stage. Indicate the number of studies and participants for which IPD were sought and for which IPD were obtained. For those studies where IPD were not available, give the numbers of studies and participants for which aggregate data were available. Report reasons for non-availability of IPD. Include a flow diagram.	8, Figure 1, Appendix
Study characteristics	18	For each study, present information on key study and participant characteristics (such as description of interventions, numbers of participants, demographic data, unavailability of outcomes, funding source, and if applicable duration of follow-up). Provide (main) citations for each study. Where applicable, also report similar study characteristics for any studies not providing IPD.	Table 1
IPD integrity	A3	Report any important issues identified in checking IPD or state that there were none.	9
Risk of bias within studies	19	Present data on risk of bias assessments. If applicable, describe whether data checking led to the up-weighting or down-weighting of these assessments. Consider how any potential bias impacts on the robustness of meta-analysis conclusions.	8-9, Appendix

Results of individual studies	20	For each comparison and for each main outcome (benefit or harm), for each individual study report the number of eligible participants for which data were obtained and show simple summary data for each intervention group (including, where applicable, the number of events), effect estimates and confidence intervals. These may be tabulated or included on a forest plot.	Figure 2, Appendix
Results of syntheses	21	Present summary effects for each meta-analysis undertaken, including confidence intervals and measures of statistical heterogeneity. State whether the analysis was pre-specified, and report the numbers of studies and participants and, where applicable, the number of events on which it is based.	Figure 2, Tables 2-5
		When exploring variation in effects due to patient or study characteristics, present summary interaction estimates for each characteristic examined, including confidence intervals and measures of statistical heterogeneity. State whether the analysis was pre-specified. State whether any interaction is consistent across trials.	
		Provide a description of the direction and size of effect in terms meaningful to those who would put findings into practice.	
Risk of bias across studies	22	Present results of any assessment of risk of bias relating to the accumulated body of evidence, including any pertaining to the availability and representativeness of available studies, outcomes or other variables.	Appendix
Additional analyses	23	Give results of any additional analyses (e.g. sensitivity analyses). If applicable, this should also include any analyses that incorporate aggregate data for studies that do not have IPD. If applicable, summarise the main meta-analysis results following the inclusion or exclusion of studies for which IPD were not available.	8-9, Appendix
Discussion			
Summary of evidence	24	Summarise the main findings, including the strength of evidence for each main outcome.	9
Strengths and limitations	25	Discuss any important strengths and limitations of the evidence including the benefits of access to IPD and any limitations arising from IPD that were not available.	9-10
Conclusions	26	Provide a general interpretation of the findings in the context of other evidence.	10-11
Implications	A4	Consider relevance to key groups (such as policy makers, service providers and service users). Consider implications for future research.	11
Funding			
Funding	27	Describe sources of funding and other support (such as supply of IPD), and the role in the systematic review of those providing such support.	8, 12-13, Appendix

A1 – A3 denote new items that are additional to standard PRISMA items. A4 has been created as a result of re-arranging content of the standard PRISMA statement to suit the way that systematic review IPD meta-analyses are reported.

D: Search Strategy

Ovid MEDLINE(R) ALL 1946 to September 30, 2024

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

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

Embase Classic+Embase 1947 to 2024 September 30

1. pediatric obesity/
2. Weight Gain/
3. obes*.ti,ab
4. (weight gain).ti,ab
5. (overweight or over weight).ti,ab
6. weight change*.ti,ab
7. ((bmi or body mass index) adj2 (gain or loss or change)).ti,ab
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. social support/
10. ((behviour or behavior) and change).ti,ab
11. ((behavio?r*) adj (therapy or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
12. ((lifestyle or life style) adj (chang* or modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
13. social support.ti,ab
14. (peer adj2 support).ti,ab
15. counsel?ing.ti,ab
16. education* adj1 (intervention* or program* or class* or counsel* or teach* or workshop* or module* or consultation* or session*)).ti,ab
17. home visit*.ti,ab
18. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19. exp Breastfeeding/
20. Infant Nutritional Physiological Phenomena/
21. Child Nutrition Sciences/
22. Infant Food/
23. ((child or toddler or infant$) adj1 (food or feeding or nutrition$)).tw.
24. ((responsive or complementary) adj1 feeding).ti,ab
25. ((diet* or nutrition) adj (modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab
26. (healthy eating).ti,ab
27. (fruit or vegetable*).ti,ab
28. (high fat* or low fat* or fatty food*).ti,ab
29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. exp Exercise/
31. exercis*.ti,ab
32. (physical activity or physical inactivity).ti,ab
33. sedentary behavio?r.ti,ab
34. (screen time).ti,ab
35. 30 or 31 or 32 or 33 or 34
36. Sleep/
37. Exp Primary prevention
38. exp Health Promotion/
39. exp Health Education/
40. prevention.mp
41. prevent*.ti,ab
42. (health promotion or health education or health communication).ti,ab
43. exp Obesity/pc (Prevention and Control)
44. exp Overweight/pc (Prevention & Control)
45. (obesity adj2 prevent*).ti,ab
46. (overweight adj2 prevent*).ti,ab
47. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
48. 8 and (18 or 29 or 35 or 36) and 47
49. exp child/ or exp infant/
50. (child* or infant* or baby or toddler* or pediatr* or paediatr* not adolescen*).ti,ab
51. (pregnan* or antenatal or parent or parent$1 or care giver or caregiver or guardian or family or families or mother$1 or father$1).ti,ab
52. 49 or 50 or 51
53. 48 and 52
54. (exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.
55. 53 not 54
56. exp clinical trial/
57. exp Randomized Controlled Trial/
58. randomization/
59. clinical trial.tw.
60. random$.tw.
61. Comparative Study/
62. clinical trial.tw.
63. (comparison group$ or control group$).tw.
64. 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63
65. 55 and 64

EBM Reviews- Cochrane Central Register of Controlled Trials end of September 2024

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

42. (health promotion or health education or health communication).ti,ab
43. (obesity adj2 prevent*).ti,ab
44. (overweight adj2 prevent*).ti,ab
45. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
46. 8 and (18 or 29 or 35 or 36) and 45
47. exp child/ or exp infant/
48. (child* or infant* or baby or toddler* or pediatr* or paediatr* not adolescen*).ti,ab
49. (pregnan* or antenatal or parent or parent$1 or care giver or caregiver or guardian or family or families or mother$1 or father$1).ti,ab
50. 49 or 50 or 51
51. 46 and 50
52. (exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.
53. 51 not 52
54. 51 and 53

CINAHL Complete (EBSCO Host) to September 2024

S70	S60 AND S69
S69	S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68
S68	TX comparison group*
S67	TX random*
S66	"clin* N25 trial*"
S65	(PT "CLINICAL TRIAL")
S64	(MH "Clinical Trials")
S63	(MH "Random Sample+")
S62	(MH "Random Assignment")
S61	(MH "Comparative Studies")
S60	S58 NOT S59
S59	(MH "Animals+")
S58	S55 AND S57
S57	S10 AND S49 AND S56
S56	S21 OR S34 OR S40 OR S41
S55	S50 OR S51 OR S52 OR S53 OR S54
S54	(TI pregnan* or antenatal or parent* or care giver or caregiver or guardian or family or families or mother$1 or father$1) OR (AB pregnan* or antenatal or parent* or care giver or caregiver or guardian or family or families or mother$1 or father$1)
S53	(TI child* or infant* or baby or toddler* or pediatr* or paediatr* not adolescen*) OR (AB child* or infant* or baby or toddler* or pediatr* or paediatr* not adolescen*)
S52	(MH "Infant+")
S51	(MH "Child")
S50	(MH "Child+")
S49	S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48
S48	(TI overweight N2 prevent*) OR (AB overweight N2 prevent*)

S47	(TI obesity N2 prevent*) OR (AB obesity N2 prevent*)
S46	(TI health promotion or health education or health communication) OR (AB health promotion or health education or health communication)
S45	(TI prevent*) OR (AB prevent*)
S44	(MH "Health Education+")
S43	(MH "Health Promotion+")
S42	"primary prevention"
S41	(MH "Sleep+")
S40	S35 OR S36 OR S37 OR S38 OR S39
S39	(TI screen time) OR (AB screen time)
S38	(TI sedentary behavio?r) or (AB sedentary behavio?r)
S37	(TI physical activity or physical inactivity) OR (AB physical activity or physical inactivity)
S36	(TI exercis*) OR (AB exercis*)
S35	(MH "Exercise+")
S34	S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33
S33	(TI high fat* or low fat* or fatty food*) OR (AB high fat* or low fat* or fatty food*)
S32	(TI fruit or vegetable*) OR (AB fruit or vegetable*)
S31	(TI healthy eating) OR (AB healthy eating)
S30	(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 session*)
S29	(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*)
S28	(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 session*)
S27	(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*)
S26	(MH "Infant Feeding+")
S25	(MH "Infant Food+")
S24	(MH "Child Nutritional Physiology+")

S23	(MH "Infant Nutritional Physiology+")
S22	(MH "Breast Feeding+")
S21	S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20
S20	(TI home visit) OR (AB home visit)
S19	(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 consultation*) OR (AB education N2 session*)
S18	(TI counselling or counseling) OR (AB counselling or counseling)
S17	(TI peer N2 support) OR (AB peer N2 support)
S16	(TI social support) OR (AB social support)
S15	(MM "Life Style Changes")
S14	(MM "Behavior Modification+")
S13	(MM "Behavioral Changes")
S12	(TI behaviour change) OR (AB behaviour change) OR (TI behavior change) OR (AB behavior change)
S11	(MH "Support, Psychosocial")
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9
S9	(TI body mass index N2 loss) OR (AB body mass index N2 loss)
S8	(TI body mass index N2 gain) OR (AB body mass index N2 gain)
S7	(TI body mass index N2 change) OR (AB body mass index N2 change)
S6	(TI weight change*) OR (AB weight change*)
S5	(TI overweight or over weight) OR (AB overweight or over weight)
S4	(TI weight gain) OR (AB weight gain)
S3	(TI obese or obesity) OR (AB obese or obesity)
S2	(MH "Weight Gain")
S1	(MH "Pediatric Obesity+")

APA PsycInfo 1806 to end of September 2024

1	exp obesity/
2	exp overweight/
3	Weight Gain/
4	obes*.ti,ab.
5	weight gain.ti,ab.
6	(overweight or over weight).ti,ab.
7	weight change*.ti,ab.
8	Body Mass Index/
9	((bmi or "body mass index") adj2 (gain or loss or change)).ti,ab.
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9

11	social support/
12	((behaviour or behavior) and change).ti,ab.
13	(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.
14	((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.
15	social support.ti,ab.
16	(peer adj2 support).ti,ab.
17	counsel?ing.ti,ab.
18	(education* adj1 (intervention* or program* or class* or counsel* or teach* or workshop* or module* or consultation* or session*)).ti,ab.
19	home visit*.ti,ab.
20	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	exp Breast feeding/
22	Nutrition/
23	Eating Behavior/
24	((child or toddler or infant$) adj1 (food or feeding or nutrition$)).tw.
25	((responsive or complementary) adj1 feeding).ti,ab.
26	((diet* or nutrition) adj (modif* or strateg* or intervention* or advice or program* or class* or counsel* or educat* or instruct* or teach* or train* or guidance or lesson* or workshop* or module* or consultation* or session*)).ti,ab.
27	healthy eating.ti,ab.
28	(fruit or vegetable*).ti,ab.
29	(high fat* or low fat* or fatty food*).ti,ab.
30	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
31	exp Exercise/
32	exercis*.ti,ab.
33	(physical activity or physical inactivity).ti,ab.
34	sedentary behavio?r.ti,ab.
35	screen time.ti,ab.
36	31 or 32 or 33 or 34 or 35
37	sleep/
38	exp prevention/
39	exp Health Promotion/
40	exp Health Education/
41	prevention.mp.
42	prevent*.ti,ab.
43	(health promotion or health education or health communication).ti,ab.
44	(obesity adj2 prevent*).ti,ab.
45	(overweight adj2 prevent*).ti,ab.
46	38 or 39 or 40 or 41 or 42 or 43 or 44 or 45
47	10 and (20 or 30 or 36 or 37) and 46
48	((child* or infant* or baby or toddler* or pediatr* or paediatr*) not adolescen*).ti,ab.
49	(pregnan* or antenatal or parent or parent$1 or care giver or caregiver or guardian or family or families or mother$1 or father$1).ti,ab.
50	48 or 49
51	47 and 50
52	(exp animals/ not humans.sh.) or (rat or rats or mouse or mice or rodent*).ti.

53	51 not 52
54	exp experimental design/
55	randomi#ed.ti,ab.
56	randomly.ab.
57	exp clinical trials/
58	trial.ti.
59	exp randomized controlled trial/ or exp randomized controlled trials as topic/
60	54 or 55 or 56 or 57 or 58 or 59
61	53 and 60

WHO ICTRP up to 4 October 2024

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

Clinicaltrials.gov up to 30 September 2024

Search string
Basic search
1. Condition: Obesity, Childhood Other Terms: prevention
2. Condition: Obesity, Childhood Other Terms: prevent

E: Risk of Bias assessments

We were able to conduct more comprehensive risk of bias checks than standard due to availability of individual participant data. For instance, we assessed the integrity of randomisation by plotting cumulative accrual to groups over time and allocation by day of the week, and missing data could be assessed across groups and for all outcomes. We conducted separate risk of bias assessments for the primary outcome, and each outcome domain (i.e., other weight-related outcomes, infant feeding, dietary intake, movement, sleep, parent/caregiver outcomes), because blinding, measurement and missing data varied across these outcomes.

Primary outcome

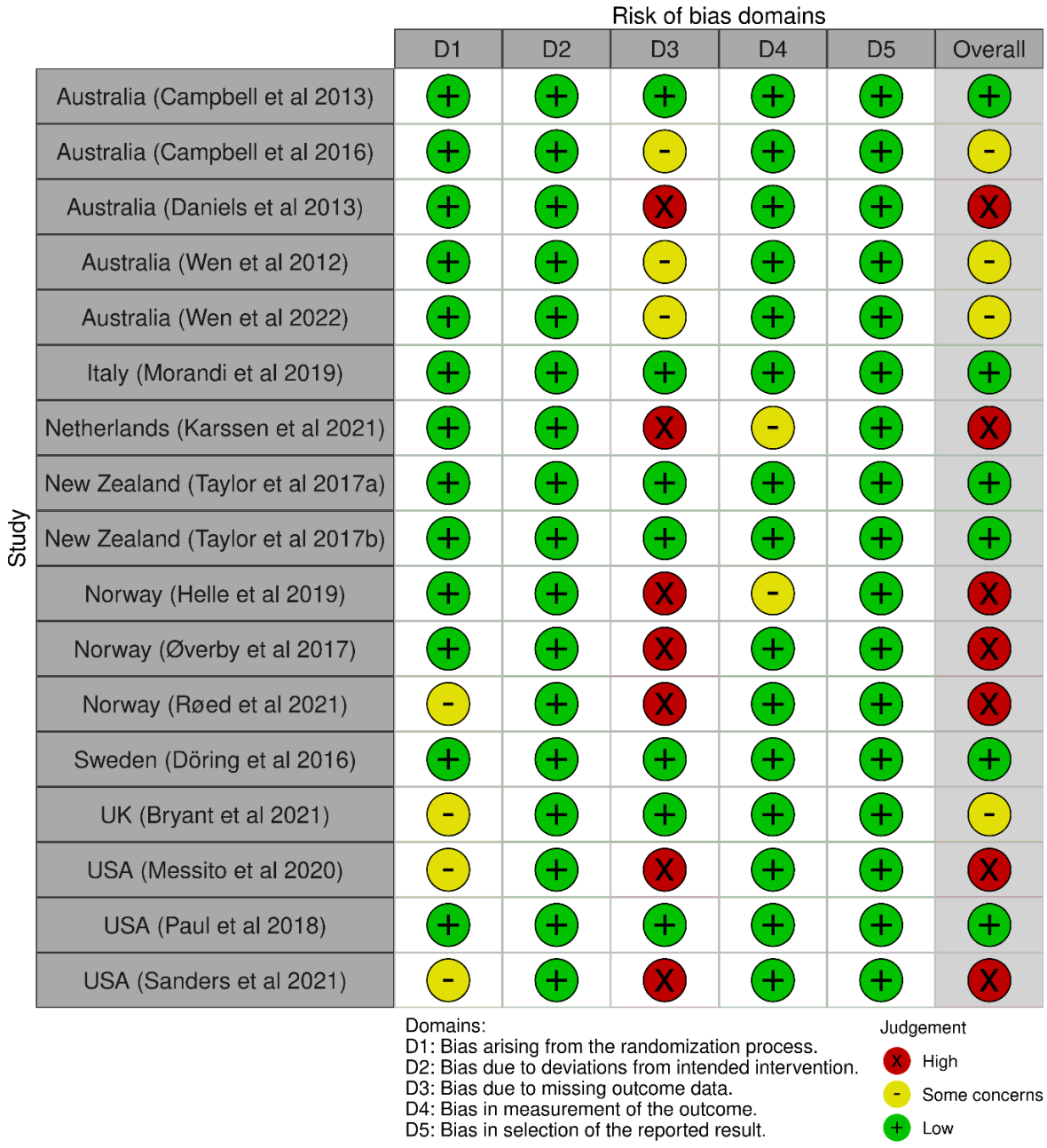

Figure 1. Risk of bias assessments for all trials for the primary outcome (BMI z-score at age 24±6 months)

Anthropometric outcomes

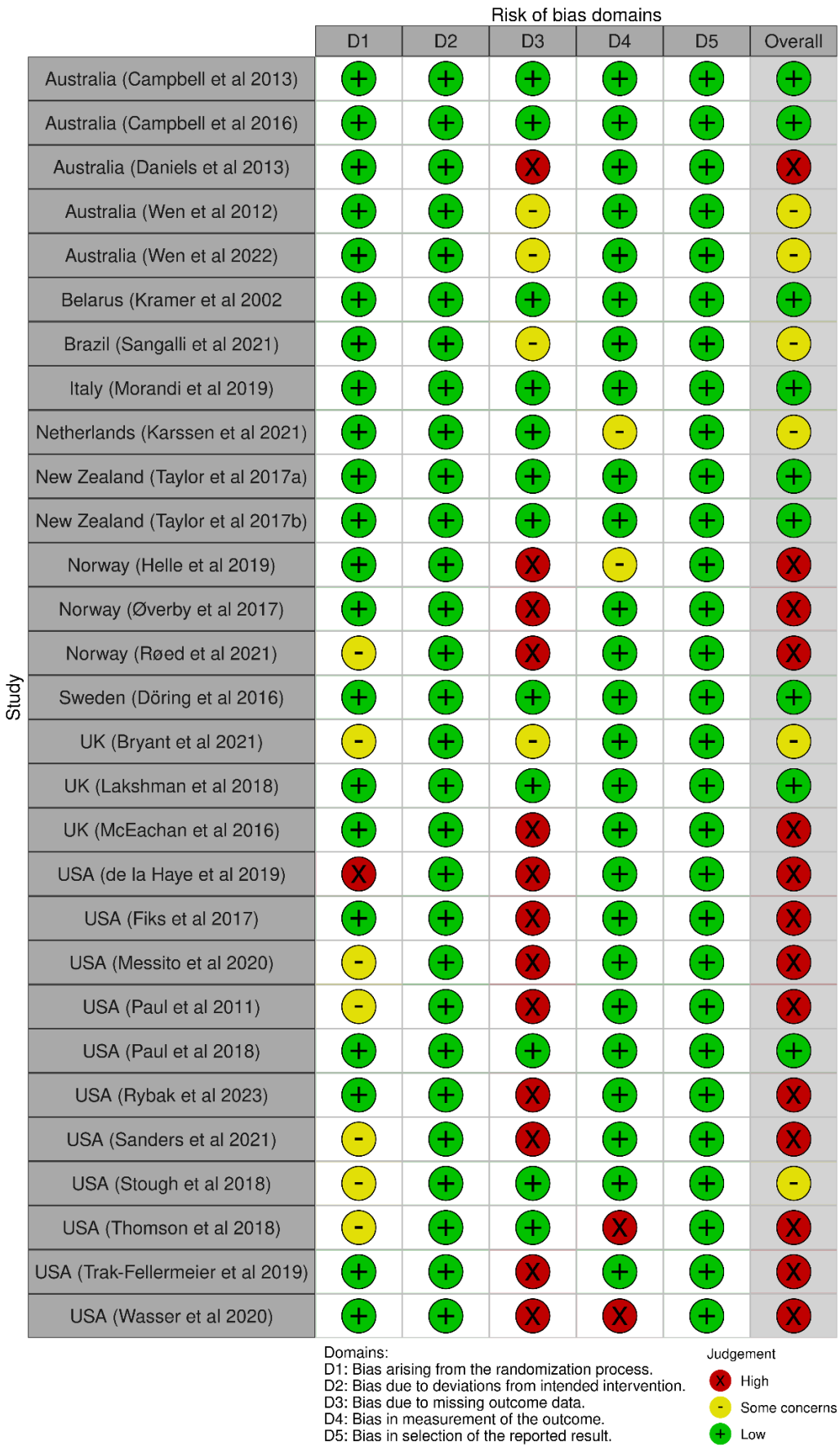

Figure 2. Risk of bias assessments for all trials for anthropometric outcomes

Breastfeeding

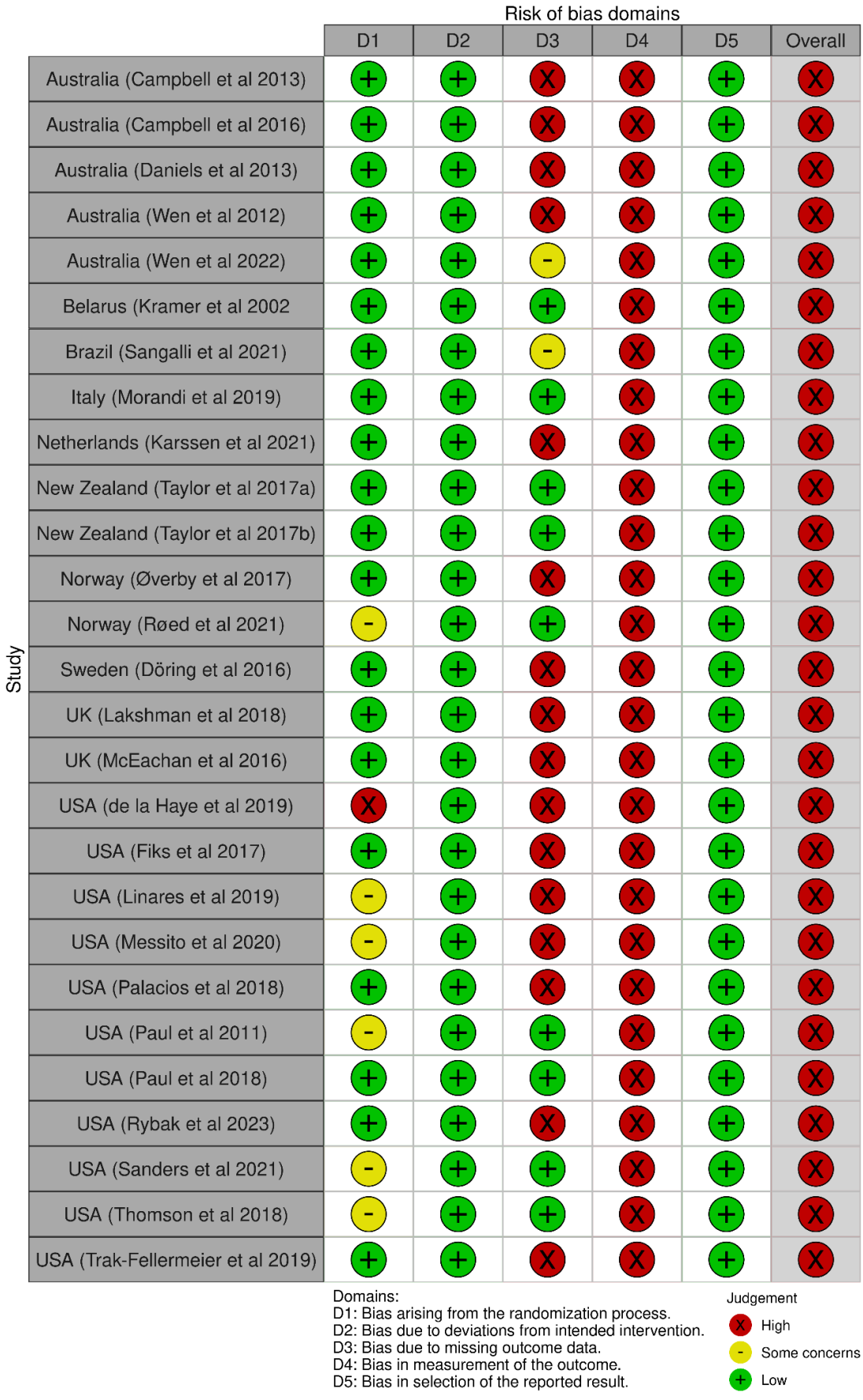

Figure 3. Risk of bias assessments for all trials for breastfeeding outcomes

Diet

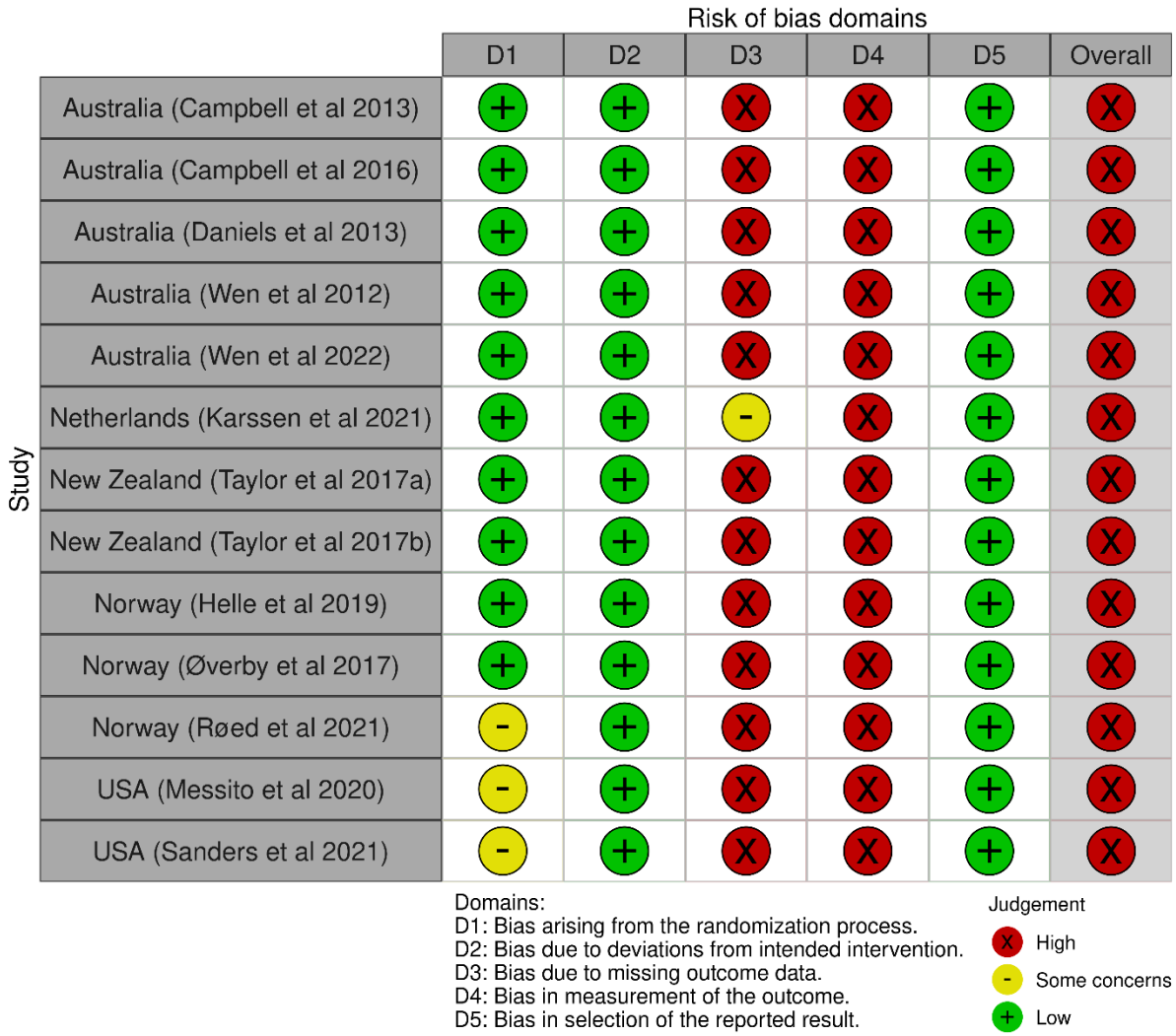

Figure 4. Risk of bias assessments for all trials for dietary outcomes

Activity

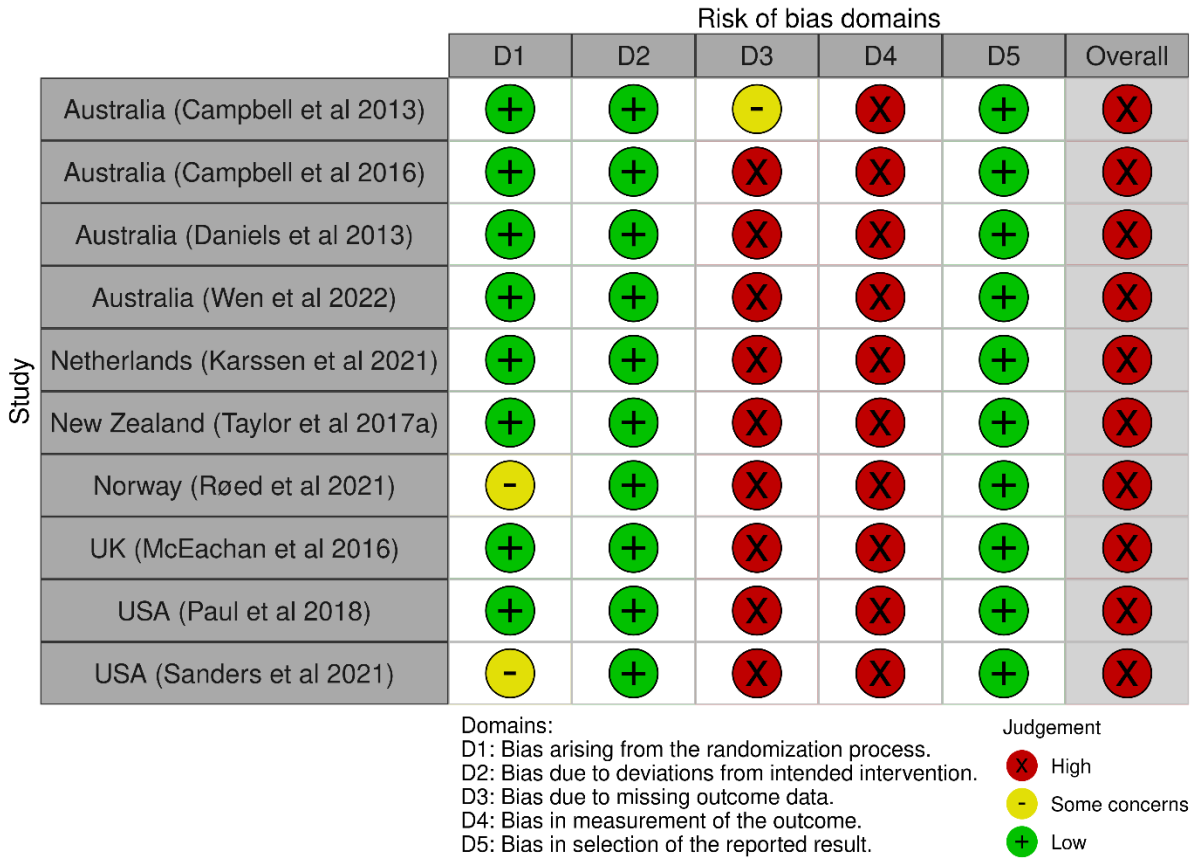

Figure 5. Risk of bias assessments for all trials for activity outcomes (including movement and sedentary behaviours)

Sleep

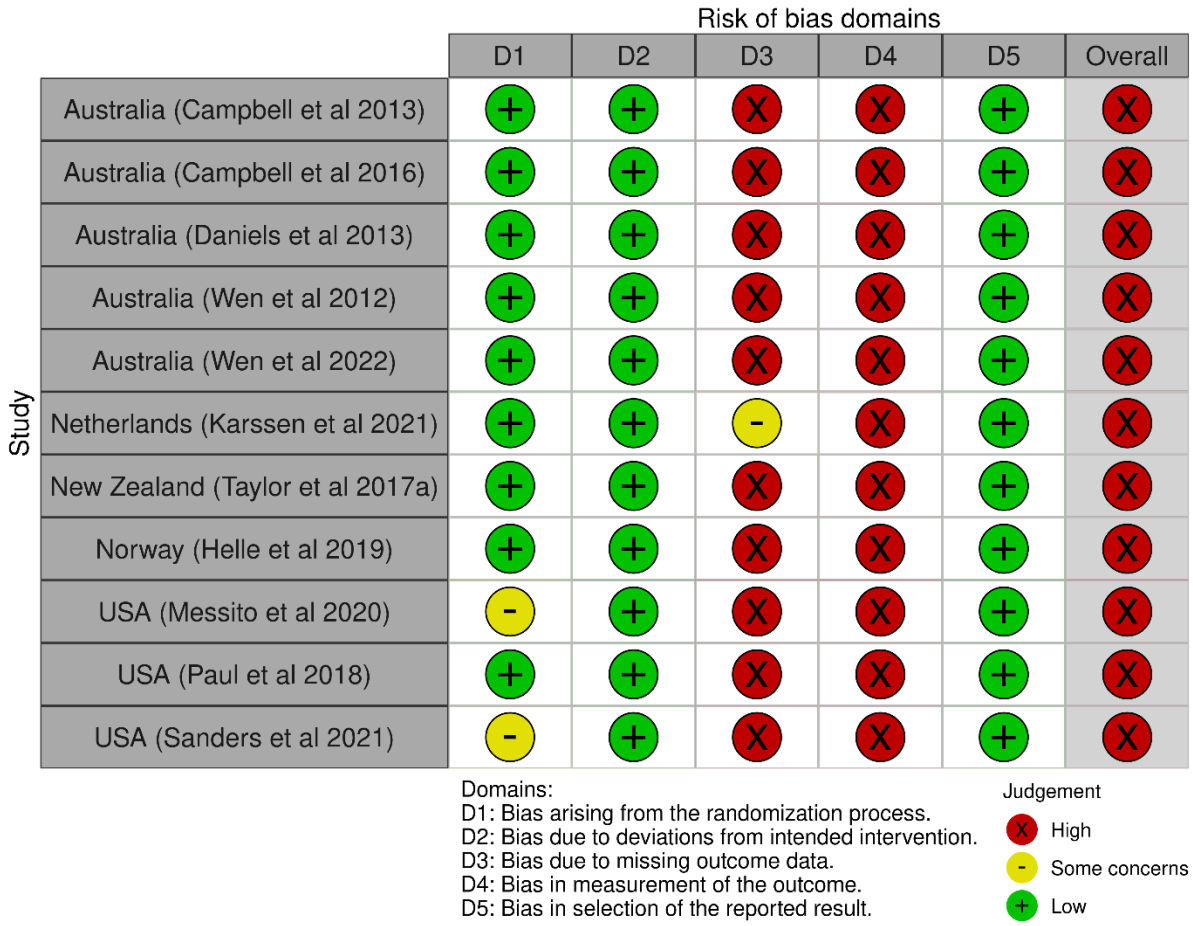

Figure 6. Risk of bias assessments for all trials for sleep outcomes

Parent

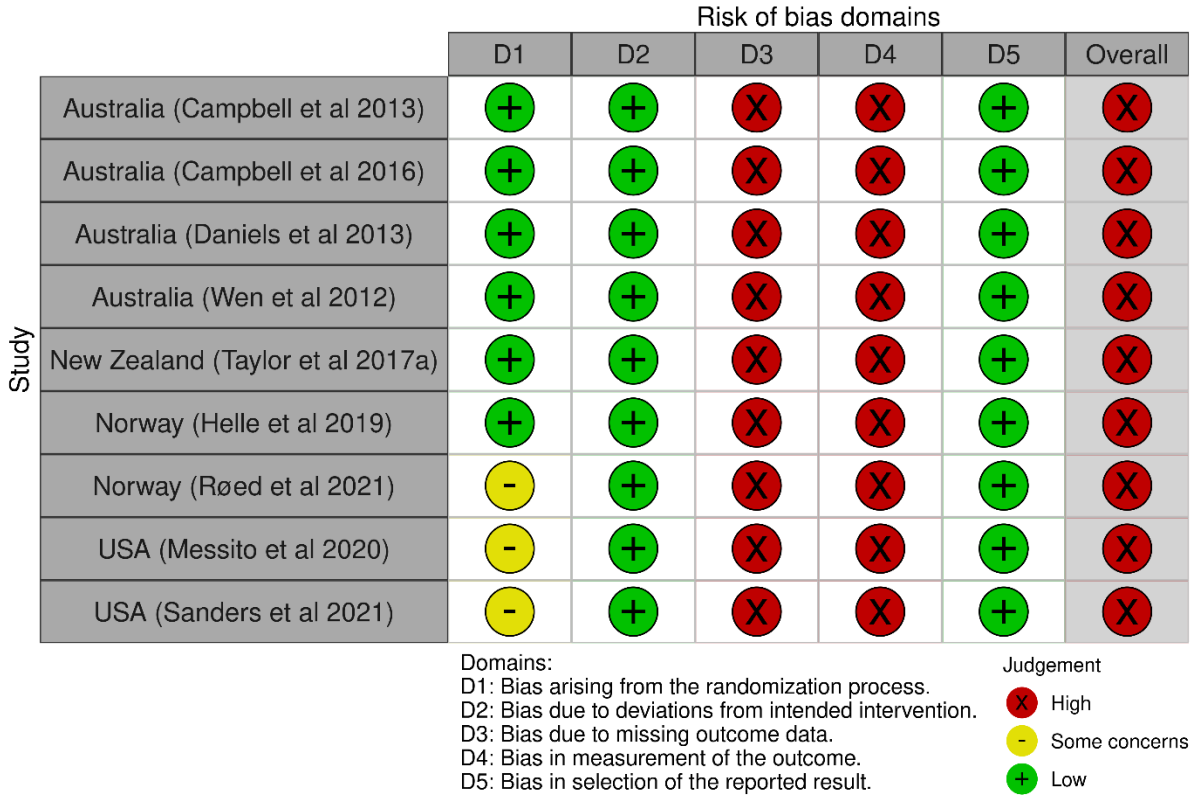

Figure 7. Risk of bias assessments for all trials for parent-related outcomes

F: Comparison of trials providing and not providing IPD

n=17 aggregate data studies

Item of assessment	Consistent with IPD trials	Details
Data availability	✗	• Only 1 out of 17 (6%) AD studies had data available for primary outcome
Statistical methods	✗	• For the 1 AD study with primary outcome data available, there was no adjustment for sex (as for IPD)
Baseline characteristics	✓	• IPD and AD studies assessed comparable populations
Study characteristics	✗	• AD studies had slightly earlier start year (median 2010 vs 2012 for IPD studies) • AD trials had smaller sample size (median 246 vs 308 for IPD studies)
Effect size	?	• Only 1 AD study had data available for primary outcome – no effect
Risk of Bias	✗	• Overall risk of bias lower for IPD studies
Trustworthiness	✗	• AD studies less trustworthy than IPD studies according to integrity tool

Decision: exclude AD from main analysis

IPD = individual participant data, AD = aggregate data

G: Trial and Baseline Characteristics

Eligible trial characteristics

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
Australia (Campbell et al 2013)[1]	Published	IPD provided	Cluster	2008/ 2010	542	First-time parent regularly attending first-time parent group	Postnatal	6 x 2-h sessions delivered within pre-existing mothers' groups (3, 6, 9, 12, 15, 18 mo) Behaviours targeted: Food provision and parent feeding practices, Movement practices (271)	Usual care plus quarterly newsletter on general child health messages excluding sleep, food and activity (271)	Dietary intake
Australia (Campbell et al 2016)[2]	Recruitment completed (not published)	IPD provided	Cluster	2011/ 2020*	514	First-time parent groups with infants aged 3-4 months	Postnatal	6 x 1.5 h group-sessions (3, 6, 9, 12, 15, 18 mo), then quarterly newsletters for additional 24 mo Behaviours targeted: Food provision and parent feeding practices, Movement practices (263)	Usual care plus quarterly generic child health newsletters (251)	Anthropometry: height, weight, waist circumference, BMI z-score at 18 and 36 months of age
Australia (Daniels et al 2013)[3]	Published	IPD provided	Individual	2008/ 2009	698	First-time mothers of healthy term infants	Postnatal	2 education peer support modules (6 fortnightly sessions each) at age 4-7 and 13-16 mo at community health venues Behaviours targeted: Food provision and parent feeding practices, Movement practices (352)	Usual care plus quarterly newsletter on general child health messages excluding sleep, food and activity (346)	Food intake, food preferences, and feeding behaviour
Australia (Wen et al 2012)[4]	Published	IPD provided	Individual	2007/ 2010	667	Women expecting their first child, between 24-34 weeks gestation	Antenatal	8 home visits (antenatal, 1, 3, 5, 9, 12, 18, 24 mo); maternal Advice Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (337)	Usual care plus written home safety/tobacco prevention information at f/up sessions plus three mail outs (330)	BMI at 2 years of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
Australia (Wen et al 2022)[5]	Published	IPD provided	Individual	2017/ 2020	1,155	Pregnant women in their third trimester	Antenatal	Arm 1 (telephone support): 9 staged intervention booklets (mailed) and 9 x 30-60 min telephone support sessions to mothers by Child & Family Health Nurses (3rd trimester, 1, 3, 5, 7, 10, 12–15, 15–18, 18–24 mo) (386) Arm 2 (SMS): 9 staged SMS interventions after mailing intervention booklets Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (384)	Usual care comprising at least one nurse visit for general support at home and possible multiple home visits for vulnerable families from the local health districts (385)	BMI and BMI z-score at 24 months of age, breastfeeding duration, and timing of introduction of solids
Belarus (Kramer et al 2001)[6]	Published	IPD provided	Cluster	1996/ 1998	17,046	Full-term singleton infants weighing at least 2500g and their healthy mothers who intended to breastfeed	Postnatal	Breastfeeding promotion and support according to the World Health Organization's Baby Friendly Hospital Initiative at hospital and follow up visits. Behaviours targeted: Infant feeding practices (8865)	Usual care (8181)	Breastfeeding (any and duration), GI infection, respiratory tract infection and atopic eczema during the first 12 months of life
Brazil (Sangalli et al 2021)[7]	Published	IPD provided	Cluster	2008/ 2010	715	Pregnant women in their third trimester	Antenatal	Breastfeeding promotion, introduction of foods, healthy eating and healthy eating habits, based on the 'Ten Steps for Healthy Feeding' guideline. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (360)	Usual care (355)	Exclusive breastfeeding at 4 months
Italy (Morandi et al 2019)[8]	Published	IPD provided	Cluster	2014/ 2017	529	Parents or guardians and their healthy full-term newborns	Postnatal	Intensive education: At each well visit until child age 2 y, parents provided with oral and written information on obesity-	Usual education about nutrition and lifestyle, during their child's first 2 years of life (251)	BMI at 2 years of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								protective behaviours for their children. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (278)		
Netherlands (Karssen et al 2021)[9]	Recruitment completed (not published)	IPD provided	Individual	2018/ 2019*	270	Parents and their infant between 7-11 months of age	Postnatal	Mobile application parenting program, Samen Happie!, teaching parents about healthy parenting practices and general healthy authoritarian parenting style. Behaviours targeted: Food provision and parent feeding practices, Movement practices, Sleep health practices (137)	Waitlist control (133)	BMI at 6 and 12 months
New Zealand (Taylor et al 2017a)[10]	Published	IPD provided	Individual	2009/ 2017	802	Pregnant women over 16 years of age, before 34 weeks gestation, and their full-term infant	Antenatal	Arm 1 (FAB): mix of 7 home visits and group based sessions promoting breastfeeding, healthy eating, physical activity (1 wk, 3, 4, 7, 9, 12, 18 mo) (205) Arm 2 (Sleep): 2 home visits (antenatal, 3 wks) targeting prevention of sleep problems, as well as a sleep treatment program if requested (6–24 months) (192) Arm 3: FAB and sleep Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (196)	Usual care: First 4 wk midwife home visits; Well Child (Plunkett) nurse: 8 visits in 5 y (209)	Weight at 6, 12 and 24 months of age; BMI at 24 months of age
New Zealand (Taylor et al 2017b)[11]	Published	IPD provided	Individual	2012/ 2016	206	Pregnant women over 16 years of age	Antenatal	BLISS (Baby-Led Introduction to Solids): lactation consultant support (3 face-to-face, 2	Usual "Well Child" care, usually consists of 6-7 home or clinic	BMI at 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						before 34 weeks gestation and their full-term infant		telephone; 10-60 min each) up to age 6 mo and 3 personalized face-to-face contacts (5.5, 7, 9 mo) Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (105)	visits (from 6 wk to 2 y of age) from trained health professional (101)	
Norway (Helle et al 2019) [12]	Published	IPD provided	Individual	2015/ 2021	533	Parent and their infant between 3-5 months of age	Postnatal	eHealth intervention: access to website with 7 x monthly short video clips (3-5 min) addressing infant feeding topics and age-appropriate baby food recipes Behaviours targeted: Food provision and parent feeding practices (269)	Usual care from their local child health clinic with consultations at child age 6, 8, 10, 12 mo (264)	Child eating behaviour, food intake, mealtime routines, maternal feeding practices at 12 months of age
Norway (Øverby et al 2017) [13]	Published	IPD provided	Individual	2012/ 2015	110	Parents and their infant between 4-6 months of age	Postnatal	2 x 4 h course days providing parent groups with nutritional information and instruction to prepare nutritious and varied dishes, delivered by home economics teacher and Masters student Behaviours targeted: Food provision and parent feeding practices (57)	Parents receive a booklet containing recipes for homemade foods for infants (53)	Food intake at 6, 15 and 24 months of age
Norway (Røed et al 2021) [14]	Published	IPD provided	Individual	2015/ 2022	237	Parent and their infant approximately 12 months of age	Postnatal	Food4toddlers eHealth intervention: website with 7 modules (2-4 lessons of ~10 min each) promoting healthy food and eating environments, recipes, discussion forum, information about food and beverages, plus 20 weekly emails with link to new lessons	Usual care at the community child health centres (119)	Child diet quality and food variety, assessed at inclusion, 18, 24, and 48 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								Behaviours targeted: Food provision and parent feeding practices (118)		
Sweden (Döring et al 2016) [15]	Published	IPD provided	Cluster	2008/ 2015	1,148	First-time mothers recruited at child health care centres and their infant between 9-10 months of age	Postnatal	9 sessions: 1 group (11 mo), 6 individual (8-9 mo, 1, 1.5, 2, 3, 4 y), 2 individual telephone (2.5, 3.5 y) delivered by nurse focusing on healthy food habits and physical activity. Behaviours targeted: Food provision and parent feeding practices, Movement practices (448)	Usual care: regular age-related health checkups of Swedish child health services (700)	BMI and waist circumference of children at 48 months of age and their mothers
UK (Bryant et al 2021) [16]	Published	IPD provided	Cluster	2017/ 2019	28	Parents and at least 1 infant/child aged 6-60 months	Postnatal	8-week HENRY (Health, Exercise, Nutrition for the Really Young) programme, including 8 weekly 2.5 h sessions delivered in children centres to groups of 8–10 parents Behaviours targeted: Food provision and parent feeding practices, Movement practices (13)	Wait list control (15)	Feasibility, child BMI z-score after 12 months
UK (Lakshman et al 2018) [17]	Published	IPD provided	Individual	2011/ 2015	669	Parents (mainly mothers) and their infants between 2-14 weeks of age that are formula-fed	Postnatal	Baby Milk supported mothers feeding their babies according to the WHO recommendations for energy requirements: 3 x 30-45 min face-to-face contacts (2,4 and 6 onths of age), 2 x 15-20 min phone calls (3 and 5 months of age) and leaflets (2 and 4 months of age). Involved components on motivation, setting goals and actions, and overcoming barriers. Behaviours targeted: Infant feeding practices (340)	Usual care group had the same number of contacts but received general information about formula-milk feeding and infant health (329)	The change in infant weight standard deviation score from birth to 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
UK (McEachan et al 2016)[18]	Published	IPD provided	Individual	2012/ 2012	120	Pregnant women with BMI ≥25 between 10–26 weeks gestation and their infant	Antenatal	HAPPY aimed to promote breastfeeding, promote healthy eating and habits, and promote physical activity: delivered through 12 group sessions (6 antenatal, 6 postnatal). Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (59)	Usual care (61)	Feasibility and acceptability, child weight after 12 months
USA (de la Haye et al 2019a)[19]	Published	IPD provided	Individual	2018/ 2022	50	Mother-child dyads enrolled in home visitation programs; Infants aged between birth to 24 months	Antenatal	HVP core curriculum with nutrition and physical activity enhancement: Home visits (weekly for 6 months). Behaviours targeted: Food provision and parent feeding practices, Movement practices (30)	Healthy families America Home visitation program: Home visits (weekly, up to 2-5 years of age). Culturally sensitive program to strengthening parent-child relationships, promote child development and link to community resources. (20)	Weight of mothers, rate of weight gain of infants, waist circumference of mother
USA (Fiks et al 2017)[20]	Published	IPD provided	Individual	2014/ 2015	85	Pregnant women, with Medicaid insurance, and BMI ≥25 and their infant	Antenatal	Grow2Gether for healthy infant growth and behaviour: 2 x in-person meetings (at enrolment and 4 months of age), 11 online group activities (2 prenatally, and until 9 months of age). Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (43)	Receive text message reminders; to schedule recommended primary care visits for their infant, and to attend appointments scheduled in CHOP Care Network (42)	Feasibility

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
USA (Linares et al 2019)[21]	Published	IPD provided	Individual	2016/ 2018	39	Hispanic pregnant women who intended to breastfeed and their infant	Antenatal	ECOR-H culturally acceptable and linguistically diverse promotion of exclusive breastfeeding: Prenatal sessions (40 min), prenatal calls (10 min), Hospital visit (30 min), postpartum home visit (40 min), postpartum calls (monthly, 10 min) (20)	Usual care provided by the Special Supplemental Nutritional for Women, Infants, and Children (WIC) program (19)	Exclusive breastfeeding from birth to 6 months of age
USA (Messito et al 2020)[22]	Published	IPD provided	Individual	2012/ 2020	533	Pregnant women with a singleton uncomplicated pregnancy	Antenatal	StEP (Starting Early Program): 15 sessions: 2 individual (3rd trimester; postpartum), 13 group (1, 2, 4, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33 mo), providing nutrition counselling and support Behaviours targeted: Infant feeding practices, Movement practices (266)	Usual care: 1 prenatal nutrition consultation, 1 childbirth or breastfeeding class, as-needed lactation support, paediatric visits as per American Academy of Pediatrics guidelines (267)	Infant feeding practices and material infant feeding knowledge at 10 months of age
USA (Palacios et al 2018)[23]	Published	IPD provided	Individual (block)	2016/ 2016	202	Caregivers and their healthy term infants between 0-2 months of age participating in Women, Infants and Children (WIC) Program	Postnatal	SMS: Weekly text messages (for 4 months) reinforcing the feeding messages provided by WIC. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (102)	Control text messages were sent, relating to general infant's health (100)	Infant weight-for-length percentile after 4 months
USA (Paul et al 2011)[24]	Published	IPD provided	Individual	2006/ 2009	160	Mother-newborn dyads, primiparous, singleton, gestational age ≥ 34 weeks	Postnatal	SLIMTIME Nurse home visits (2-3 weeks after birth and at 4-6 months of age). Arm 1 Introduction to Solids: Instruction on delay of complementary foods and importance of repeat exposure to foods.	Usual care (41)	Weight-for-length percentile at 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (38) Arm 2 Soothe/Sleep: Parents were taught alternate strategies to feeding as an indiscriminate first response to infant distress. Behaviours targeted: Infant feeding practices, Sleep health practices (39) Arm 3 Soothe/Sleep and introduction to solids: both programs above. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Sleep health practices (42)		
USA (Paul et al 2018)[25]	Published	IPD provided	Individual	2012/ 2023	291	Full term singleton infants born to primiparous mothers	Postnatal	Responsive parenting: 4 home visits by research nurses (age 3, 16, 28, 40 wk), annual research center visits until 3 y; focused on feeding, sleep, interactive play, emotion regulation. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (145)	Home safety intervention (146)	BMI z-score at 36 months of age
USA (Rybak et al 2023)[26]	Published	IPD provided	Individual	2021/ 2022	65	Mothers and infants from singleton pregnancies, >2 500g at birth and between 37-42 weeks gestation	Postnatal	A strengths-based responsive parenting intervention (THRIVE) delivered via Integrated Behavioral Health at well-child visits (1, 2, 4 and 6 months of age) that helps caregivers recognize and respond to infant	An socioemotional development and positive parenting intervention matched for time, attention, and level of provider, but did not contain the	Feasibility (enrolment), acceptability (retention and adherence)

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								cues for hunger, fullness, and distress, emphasizing non-feeding soothing strategies, responsive feeding practices, and sleep-promoting behaviours. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Sleep health practices (33)	specific active ingredients of the THRIVE intervention related to infant feeding, sleep, and regulation (32)	
USA (Sanders et al 2021)[27]	Published	IPD provided	Cluster	2010/ 2014	865	Caregiver and infant approximately 2 months of age, born >1500g	Postnatal	Greenlight toolkit- low literacy booklets that reviewed dietary, physical activity, sleep, and screen time advice for parents and education for providers on health communication. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (459)	Attention placebo-Injury prevention counselling according to The Injury Prevention Program by the American Academy of Pediatrics (406)	Percent of children with a BMI ≥85th percentile at 24 months of age
USA (Stough et al 2018)[28]	Recruitment completed (not published, results publicly available)	IPD provided	Individual	2018/ 2020*	32	Parent and infant between 2-3 months of age, born >38 weeks gestation, and above 10th percentile of length-for-weight	Postnatal	Healthy Start to Feeding has 3 individual sessions providing parent education and skills training on responsive feeding approach to introduction of healthy foods. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (16)	Participants and their parents will complete pre- and post-treatment period study visits to assess study outcomes. They will receive no intervention (16)	Weight-for-Length percentile, appetite regulation, fruit & vegetable variety at 3 and 9 months of age
USA (Thomson et al 2018)[29]	Published	IPD provided	Individual	2013/ 2016	54	Pregnant women at least 18 years of age and <19 weeks	Antenatal	Parents as Teachers Experimental arm will receive the enhanced nutrition and physical activity lessons and materials which will follow the	Parents as Teachers curriculum, home visits, optional group sessions (monthly), developmental	Maternal: gestational weight gain, weight retention, dietary intake, physical

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						gestation and their infant		family well-being Parents as Teachers curriculum. The added maternal weight management and early childhood obesity prevention components are based on social cognitive theory and behaviour change. Monthly lessons at in home visits from gestational month 4 to 12 months of age. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (24)	screenings and resource network for families. To increase parental knowledge of child development, improve parenting, early detection of developmental delay, prevent abuse and increase child reading (30)	activity; Infant dietary at 12 months of age
USA (Trak-Fellermeier et al 2019) [30]	Published	IPD provided	Individual	2013/ 2015	31	Pregnant women with a BMI >25, between 8-16 weeks gestation and their infant	Antenatal	Health empowerment program, individual visits; 2 visits (prenatal ~16 and ~27 weeks gestation), group sessions; 6 sessions of 2h (starting 1-2 weeks after randomisation, occurring every 2 weeks), phone calls; 6 calls of 30min (monthly). Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (15)	Group sessions with health advice about dental care and child safety (16)	Gestational weight gain
USA (Wasser et al 2020) [31]	Published	IPD provided	Individual (stratified)	2013/ 2017	429	Non-Hispanic black pregnant women <28 weeks gestation and their infant from a singleton pregnancy	Antenatal	Home visits; 6 visits by peer educators over 2 years (prenatal <28 weeks gestation and antenatal 1, 3, 6, 9, 12 months); maternal and study partner advice Behaviours targeted: Infant feeding practices, Food provision and parent feeding	Attention-control received maternal advice on injury prevention (214)	Infants' mean weight-for-length z-score at 15 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								practices, Movement practices, Sleep health practices (215)		
Brazil (Vitolo et al 2005) [32]	Published	IPD provided (excluded – missing data)	Individual (block)	2001/ 2015	500	Mothers who gave birth to healthy infants >2500g and ≥37 weeks gestation	Postnatal	Ten Steps to Healthy Eating: Food Guide for Children Under Two Years 4 given to mothers during 10 home visits, carried out in the first 10 days after delivery and then monthly until at 6 months, at 8, 10 and 12 months Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (200)	Usual care (300)	Exclusive breastfeeding at 1 year of age, infant dietary intake at 1, 4, 8, 12 years of age
USA (Golova et al 2023) [33]	Published	IPD provided (excluded – quasi-randomised)	Quasi (Doctor by day of the week)	2017/ 2017	144	Parents and their full term infant between 8-16 weeks of age	Postnatal	Handouts about sugar sweetened beverages, videos on healthy nutrition and sugar sweetened beverages Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (67)	Not defined (77)	Intake of and knowledge about sugar sweetened beverages after 12 months
USA (Reifsnider et al 2018) [34]	Published	IPD provided (excluded – missing data)	Individual	2012/ 2017	174	Latina women I their third trimester of pregnancy, 18-40 years of age with a pre-pregnancy BMI ≥25	Antenatal	Education Home Visits delivered by community health workers based on the Institute of Medicine recommendations Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (91)	Usual care (83)	BMI at 36 months
UK (Bryant et al 2024) [35]	Planned (recruitment not started)	Agreed to collaborate	Cluster	2023/ 2026	984	Parents and their infants/children between 6-60 months of age	Postnatal	HENRY core practitioner training and group facilitation training Behaviours targeted: Infant feeding practices, Food provision and parent feeding	Usual care	BMI at 12 months

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								practices, Movement practices, Sleep health practices		
USA (de la Haye et al 2019b)[36]	Ongoing	Agreed to collaborate	Cluster	2018/ 2023	77	Mother or primary caregiver of an infant between 2-8 months of age, with a BMI >18.5	Postnatal	Standard Healthy Families America home visitation (HVP)curriculum with the obesity prevention enhancement module, delivered by trained home visitors	Standard HVP Curriculum	Mother or carer BMI at 6 and 12 months. Infant weight at 6 and 12 months.
USA (Salvy et al 2018)[37]	Ongoing	Agreed to collaborate *(AD NA)*	Cluster	2019/ 2024	296	Healthy mothers enrolled in the First Teacher Home Visiting Program and their children 0-48 months of age	Postnatal	Home visitation program and the HABITS program. The HABITS module will target 5 key behaviors (physical activity, increasing fruit and vegetable consumption, decreasing sugary beverages, decreasing fried foods, and encouraging regular self-monitoring and self-weighing)	Standard home visitation program	Mother or caregiver weight, and infant weight after 6 and 12 months.
USA (Widen and Jacobvitz 2019)[38]	Ongoing	Agreed to collaborate	Individual	2019/ 2026	165	Mothers or caregivers of infants 4-5 months of age - postnatal	Postnatal	MAGIC: responsive feeding coaching to help them recognize hunger and satiety cues and nutrition coaching that involves recommending a sequence of introducing complementary foods	Infant Safety and Injury Prevention	Infant BMI percentile at 12 and 24 months of age
Canada (Dennis et al 2021)[39]	Ongoing	Agreed to collaborate	Individual (by family)	2017/ 2032	5,230	Women (and their partner) planning to get pregnant within 3 years, without children or a maximum of one child and are between 3-12	Antenatal	HeLTI-Canada: 4 phases: (1) preconception, (2) pregnancy, (3) infancy and (4) early childhood. Public health nurse collaborative care and access to an individualized e-health cloud platform that includes web-based resources and multi-platform interventions	Access to an e-health cloud platform that includes web-based resources that pertain to safety only.	Child overweight and obesity rate at 60 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						months postpartum		pertaining to preconception risk factors		
Ireland (O'Reilly et al 2021)[40]	Ongoing	Agreed to collaborate	Block	2021/ 2024	800	Pregnant women <24 weeks gestation, at high risk of gestational diabetes	Antenatal	Bump2Baby: Personalised tele-health coaching service provided through a smartphone application. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices	Usual care	Mother BMI at 12 months postpartum
USA (Goran et al 2017)[41]	Ongoing	Agreed to collaborate	Individual	2017/ 2025	211	Pregnant women or mothers and their infant <1 month of age, who have or have had a singleton pregnancy, who identify as Hispanic and consume sugar sweetened beverages	Postnatal	MAMITA: Arm 1: A health education program incorporating sugar reduction education delivered by the health educator during in-person home visits, or virtually via phone or video calls. Plus home delivery of bottled water administered over 24 months. Arm 2: Sugar reduction education only	Health education program	Mother and infant anthropomorphic measurements at 6, 12 and 24 months
China (Xia et al 2020)[42]	Ongoing	Agreed to collaborate	Individual	2021/ 2029	138	Infants ≤1 month of age born term and large for gestational age	Postnatal	Feeding guidance, motor development assessment and guidance and Healthcare education	Usual care	Rate of overweight and obesity at 2 and 7 years of age
USA (Stough et al 2021)[43]	Ongoing	Agreed to collaborate	Individual	2022/ 2023	30	Mothers and infants <2 months of age, born from a singleton pregnancy >37	Postnatal	Heathy Eating for My Infant (HEMI): Two standard treatment modules will be provided to each family by a study interventionist focusing on infant nutritional requirements,	Usual care	BMI at 9 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						weeks gestation - postnatal		responsive feeding, and mealtime behaviours. Two additional treatment modules will be selected to address the unique needs articulated by each family (e.g., food insecurity, eating healthy on a limited income, emotional eating, engaging other caregivers, maternal mental health). two peer counselor-led sessions during which families can discuss implementation of recommendations and barriers to change.		
Sri Lanka (Kiridan et al 2021)[44]	Ongoing	Agreed to collaborate	Individual (block)	2021/ 2024	776	Newborn infants from singleton pregnancy	Postnatal	Parental guide on Infant and Young; Child Feeding (IYCF) and advice on exclusive breast feeding will be given along with knowledge on hunger cues and satiety cues of the infant which will help establish responsive feeding	Usual care	Weight z-score at 12 months of age
USA (Karasz and Bonuck 2018)[45]	Recruitment completed (not published)	Agreed to collaborate	Individual	2017/ 2021	380	Infants < 6 months	Postnatal	CHALO: 6 home visits with mothers/families over a 12 month period along with follow-up phone support, and patient navigation support for child to receive 2 dental visits: one by 12 months of age and one by 18 months of age	Enhanced usual care-pamphlet and dental referral list	Amount of sippy cups and bottles consumed per day at 18 months of age
USA (Campos et al 2020)[46]	Recruitment completed (not published)	Agreed to collaborate	Cluster	2018/ 2023	530	Pregnant women in their third trimester with a singleton pregnancy, enrolled in the	Postnatal	Baby Act Trial: Enhanced WIC program with additional nutritional education and services. An interactive distance learning platform, short	Standard WIC program	Weight for length z-score at 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						Women, Infants and Children program		messaging platforms, telephone calls		
USA (Palacios et al 2021)[47]	Recruitment completed (not published)	Agreed to collaborate	Individual	2021/ 2022	50	Parents and infants 4-12 months of age	Postnatal	Baby Feed: online web portal to evaluate infant diets and provide recommendations	Usual care	Infants diet (FFQ) and DQIS score 3 months after intervention
UK (Manikam et al 2022)[48]	Recruitment completed (not published, results publicly available)	Agreed to collaborate *(AD NA)*	Cluster	2019/ 2023	186	Mothers or female carers and infants <24 months of age with Indian, Sir Lankan, Pakistani or Bangladeshi background	Postnatal	Nurture Early for Optimum Nutrition (NEON): Arm 1: Face-to-face in children centres/community centres using the NEON intervention toolkit. Arm 2: Virtual delivery of NEON intervention toolkit	Usual care	Infants BMI z-score after 3.5 and 6 months
USA (Ventura et al 2022)[49]	Published	Agreed to collaborate *(AD NA)*	Cluster	2019/ 2019	246	Mothers and infants <60 days of age from a singleton pregnancy, enrolled in the Women, Infants and Children Program	Postnatal	More Inclusive Assessment of Early Infant Feeding Decisions as a Foundation for Tailored Intervention. Enhancing WIC Resources to Support Optimal Infant Feeding, Including Healthy Bottle-Feeding, Throughout the First Year of Life. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (124)	Standard WIC program (122)	Infant weight z-score at 3 and 6 months of age
Guatemala (Acero et al 2020)[50]	Recruitment completed (not published)	IPD requested	2 stage: cluster then individual	2018/ 2021	1,280	Pregnant women in their third trimester or mothers and infants <4.5 months of age	Antenatal and postnatal	SPOON: Arm 1: Small Quantity Lipid-based Supplements (SQ-LNS) from 6-24 months. Arm 2: Behavioural change strategy includes individual home-visits,	Active comparator: standard care and supplementation with micronutrient powders	Infant feeding, infant height and weight z scores and gain rates, haemoglobin and prevalence of anaemia, prevalence of

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								group sessions, and community mobilization activities		obesity and stunting after 24 months
USA (Hodges et al 2020)[51]	Recruitment completed (not published, results publicly available)	IPD requested *(AD NA)*	Individual	2017/ 2019	71	Mothers and infants between 3-9 months of age	Postnatal	LiTTLeMe: Responsive Feeding Training given over 4 monthly 1-hour sessions. Behaviours targeted: Food provision and parent feeding practices (37)	Usual care (34)	Infant weight-for-length z-score after 6 months
USA (Paul et al 2005)[52]	Recruitment completed (not published)	Data not available	Individual	2005/ 2006	40	New mothers and their infant from a singleton pregnancy, born ≥37 weeks gestation and ≥2500g	Postnatal	Teaches infants to sleep through the night by 8 weeks of age through feeding an environment	Usual care	Infant sleep at 8 weeks of age
Netherlands (Vlasblom et al 2020)[53]	Published	Data not available (data sharing not approved by institution) *(AD NA)*	Cluster	2008/ 2013	1995	Parents and their infant 2 weeks of age	Postnatal	BeeBOFT Arm 1: BBOFT: a focus on child rearing issues that are relevant for the development of behaviors related to overweight, starting at birth and using elements of learning theory, stimulus control and modelling. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (901)	Standard youth health care program (1094)	Infant overweight behaviours, healthy sleep, BMI and prevalence of overweight and obesity at 36 months of age
USA (Schroeder et al 2015)[54]	Published	Data not available (excluded due to integrity issues)	Individual (cluster-stratified)	Not disclosed	278	Healthy newborns born ≥2000g, not requiring any specialized medical or nutritional care	Postnatal	The intervention was based on the modules of Growing Leaps and Bounds (GLB). 12 sets of educational brochures were designed to be presented and discussed with caregivers at pediatric visits at 1, 2, 4, 6, 9, 12,	Not specified (144)	Anthropometric measurements at 12 and 24 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
		(AD extracted)						15, 18, and 24 months of age and at annual visits thereafter up to age 5 years (134)		
USA (Savage et al 2023) [55]	Published	Data not available *(AD NA)*	Individual	2016/ 2019	346	Mothers and their infants from full-term singleton pregnancies, enrolled in the Women, Infant and Children program	Postnatal	WEE Baby: Responsive parenting program using advanced health technology strategies, delivered at regular WIC visits. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (178)	Standard WIC program (168)	Anthropometric measurements at 2,5 and 7 months
Belgium (Verbestel et al 2014) [56]	Published	Data not available (data sharing not approved by institution) *(AD NA)*	Cluster	2008/ 2009	203	Mothers and their infants between 9-24 months of age attending a participating day care centre	Postnatal	A family-based healthy lifestyle intervention was developed and implemented through day-care centres. The intervention aimed at increasing daily consumption of water (instead of soft drinks), milk, fruit and vegetables, increasing daily physical activity and decreasing daily consumption of sweets and savoury snacks and daily screen-time behaviour	Usual care	Infant BMI and lifestyle behaviours after 12 months
USA (Thomas et al 2018) [57]	Ongoing	Declined	Individual	2018/ 2023	416	Infants/children 0-60 months of age	Postnatal	Back to Basics: Increase consumption of local traditional foods and nutrient-dense non-traditional foods, decrease SSB consumption, and decrease prevalence of obesity in children	Standard Rural CAP	Child BMI measured annually for 48 months, change in calories derived from traditional foods
USA (Lavner et al 2022) [58]	Published	Declined *(AD NA)*	Individual (stratified by sex-specific birth weight)	2018/ 2021	212	African American mothers and their newborns	Postnatal	Sleep Soothe: AN adaptation of the INSIGHT 2-week responsive parenting program. Information on how to respond to their baby's cues related to sleeping and fussiness (108)	Information on a safe sleep environment, as well as other strategies to keep baby safe (104)	Infant conditional weight gain at 16 weeks

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
Netherlands (de Vries et al 2015)[59]	Published	Declined *(AD NA)*	Cluster	2006/ 2009	161	Women in their third trimester of pregnancy or mothers and their newborns	Postnatal	Physical activity stimulating program. Advice to stimulate motor activity and motor development at the age of two weeks, two months, four months, eight months and eleven months (96)	Usual care (65)	Child growth and body composition at 30 months of age
Canada (Maguire et al 2022)[60]	Planned (recruitment not started)	Contacted	Individual	2024/ 2027	620	First time parents with an infant 0-1 week of age	Postnatal	Nutrition Recommendation Intervention trialS in children's Healthcare (NuRISH): Factorial design for beastfeedin support and childcare navigation support to prevent obesity and improve cardiovascular, development and mental health Arm 1: Childcare navigator support Arm 2: Breastfeeding support Arm 3: Both	Usual care	Infant BMI z-score at 24 months of age
USA (Feinberg et al 2022)[61]	Planned (recruitment not started)	Contacted	Individual	2023/ 2027	825	Two-parent military families expecting their first child, up to 7 months gestation	Antenatal	Healthy Family Foundations (HFF): 10 weekly 2 hour classes (5 prenatal and 5 postnatal) in groups of 5-10 couples online. Postnatal classes will occur 2-8 months after birth and will also be weekly and last 2 hours each.	Usual care	Infant BMI at 12 months of age
China (Wu et al 2021)[62]	Ongoing	Contacted	Cluster	2018/ 2029	4,500	Women 20-42 years of age, planning to become pregnant within 6 months or pregnant and <14 weeks gestation with a singleton pregnancy	Antenatal	SCHeLTI: Healthy conversations group, Patient centered, one-on-one, face-to-face sessions, and frequent contacts with a multidisciplinary team, group educational activities and social support, personalised text messaging, motivation tools, community based activities	Usual care and access to web-based tools and Apps that provide information on child health and safety	Child BMI at 60 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
India (Kumaran et al 2021)[63]	Ongoing	Contacted	Cluster	2021/ 2028	6,000	Married women with 0-1 child, planning to become pregnant within 24 months	Antenatal	EINSTEIN: optimise nutrition, group parenting program, lifestyle support for diet, feeding and eating habits, reduction of environmental pollutions	Enhanced standard care. Vaccination promotion, iron and folate supplementation, and standard health advice during and after pregnancy	Child adiposity using fat-mass index at 5 years of age
South Africa (Norris et al 2022)[64]	Ongoing	Contacted	Individual	2019/ 2026	6,800	Women 18-28 years of age	Antenatal	BUKHALI: Beginning pre-conceptually to provide health and nutritional information, offer health services, identify healthy behaviours and act as a health care support network. The resource book and facilitator's manual cover 8 modules (women's health, chronic diseases, diet, sleep, physical activity and fitness, sitting, body size and image, and emotional awareness) in 18 sessions.	Standard care plus. Email, SMS and phone information for practical life skills, and HIV and pregnancy testing counselling.	Child fat mass index at 60 months of age
Denmark (Skovgaard et al 2022)[65]	Ongoing	Contacted	Cluster (stepped-wedge)	2021/ 2026	446	Infants aged 9 to 10 months in the PUF-program with high levels of cognitive, emotional and regulatory problems	Postnatal	Video-Feedback Intervention to Promote Positive Parenting (VIPP) adapted to PUF context: Home based intervention delivered over six sessions of about two hours, with two to three weeks intervals	Usual care through the PUF program	Child mental health, and social and emotional development at 2 years of age
France (Schwartz et al 2022)[66]	Ongoing	Contacted	Individual	2022/ 2027	330	First time parents of newborn infants 1- 54 days of age and their parents	Postnatal	feediNg gUidelines infanT RandomIzEd coNtrolled Trial (NUTRIENT): Smartphone application and brochures delivering relevant infant feeding messages, providing information and very short videos illustrating some aspects	Brochures delivering Infant feeding messages	BMI z-score at 3 years of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
China (Fan et al 2021)[67]	Ongoing	Contacted	Individual	2022/ 2024	480	Newborn infants up to 28 days of age	Postnatal	a tailored sleep intervention strategy, which involves appropriate sleep schedule and bedtime routine, putting the child to bed while still sleepy rather than when already asleep, and waiting 1 to 2 minutes before attending to the child during nocturnal awakenings	Sleep monitoring only	Childs sleep condition, anthropometrics, metabolism index and circadian rhythm at 4, 6 and 12 months, and 2 years of age
France (Lioret et al 2016)[68]	Ongoing	Contacted	Individual	2017/ 2027	800	Healthy pregnant women in their third trimester from a socially disadvantaged background	Antenatal	The prEgnanCy and eArly Childhood nutrItion triaL (ECAIL): Home based (during 3rd trimester, and at 3, 6, 12, 18 and 24 mo of age) educational component to build knowledge, skills and social support for parents regarding feeding practices, and lifestyle behaviours, consistent with the French Nutrition and Health Program (PNNS) guidelines. Fresh fruit and vegetable baskets, kitchen utensils and cooking devices are made available at a reduced price. Provision of follow-on formula, baby and family food vouchers	Usual care, general information on healthy eating.	Vegetable consumption (times/day) at 2 years of age
USA (Lewis et al 2022)[69]	Ongoing	Contacted	Individual	2022/ 2023	20	Infants/children 6-48 months of age enrolled in the Women, Infants and Children program who consume 2 or more sugar sweetened	Postnatal	WHISPER: A 6-month intervention based on the use of 5 components: 2 educational videos, provision of a water-promotion "toolkit," a mobile phone application (app), a series of 14 computerized interactive voice response (IVR) phone calls to parents and 2 counselling sessions by a WIC	Standard WIC program	Consumption of sugar sweetened beverages at 3 and 6 months

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						beverages per day		nutritionist to compare families' SSB's consumption behaviors		
USA (Ingalls et al 2019) [70]	Recruitment completed (not published)	Contacted	Individual (block)	2017/ 2023	259	Pregnant Native American women between 14-24 years of age are <32 weeks gestation with one or no other children	Antenatal	Family Spirit Nurture (FSN) and optimised standard care: FSN home-visiting module consists of 36, 60-minute lessons delivered by trained local Family Health Coaches (FHCs), from 28 weeks gestation to 18 months postpartum. Breastfeeding promotion, complementary and responsive feeding, healthy diet and physical activity, mental health, healthy choices and home safety	Home visit Injury prevention education and optimised standard care. 8 30-minute lessons delivered by trained local Family Health Liaisons (FHL), from 28 weeks gestation to 18 months postpartum	Breastfeeding, infant feeding style, consumption of fruit and vegetables, sugar sweetened beverages, snack and desserts, physical activity, sedentary behaviour and BMIz at 2 years of age
USA (Beck et al 2018) [71]	Recruitment completed (not published)	Contacted	Individual	2018/ 2021	194	Parents who self-identify as Latino and their newborn infant from a singleton pregnancy	Postnatal	Parents will receive education on infant feeding, sleep, and screen time practices just after well-child visits in the first year of life. The education will be provided by a lay health educator. Parents will also receive text messages to reinforce the intervention content	Parents will receive basic education on financial topics including budgeting, savings, and managing debt as well as coaching on these topics just after well-child visits in the first year of life. Text message follow up.	Dietary intake, screen time and parent health-related quality of life at 15 months of age
USA (Virudachalam et al 2012) [72]	Recruitment completed (not published)	Contacted	Individual	2012/ 2013	47	Pregnant women or caregivers of children 0-36 months of age with income below federal poverty level	Antenatal and postnatal	Cooking with Friends: community-located, peer mentoring intervention aimed at improving home food preparation practices in families with young children. 5 weekly classes.	Delayed entry control	Food frequency questionnaire at 23 weeks

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
USA (Horodynski et al 2015)[73]	Recruitment completed (not published, results publicly available)	Contacted *(AD NA)*	Individual	2014/ 2016	164	Low-income, first-time mothers between 15-19 years of age and their infant <2 months of age, who feed their infant at least once per day and had a birth at 37-42 weeks gestation and 2500-3750g	Postnatal	T4TM: Web application with a daily challenge accessed over 6 week intervention, daily text messages, information to infant feeding, open communication with health staff.	MIHP standard care consists of voluntary home visits: one week postpartum, at six weeks, and six months, and on-going as needed provided by a RN, licensed social worker, RD, infant mental health specialist and/or paraprofessional	Change in infant growth at 3 and 6 months of age
USA (Spieker et al 2015)[74]	Recruitment completed (not published)	Contacted	Individual	2014/ 2017	58	Women aged 18-35 with low risk-pregnancy within the military health system, with BMI >18 and ≤29.2	Antenatal	Positive-gain-based health promotion interventions capitalize on the basic human desire to maintain consistency between one's words and actions for beneficial outcomes. Sessions once during each trimester and at 2 weeks, 2 months, 4 months and 6 months postpartum	Standard VA/DoD care	Maternal weight gain at delivery
USA (Whooten et al 2021)[75]	Recruitment completed (not published)	Contacted	Individual (stratified by clinic)	2020/ 2023	657	Both first time parents during the second trimester of pregnancy who's infant is born ≥37 weeks gestation	Antenatal	First Heroes: First 1000 Days program adapted for fathers. Fathers who were present at the 8–10 week prenatal visit completed an intake questionnaire with additional followup from a patient navigator to enroll fathers in an educational text messaging campaign and discuss any psychosocial stressors identified	Attention control: enhanced usual care with safety education	Rapid infant weight-gain and prevalence of overweight at 6 and 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								on the intake questionnaire. Patient navigators called each father four weeks after the initial contact to follow-up		
Columbia (Aldana-Parra et al 2020)[76]	Recruitment completed (not published, results publicly available)	Contacted *(AD NA)*	Individual	2018/ 2019	90	Pregnant women in their third trimester with overweight or obesity	Antenatal	Breastfeeding counselling intervention for overweight women base on Carl Rogers' Client-Centred Theory. The intervention will be conducted by a certified breastfeeding counsellor during pregnancy, at birth and early infancy (43)	Standard counselling (47)	Duration of breastfeeding, growth velocity and maternal weight loss at 4 months of age
Netherlands (van Vilet et al 2022)[77]	Published	Contacted *(AD extracted)*	Individual (factorial)	2016/ 2020	246	Mothers and infants 4- 6 months of age	Postnatal	Baby's First Bites: Arm 1: Vegetable exposure. Repeated exposure to a variety of vegetables from the start of complementary feeding (61) Arm 2: VIPP-feeding infants. Promotion of responsive feeding practices from the start of complementary feeding (62) Arm 3: Both (60)	Phone calls with mother about development of child, no advice on complementary feeding (63)	Change in vegetable intake, change in vegetable liking, change in self-regulation of energy intake at 18, 24 and 36 months and self-regulation of energy intake at 18 months
USA (French et al 2012)[78]	Published	Contacted *(AD NA)*	Cluster	2005/ 2007	306	Mothers and infants <2 months of age	Postnatal	Arm 1: Maternal-focused intervention (MOMS): Maternal eating habits, diet and healthy dietary choices (101) Arm 2: Ounce of prevention: Guidance on serving size per age and tips for introducing new foods for the infant (101)	Bright futures standard care (104)	Infant weight-for-height at 12 months of age
USA (Horodynski et al 2011)[79]	Published	Contacted *(AD NA)*	Individual	2012/ 2013	547	Low income mothers or carers of infants <4 months of	Postnatal	Healthy Babies Infant-centered feeding: 6 in-home lessons before infant is 6 months old. In-home lesson content for infant-	Active control: Standard care from the Expanded Food and Nutrition	Maternal responsiveness, feeding styles and feeding practices at

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
						age who have not started solids		centered feeding involves - interpreting hunger and satiety cues and introduction to solid foods Duration of lessons - 60-80 minutes (weekly or monthly)	Education Program (ENFEP): Healthy Families	6 and 12 months of age
Denmark (Carlsen et al 2013)[80]	Published	Contacted *(AD NA)*	Individual	2010/ 2013	226	Mothers who participated in the TOP-Study and their infant <48h of age born term	Postnatal	Regular telephone-based advisory support to prolong breast-feeding period (108)	Usual care (118)	Infant anthropometric measurements at 6 months
France (Parat et al 2019)[81]	Published	Contacted *(AD NA)*	Individual	2008/ 2013	275	Pregnant women ≤21 weeks gestation and BMI ≥25 who have a singleton pregnancy	Antenatal	ETOIG: 4 group education sessions: healthy diet and physical activity, infant feeding, infant diet, weaning nutrition and health (138)	oral and written information about diet and exercise at baseline during a face-to-face dietician visit at 26 weeks gestation (137)	Infant weight gain at 2 years of age
USA (Cloutier et al 2018)[82]	Published	Contacted (Excluded due to integrity issues) *(AD NA)*	Cluster	2013/ 2016	57	Pregnant women or mothers of newborn infants from a singleton pregnancy >34 weeks gestation	Antenatal and postnatal	ECHO: Enhanced Nurturing family Network visitation program: additional breastfeeding support, family wellness, education and skill-building around nutrition, feeding, eating habits and healthy behaviours, toolkit to support change, community programs (30)	Standard Nurturing family Network visitation program (27)	Breastfeeding duration, introduction of solids, consumption of sugar sweetened beverages, infant weight-for-length and infant BMI at 6 and 12 months
USA (Rosenstock et al 2021)[83]	Published	Contacted *(AD NA)*	Individual	2017/ 2019	134	Navajo mothers and their infant <14 weeks of age	Postnatal	Family Spirit Nurture: Home-visiting module, consisting of six 45-minute lessons delivered biweekly by trained local American Indian Family Health Coaches, from 3 to 6 months postpartum. Delivery of drinking water (68)	3 safety and injury prevention home-based lessons (66)	Early parent feeding practices and sugar sweetened beverage consumption at 6, 9 ,and 12 months of age

Study ID*	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
Poland (Woźniak et al 2022)[84]	Published	Contacted *(AD NA)*	Individual	2019/ 2022	203	Both parents and their infant 6-8 weeks of age	Postnatal	Intensive nutritional education delivered to parents via short text messages about their infants' nutrition (approximately four to six times a week). Text messages' content was adjusted to a few conditions (e.g., infant's age, stage of development or season of the year) (102)	Usual care (101)	Infant BMI z-score and blood metabolites (cholesterol, glycerides, lipoproteins, glucose, protein and albumins) at 12 months of age
Spain (Pérez López et al 2017)[85]	Unknown	Contacted	Cluster	2015/ 2018	414	Pregnant women between 12-16 weeks gestation	Postnatal	PROGESPI: Primary care centres during pregnancy and the first 2 years of the child. Intervention consists of six 90 minutes workshops, two of those during pregnancy and the other four within the following two years after the birth of the children. They intend to encourage the shift towards healthy lifestyles to parents on issues related to diet, physical activity and smoking habit, encourage breastfeeding.	Standard Comprehensive Program of Woman Assistance	Infant BMI z-score at 2 years of age

For unpublished trials, trial registrations have been used, where year of registration and Principal Investigator is indicated.

Data for this table reflect trial information at time of analyses and may not be current. Trials providing intervention materials have more detailed intervention and control descriptions, with behaviours targeted.[86]

The availability of aggregate data (AD) for the primary outcome, BMI z-score at 24 months of age, has been indicated as 'extracted' or NA – not available.

Newly identified eligible trials from March 2023 up to October 2024

An updated search for eligible trials was conducted on 30 September 2024 (MEDLINE, Embase, CENTRAL, CINAHL, PsycInfo, ClinicalTrials.gov) and on 4 October 2024 for WHO ICTRP due to website outages. Seven trials were identified as eligible (two published, five incomplete unpublished trials). The two completed eligible trials had a combined sample size of 120 participants. These data were not included in our study due to the time intensive nature of IPD meta-analysis. However, we will endeavour to include these data (and other data from completed eligible trials) in any future analysis cycles.

Study ID	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
USA (Cheney et al 2023)[87]	Recruitment completed (not published)	Not yet contacted	Individual	2023/ 2024	96	Latino mothers and their infant < 4 months of age and normal birth weight. Eligible for government program such as WIC, Early Head Start, MediCal, CalFresh, etc. Have another caregiver >18 years of age who performs >3 h of care per week.	Postnatal	Grow Well will receive the adapted Healthy Beginnings Curriculum. The intervention will be on mothers' and caregivers' infant feeding knowledge, use of recommended feeding practices, and infant anthropometric measurement outcomes.	Healthy Steps curriculum or treatment as usual as this is the curriculum commonly shared during well baby visits	Efficacy of the intervention, infant feeding practices, and anthropometric data at 12 months
Italy (Morandi et al 2023)[88]	Not yet recruiting	Not yet contacted	Individual	2024/ 2028	3000	Newborn infants < 5 days of age	Postnatal	TAPEObesity: Nutritional and lifestyle counselling. At risk children Intervention Arm: schedule at least 4 visits/year with anthropometric monitoring, educate parents on appropriate diet, active lifestyle from the first year of life, regular self-monitoring of their child's anthropometry and appropriate dietary composition and portion control, provide tailor-made nutritional suggestions.	Usual care	Percentage of children growing on an obesity trajectory at 3 years of age

Study ID	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								Not-at-risk children Intervention Arm: educational website with interactive tools for growth self-monitoring and diverse lifestyle suggestions.		
Australia (Yoong et al 2024)[89]	Not yet recruiting	Not yet contacted	Cluster	2024/ 2027	540	Infants between 4-12 months of age at sites that enrol at least 5 or more infants	Postnatal	The Tiny Bites program is a primarily digital intervention that supports early childhood education and care (ECEC) services and primary caregivers of children aged <2 years with improving child nutrition. Tiny Bites will be delivered across ~18 months. Weekly-fortnightly test messages, monthly-bimonthly digital newsletters, access to digital resources including seminars.	Usual care: access to usual child and family health sites and government resources and links to infant feeding guidelines.	BMI z-score after 18 months
USA (Beck et al 2024)[90]	Not yet recruiting	Not yet contacted	Individual	2024/ 2029	576	Parents or caregivers who self-identify as Latino and their infant born > 37 weeks gestational age and >2600g birthweight	Postnatal	Futuros Fuertes 2.0 intervention: includes brief health education and coaching sessions just after well child visits in the first 2 yrs of life (total of 7 sessions), 2 text messages per week for the primary caregiver and up to 2 additional family members, and environmental prompts that support healthy behaviours including optimal infant feeding, screen time, sleep practices.	Brief health education and coaching sessions just after well child visits in the first 2 yrs of life (total of 7 sessions), 2 text messages per week for the primary caregiver and up to two additional family members, and environmental prompts that support healthy behaviours, incouding home safety, home management of common childhood illnesses, and	BMI z-score after 2 years

Study ID	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
									promotion of language development.	
Spain (Gómez Santos et al 2024)[91]	Recruiting	Not yet contacted	Individual (stratified)	2024/ 2027	1200	Children aged 0-5 years old and their parents who attend a participating child day care centre or nursery school in Barcelona and Madrid	Postnatal	PRESAFALIN: Phase 1, a 10-month intervention that encompasses 7 workshops, including 2 individual and 5 familiar workshops focused on promotion of parental social skills, self-efficacy and resilience to build up children's healthy lifestyles, such as sleep quality, emotional well-being, healthy eating, and physical activity. Phase 2, Children will be reevaluated at 6, 8, 10 and 12 years old while parents will be evaluated every year since their children will be 6 years old and until 12 years old.	Usual care	BMI z-score and anthropometric data
USA (Davis et al 2023)[92]	Completed	Published	Individual	2018/ 2021	38	Parent aged at least 18 years, of an infant 3-30 days of age with no special medical conditions or prematurity	Postnatal	Gain-framed short text messages with Health Belief Model concepts of perceived benefits, perceived barriers, self-efficacy and cues to action. 4 messages per week from start to 4 weeks, 2 messages per week from 5-8 weeks and 1 message each fortnight from 9 weeks to 12 months of age (21)	Child safety messages at similar frequency (19)	Weight-for-length percentiles and z scores at 2–4, 6–9, and 12 months
Australia (Gelmini et al 2024)[93]	Completed	Published	Individual	2014/ 2015	82	Parents and their children 4-18 months of age	Postnatal	Baby Healthy Living Triple P brief parenting discussion group. One 2-hr discussion group with the following sections: the challenges of raising a healthy baby, including the rise of infant	Usual care (40)	Infant Feeding Style Questionnaire, The Mealtime Scenarios scale, The Family Lifestyle Scale, The

Study ID	Study status	IPD status	Unit of randomisation	Dates	Sample size	Participants	Intervention start	Intervention/s (n)	Control (n)	Primary outcome/s
								obesity; infant self-regulation of energy intake and child-led feeding; healthy physical activity habits; infant sleep; role modelling as an early teaching strategy; positive parenting strategies (e.g., praise, backing up instructions) and coping skills to deal with emotions (e.g., anxiety). Two generic follow-up emails were also sent (42)		Anxiety and Confidence Scale

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Baseline characteristics of trials contributing to the primary outcome

For data quality, we systematically checked for completeness (of variables, participants, and values), compliance with our pre-defined and harmonised variable definitions (B: Statistical Analysis Plan pg 41), internal consistency/logic, consistency with published reports and trial registration records, and validity (including checks for extreme or implausible values and order of dates).

Child

Table G1. Baseline characteristics of children contributing IPD to the primary outcome

Characteristic	**Overall**, N = 9,128[1]	**Intervention**, N = 4,881[1]	**Control**, N = 4,247[1]
Birthweight (grams)	3,418.54 (529.83)	3,414.29 (512.20)	3,423.43 (549.49)
Missing	582	304	278
Birth length (cm)	50.10 (2.68)	50.14 (2.73)	50.06 (2.64)
Missing	8,379	4,507	3,872
Gestational age at birth, wks	39.91 (1.58)	39.94 (1.57)	39.87 (1.59)
Missing	4,700	2,576	2,124
Female	4,415 / 8,964 (49%)	2,374 / 4,784 (50%)	2,041 / 4,180 (49%)
Missing	164	97	67
Mother/birthing parent enrolled during pregnancy	3,363 / 9,128 (37%)	2,071 / 4,881 (42%)	1,292 / 4,247 (30%)
Missing	0	0	0
Age at study enrolment, wks (if enrolled after birth)	17.39 (12.84)	16.78 (12.82)	17.98 (12.83)
Missing	3,437	2,111	1,326
Size for gestational age			
Small for gestational age	76 / 2,856 (2.7%)	32 / 1,351 (2.4%)	44 / 1,505 (2.9%)
Appropriate for gestational age	2,247 / 2,856 (79%)	1,088 / 1,351 (81%)	1,159 / 1,505 (77%)
Large for gestational age	533 / 2,856 (19%)	231 / 1,351 (17%)	302 / 1,505 (20%)
Missing	6,272	3,530	2,742

[1]Mean (SD); n / N (%)

Carer

Table G2. Baseline characteristics of carers contributing IPD to the primary outcome

Characteristic	**Overall**, N = 9,128[1]	**Intervention**, N = 4,881[1]	**Control**, N = 4,247[1]
Maternal age at birth of child (yrs)	30.36(5.34)	30.61 (5.32)	30.08 (5.34)
Missing	1,491	754	737
Maternal pre-pregnancy body mass index (kg/m^2)	25.33 (5.45)	25.26 (5.36)	25.41 (5.56)
Missing	730	321	409
Maternal gestational weight gain	13.15 (6.65)	13.05 (6.60)	13.26 (6.69)
Missing	6,749	3,674	3,075
Maternal type 1 diabetes	5 / 1,435 (0.3%)	2 / 593 (0.3%)	3 / 842 (0.4%)
Missing	7,693	4,288	3,405
Maternal type 2 diabetes	5 / 1,435 (0.3%)	2 / 593 (0.3%)	3 / 842 (0.4%)
Missing	7,693	4,288	3,405
Maternal gestational diabetes	382 / 1,967 (19%)	250 / 1,175 (21%)	132 / 792 (17%)
Missing	7,161	3,706	3,455
Maternal smoking during pregnancy	412 / 3,623 (11%)	250 / 2,033 (12%)	162 / 1,590 (10%)
Missing	5,505	2,848	2,657
Multiple pregnancy	50 / 5,579 (0.9%)	16 / 2,882 (0.6%)	34 / 2,697 (1.3%)
Missing	3,549	1,999	1,550
Mode of delivery at birth			
Vaginal	1,078 / 1,596 (68%)	674 / 984 (68%)	404 / 612 (66%)
Caesarean	518 / 1,596 (32%)	310 / 984 (32%)	208 / 612 (34%)
Missing	7,532	3,897	3,635
Partner status at enrolment			
In a partnership (married, de facto, living with partner)	6,401 / 6,919 (93%)	3,577 / 3,870 (92%)	2,824 / 3,049 (93%)
Single (single, divorced and widowed)	518 / 6,919 (7.5%)	293 / 3,870 (7.6%)	225 / 3,049 (7.4%)
Missing	2,209	1,011	1,198
Parity/first-time parent	5,547 / 7,312 (76%)	2,851 / 3,930 (73%)	2,696 / 3,382 (80%)
Missing	1,816	951	865
Carer born in study country	3,116 / 4,772 (65%)	1,539 / 2,458 (63%)	1,577 / 2,314 (68%)

Characteristic	**Overall**, N = 9,128[1]	**Intervention**, N = 4,881[1]	**Control**, N = 4,247[1]
Missing	4,356	2,423	1,933
Weighted standardised median household income* at enrolment	-0.06 (0.46)	-0.09 (0.46)	-0.02 (0.45)
Missing	5,935	2,933	3,002
Carer education at enrolment			
Low (<High school graduate)	626 / 6,769 (9.2%)	323 / 3,679 (8.8%)	303 / 3,090 (9.8%)
High school graduate	1,459 / 6,769 (22%)	757 / 3,679 (21%)	702 / 3,090 (23%)
Non-university tertiary education or qualification	1,077 / 6,769 (16%)	558 / 3,679 (15%)	519 / 3,090 (17%)
University graduate or postgraduate	3,607 / 6,769 (53%)	2,041 / 3,679 (55%)	1,566 / 3,090 (51%)
Missing	2,359	1,202	1,157
Carer employment status at enrolment			
Any employment (including paid leave)	3,974 / 8,015 (50%)	2,181 / 4,364 (50%)	1,793 / 3,651 (49%)
Unemployed	4,041 / 8,015 (50%)	2,183 / 4,364 (50%)	1,858 / 3,651 (51%)
Missing	1,113	517	596

[1]Mean (SD); n / N (%)

Note that 55 (0.6%) of the 9128 carers in the analyses are not the mother/birthing parent, but are fathers or other carer type. These 55 carers were not counted towards maternal characteristics.

Baseline characteristics of all trials providing IPD

Table G3. Baseline characteristics of mother/birthing parent and child contributing IPD

	Overall, N = 28,825[1]	**Intervention,** N = 15,122[1]	**Control,** N = 13,703[1]
Mother/birthing parent			
Maternal age at birth of child (yrs)	26.67 (5.71)	26.77 (5.78)	26.57 (5.63)
Missing	1,636	831	805
Maternal pre-pregnancy body mass index (kg/m^2)	25.62 (5.68)	25.54 (5.56)	25.72 (5.82)
Missing	18,012	9,311	8,701
Maternal gestational weight gain	12.3 (6.04)	12.4 (5.81)	12.2 (6.28)
Missing	22,375	11,694	10,681
Maternal type 1 diabetes	21 / 19,420 (0.1%)	11 / 9,973 (0.1%)	10 / 9,447 (0.1%)
Missing	9,405	5,149	4,256
Maternal type 2 diabetes	18 / 19,260 (<0.1%)	12 / 9,854 (0.1%)	6 / 9,406 (<0.1%)
Missing	9,565	5,268	4,297
Maternal gestational diabetes	882 / 17,222 (5.1%)	454 / 9,423 (4.8%)	428 / 7,799 (5.5%)
Missing	11,603	5,699	5,904
Maternal smoking during pregnancy	1,081 / 22,762 (4.7%)	638 / 11,955 (5.3%)	443 / 10,807 (4.1%)
Missing	6,063	3,167	2,896
Multiple pregnancy	52 / 24,460 (0.2%)	17 / 12,704 (0.1%)	35 / 11,756 (0.3%)

Missing	4,365	2,418	1,947
Mode of delivery at birth			
Vaginal	16,738 / 19,510 (86%)	8,742 / 10,329 (85%)	7,996 / 9,181 (87%)
Caesarean	2,772 / 19,510 (14%)	1,587 / 10,329 (15%)	1,185 / 9,181 (13%)
Missing	9,315	4,793	4,522
Partner status at enrolment			
In a partnership (married, de facto, living with partner)	24,311 / 26,171 (93%)	12,860 / 13,889 (93%)	11,451 / 12,282 (93%)
Single (single, divorced, widowed)	1,860 / 26,171 (7.1%)	1,029 / 13,889 (7.4%)	831 / 12,282 (6.8%)
Missing	2,654	1,233	1,421
Parity/first time parent	16,087 / 25,761 (62%)	8,522 / 13,535 (63%)	7,565 / 12,226 (62%)
Missing	3,064	1,587	1,477
Carer born in study country	3,589 / 5,358 (67%)	1,777 / 2,751 (65%)	1,812 / 2,607 (70%)
Missing	23,467	12,371	11,096
Weighted standardised median household income at enrolment	-0.15 (0.70)	-0.16 (0.66)	-0.14 (0.74)
Missing	24,636	12,643	11,993
Carer education at enrolment			
Low (<High school graduate)	2,089 / 26,278 (7.9%)	1,137 / 13,823 (8.2%)	952 / 12,455 (7.6%)
High school graduate	15,589 / 26,278 (59%)	7,967 / 13,823 (58%)	7,622 / 12,455 (61%)
Non-university tertiary education or qualification	2,061 / 26,278 (7.8%)	1,101 / 13,823 (8.0%)	960 / 12,455 (7.7%)
University graduate or postgraduate	6,539 / 26,278 (25%)	3,618 / 13,823 (26%)	2,921 / 12,455 (23%)
Missing	2,547	1,299	1,248
Carer employment status at enrolment			
Any employment (including paid leave)	4,375 / 9,098 (48%)	2,409 / 4,945 (49%)	1,966 / 4,153 (47%)
Unemployed	4,723 / 9,098 (52%)	2,536 / 4,945 (51%)	2,187 / 4,153 (53%)
Missing	19,727	10,177	9,550
Child			
Birthweight	3,422.56 (464.70)	3,420.97 (459.06)	3,422.22 (470.88)
Missing	864	443	421
Birthlength	51.75 (2.32)	51.69 (2.29)	51.80 (2.35)
Missing	10,271	5,511	4,760
Gestational age at birth, wk	39.85 (1.18)	39.90 (1.19)	39.80 (1.18)
Missing	5,525	2,990	2,535
Female	13,786 / 28,453 (48%)	7,264 / 14,922 (49%)	6,522 / 13,531 (48%)
Missing	372	200	172
Mother/birthing parent enrolled during pregnancy	4,836 / 28,825 (17%)	2,807 / 15,122 (19%)	2,029 / 13,703 (15%)
Age at study enrolment, wk (if enrolled after birth)	4.26 (9.76)	3.93 (9.38)	4.61 (10.13)
Missing	5,093	2,981	2,112
Size for gestational age			
Small for gestational age	1,733 / 21,675 (8.0%)	890 / 11,131 (8.0%)	843 / 10,544 (8.0%)
Appropriate for gestational age	17,820 / 21,675 (82%)	9,206 / 11,131 (83%)	8,614 / 10,544 (82%)
Large for gestational age	2,122 / 21,675 (9.8%)	1,035 / 11,131 (9.3%)	1,087 / 10,544 (10%)
Missing	7,150	3,991	3,159

[1]Mean (SD); n / N (%)

Note that 55 (0.6%) of the 9128 carers in the analyses are not the mother/birthing parent, but are fathers or other carer type. These 55 carers were not counted towards maternal characteristics.

H: GRADE Certainty of Evidence

Question: Parent/caregiver-focused behavioural obesity prevention interventions compared to control for obesity prevention in children

Setting: Various

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute (95% CI)	
BMI z-score at age 24 ±6 months											
17	randomised trials	not serious	not serious	not serious	not serious	none	3496	3009	-	MD **0.01 lower** (0.08 lower to 0.05 higher)	⊕⊕⊕⊕ High
Duration of exclusive breastfeeding assessed at 6 ±2 months											
5	randomised trials	serious[a]	not serious	not serious	not serious	none	1007 participants	646 participants	**HR 0.86** (0.74 to 1.00) [Duration of exclusive breastfeeding assessed at 6 ±2 months]	**44 fewer per 1,000** (from 84 fewer to 0 fewer)	⊕⊕⊕◯ Moderate[a]
							-	39.0%		**44 fewer per 1,000** (from 84 fewer to 0 fewer)	
Vegetable intake per day at age 24 ±6 months											
12	randomised trials	serious[a]	not serious	not serious	not serious	none	2611	2005	-	MD **3.11 higher** (0.64 lower to 6.85 higher)	⊕⊕⊕◯ Moderate[a]

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative (95% CI)	Absolute (95% CI)	
Screen time per day at age 24 ±6 months											
9	randomised trials	serious[a]	not serious	not serious	not serious	none	2101	1549	-	MD **9.6 Minutes fewer** (13.72 fewer to 5.47 fewer)	⊕⊕⊕◯ Moderate[a]
Physical activity per day at age 24 ±6 months											
1	randomised trials	serious[a]	serious[b]	not serious	serious[c]	none	164	150	-	MD **24.14 minutes fewer** (57.17 fewer to 8.9 more)	⊕◯◯◯ Very low[a,b,c]
Combined sleep duration per night and day at age 24 ±6 months											
10	randomised trials	serious[a]	not serious	not serious	not serious	none	2121	1718	-	MD **0.06 Hours more** (0.02 fewer to 0.15 more)	⊕⊕⊕◯ Moderate[a]
Parent feeding practices: Control (Restriction) at age 24 (±6) months											
2	randomised trials	serious[a]	not serious	not serious	serious[d]	none	81/269 (30.1%)	91/276 (33.0%)	**RR 0.90** (0.72 to 1.13)	**33 fewer per 1,000** (from 92 fewer to 43 more)	⊕⊕◯◯ Low[a,d]

CI: confidence interval; **HR:** hazard ratio; **MD:** mean difference; **OR:** odds ratio; **RR:** risk ratio

Explanations

a. More than half of the evidence from trials judged high risk of bias

b. Cannot judge since only 1 trial contributing evidence

c. Confidence interval crosses line of no effect

d. Wide confidence interval crossing line of no effect

I: Other Secondary Outcomes

Note: Statistically significant effect estimates are bolded

Table I1. Effect estimates of other secondary outcomes

Outcome	N trials	N participants	Intervention Mean[a] (SD) or n/N (%)	Control[b] Mean[a] (SD) or n/N (%)	Unit	Effect estimate (95% CI)	Heterogeneity (T^2)
BMI z-score at age 12 ±3 months	26	23363	0.85 (1.09)	0.91 (1.05)	z-score	**Mean difference -0.06 (-0.11, -0.02)**	0.00
Weight z-score at age 12 months ±3 months	27	23584	0.79 (0.94)	0.83 (0.91)	z-score	Mean difference -0.04 (-0.08, 0.00)	0.00
Weight z-score at age 24 months ±6 months	17	6490	0.53 (0.97)	0.55 (0.98)	z-score	Mean difference -0.00 (-0.06, 0.06)	0.00
Overweight at age 24 months ±6 months	17	6505	359/3496 (10%)	315/3009 (10%)	events	Risk Ratio 0.94 (0.81, 1.09)	0.00
Obesity at age 24 months ±6 months	17	6505	49/3496 (1.4%)	45/3009 (1.5%)	events	Risk Ratio 1.05 (0.67, 1.63)	0.00
Waist circumference at age 24 months ±6 months	5	2369	47.71 (3.43)	48.01 (3.38)	centimetres	Mean difference -0.04 (-0.31, 0.24)	0.00
Waist-to-height ratio at age 24 months ±6 months	5	2334	0.56 (0.04)	0.57 (0.04)	numeric	Mean difference -0.00 (-0.01, 0.00)	0.00
Any breastfeeding	11	3808	2114/2255 (94%)	1415/1553 (91%)	events	Odds Ratio 1.21 (0.91, 1.60)	0.00
Duration of any breastfeeding (from birth until 24± 6 months of age)	9	2842	43.00 (33.34)	36.63 (29.50)	weeks	**Hazard Ratio 0.89 (0.82, 0.97**)	0.00
Age at introduction of solid foods (censored at 6 months)	9	3614	5.08 (1.14)	4.87 (1.26)	months	**Hazard Ratio 0.77 (0.63, 0.95)**	0.10
Energy intake per day at age 24 months ±6 months	2	435	4734.22 (1243.10)	4630.71 (1244.10)	kilojoules	Mean difference 86.00 (-110.98, 282.97)	0.00
Fruit consumed per day at age 24 months ±6 months	11	4206	252.25 (168.28)	231.77 (159.58)	grams	Mean difference 3.42 (-2.42, 9.26)	0.00
Intake of energy-dense-nutrient poor foods per day at age 24 months ±6 months	1	317	11.33 (11.63)	11.61 (12.13)	grams	Mean difference -0.34 (-3.09, 2.42)	0.00
Intake of sugar-sweetened beverages per day at age 24 months ±6 months	9	3325	52.07 (168.41)	69.54 (214.76)	millimetres	Mean difference -0.22 (-3.14, 2.71)	3.94
Average time per day restrained while awake at age 24 months ±6 months	3	1209	102.25 (112.93)	145.17 (122.26)	minutes	**Mean difference -2.85 (-5.67, -0.02)**	0.00
Tummy time at 6 months ±1 month	3	1393	73.18 (99.02)	89.65 (116.43)	minutes	Mean difference -3.97 (-23.93, 15.99)	335.43
Sleep duration per night at age 24 months ±6 months	9	3530	10.86 (1.47)	10.82 (1.50)	hours	Mean difference 0.06 (-0.05, 0.16)	0.02

Sleep duration per day at age 24 months ±6 months	8	2760	1.84 (0.88)	1.88 (0.84)	hours	Mean difference -0.02 (-0.07, 0.04)	0.00
Sleep quality – frequency of waking during the night at age 24 months ±6 months	5	1761	0.96 (1.07)	0.81 (1.00)	events	Rate Ratio 0.99 (0.89, 1.10)	0.00
Sleep quality – duration of disrupted sleep episodes at age 24 months ±6 months	2	439	15.58 (19.14)	15.15 (25.03)	minutes	Mean difference -2.37 (-6.56, 1.82)	0.00
Parenting self-efficacy at age 24 months ±6 months	5	1875	707/977 (72%)	642/898 (71%)	domain score ≥4 events[c]	Odds Ratio 1.02 (0.83, 1.25)	0.00
Parent feeding practices – Control (Pressure to eat) at age 24 months ±6 months	6	2570	518/1440 (36%)	480/1130 (42%)	domain score ≥3 events[d]	Odds Ratio 0.76 (0.52, 1.10)	0.21
Parent feeding practices – Control (Food as a reward) at age 24 months ±6 months	6	2398	181/1322 (14%)	212/1076 (20%)	domain score ≥3 events[d]	**Odds Ratio 0.66 (0.52, 0.84**)	0.00
Parent feeding practices – Structure (Monitoring and rules) at age 24 months ±6 months	6	2550	1249/1432 (87%)	983/1118 (88%)	domain score ≥3 events[d]	**Odds Ratio 0.75 (0.58, 0.98)**	0.00
Severe underweight at age 24 ±6 months)	17	6490	3/3498 (<0.1%)	0/2992 (0%)	events	Not estimable	-

[a] Means are crude estimates not adjusting for clustering by trial or centre, or censoring
[b] For multi-arm trials, the "Approximate adjustment" method was used to avoid unit-of-analysis errors [1]
[c] For parenting self-efficacy, a score ≥ 4 is defined as 'high self-efficacy' and a score < 4 is defined as 'low self-efficacy' [2]
[d] For parent feeding practices, a score ≥ 3 is defined as "regular use" of feeding practice [3]

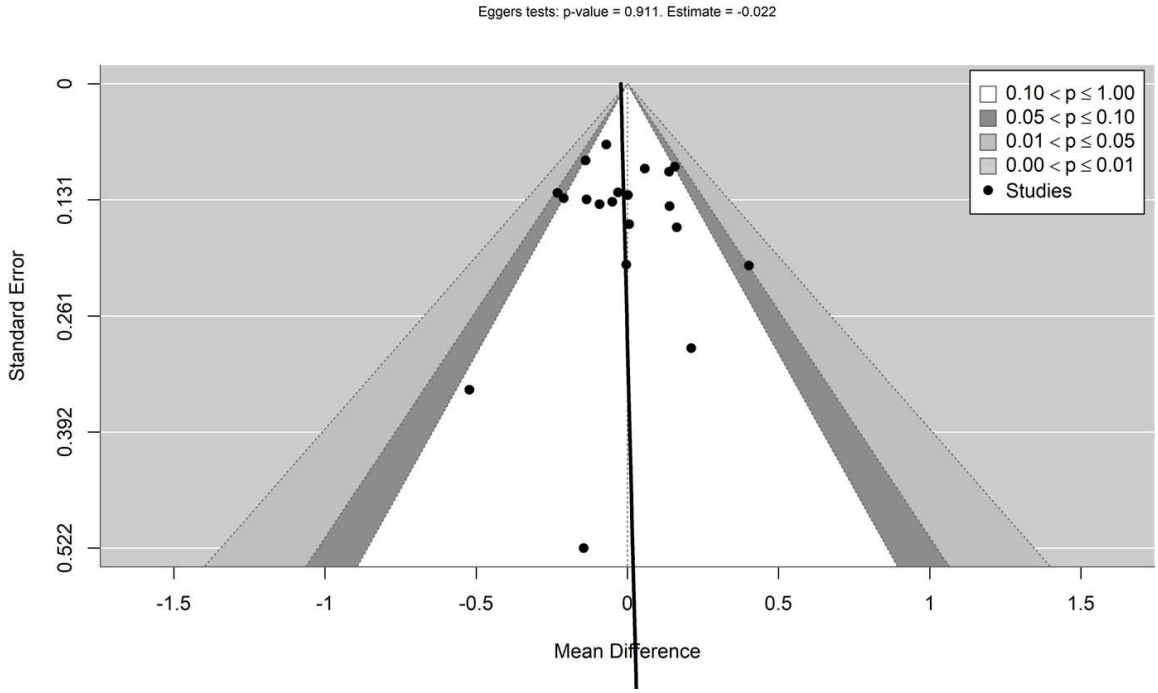
References

1. Rücker, G., C.J. Cates, and G. Schwarzer, *Methods for including information from multi-arm trials in pairwise meta-analysis.* Research synthesis methods, 2017. **8**(4): p. 392-403.
2. Xu, H., et al., *Parenting style and dietary behaviour of young children. Findings from the Healthy Beginnings Trial.* Appetite, 2013. **71**: p. 171-177.
3. Russell, C.G., et al., *Parental feeding practices associated with children's eating and weight: What are parents of toddlers and preschool children doing?* Appetite, 2018. **128**: p. 120-128.

J: Sensitivity, post-hoc and imputation analyses

Publication bias funnel plot for the primary outcome

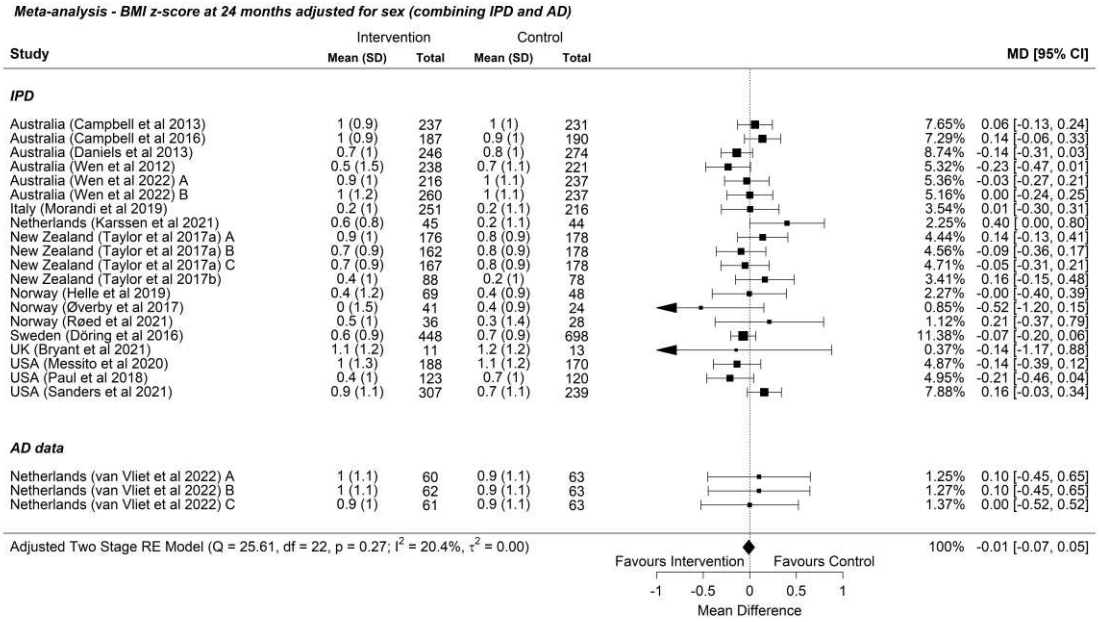
- Version 11/04/2025



Pre-specified sensitivity analyses for the primary outcome

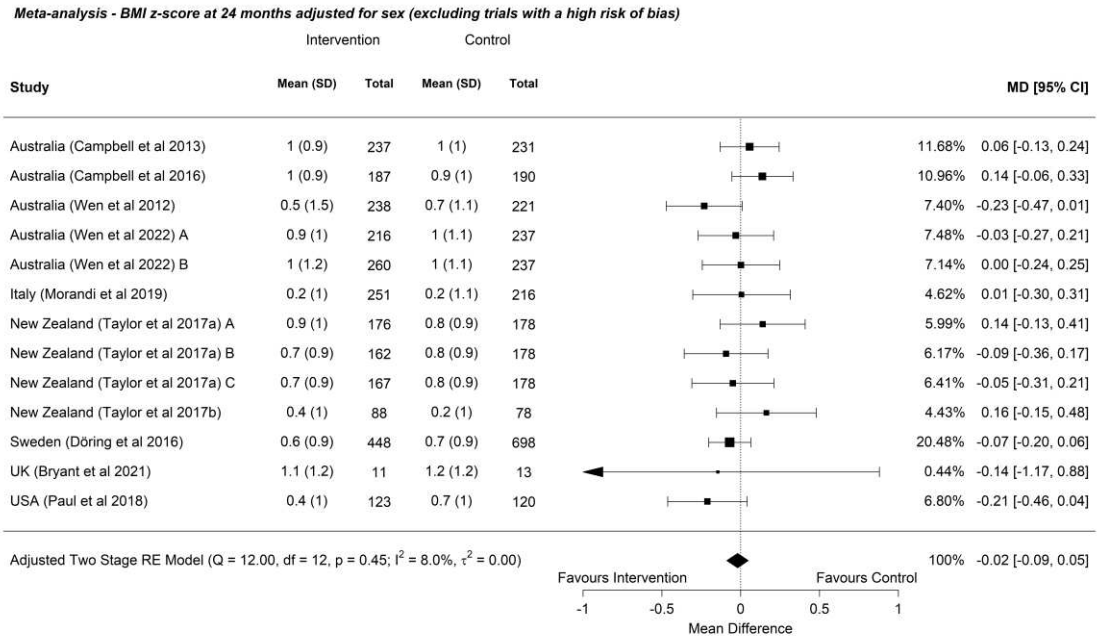
Combining individual participant data (IPD) and aggregate data (AD)

- Version: 05/02/2025
- P = 0.76



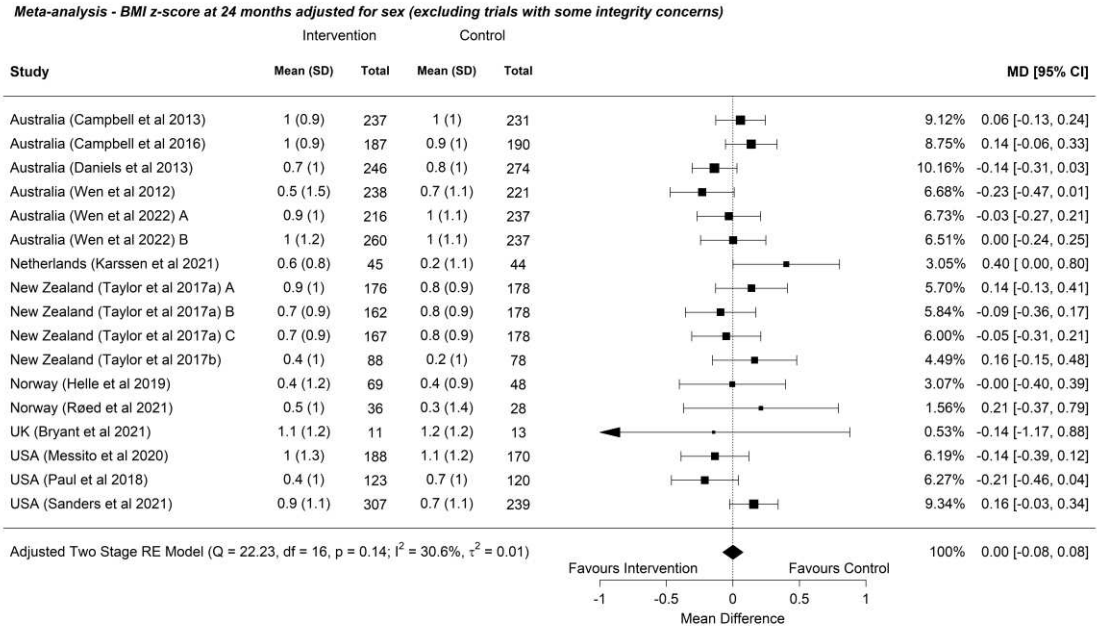
Excluding trials with a high risk of bias for sequence generation and/or allocation concealment and/or loss to follow-up

- Version: 20/02/2025
- P = 0.57



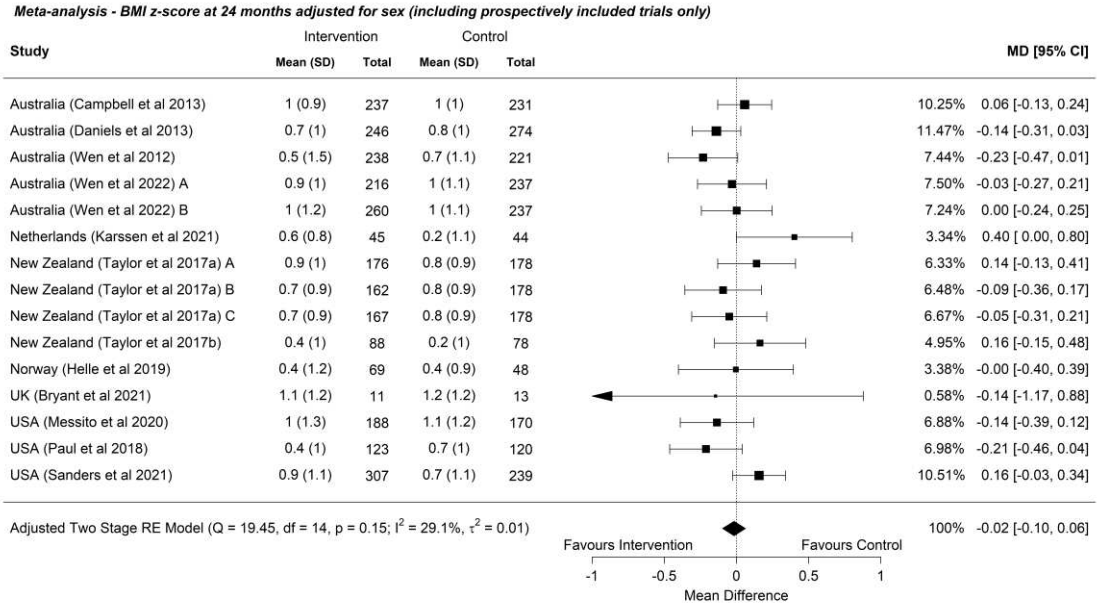
Excluding trials with some integrity concerns, but where these concerns are not sufficient to warrant exclusion from the meta-analysis entirely

- Version: 20/02/2025
- P = 0.99



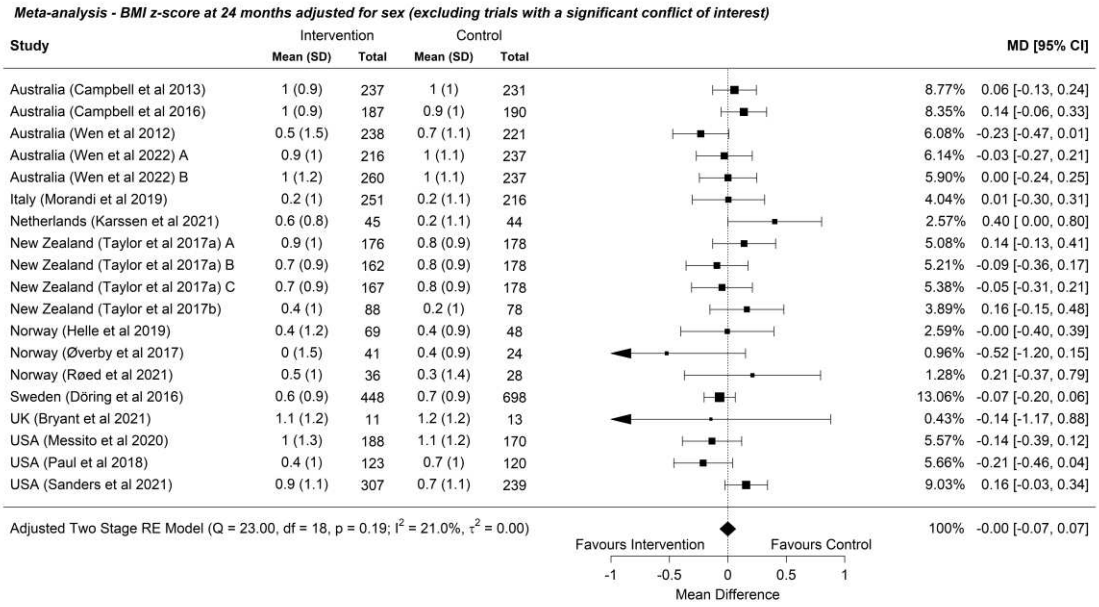
Including prospectively included trials only (nested PMA), that is, planned/ongoing trials for which results were not yet known to investigator/s at the time the main components of the TOPCHILD protocol (i.e. aims and objectives, hypotheses, eligibility criteria, main outcomes, subgroup and sensitivity analyses) were initially agreed in December 2020

- Version: 05/02/2025
- P = 0.67



Excluding trials with a significant conflict of interest (e.g. funded by industry)

- Version: 05/02/2025
- P = 0.99



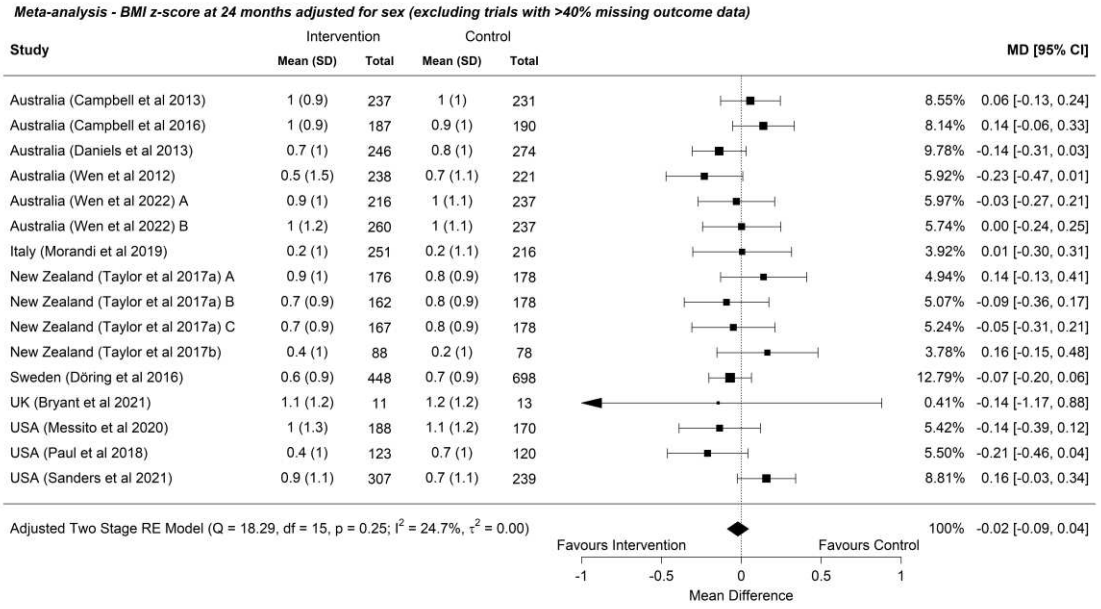
Excluding trials with more than 40% of the primary outcome missing

- Version: 05/02/2025
- P = 0.52
- Trials with over 40% missingness of primary outcome have been highlighted

Trial ID	NA counts	Number of participants	Proportion missing (%)
Australia_Campbell_InFANT_2013	74	542	13.7
Australia_Campbell_InFANTExtend_2016	137	514	26.7
Australia_Daniels_NOURISH_2013	178	698	25.5
Australia_Wen_CHAT_2020	442	1,155	38.3
Australia_Wen_HealthyBeginnings_2012	208	667	31.2
Italy_Maffeis_PROBIT_2019	62	529	11.7
Netherlands_Karssen_2017	181	270	67.0
NewZealand_Taylor_BLISS_2017	40	206	19.4
NewZealand_Taylor_POInz_2017	119	802	14.8
Norway_Helle_2019	416	533	78.0
Norway_Overby_2017	45	110	40.9

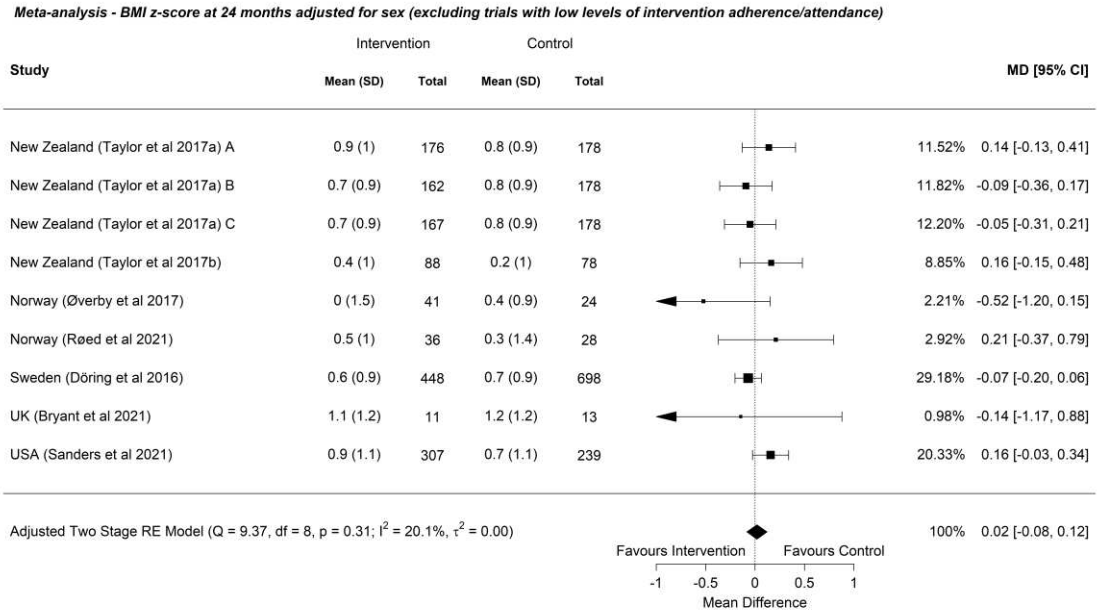
Norway_Roed_2021	173	237	73.0
Sweden_Rasmussen_PRIMROSE_2016	2	1,148	0.2
UK_Bryant_HENRYPilot_2018	4	28	14.3
USA_Messito_2016	175	533	32.8
USA_Paul_INSIGHT_2018	48	291	16.5
USA_Rothman_Greenlight_2014	319	865	36.9

- Excluding Netherlands_Karssen_2017, Norway_Helle_2019, Norway_Overby_2017, and Norway_Roed_2021.



Excluding trials with low levels of intervention adherence/attendance (trial-level)

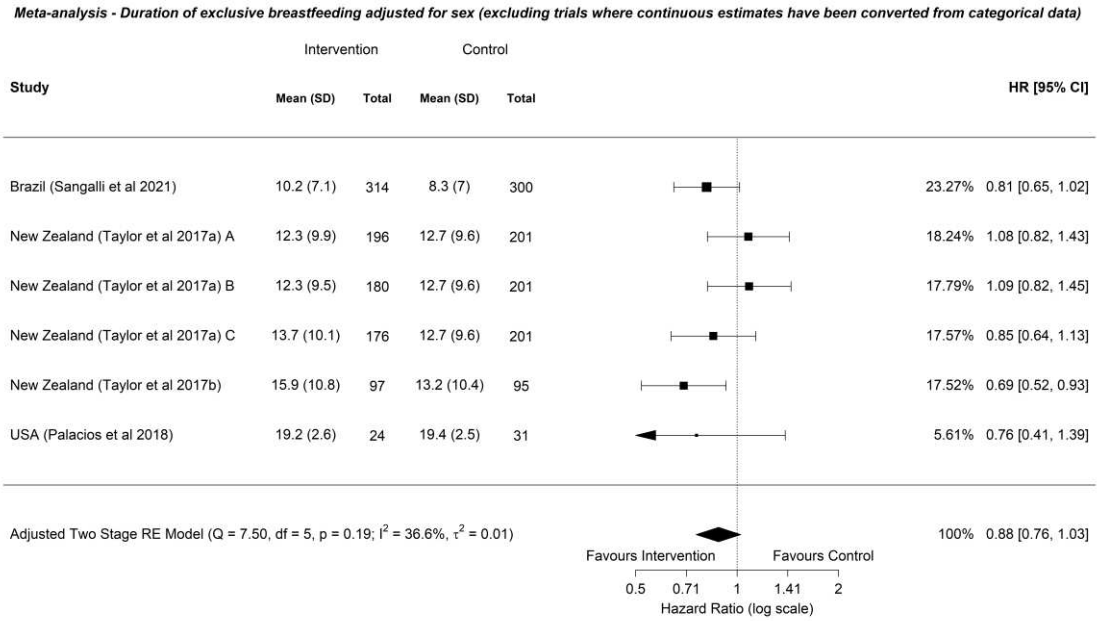
- Version: 05/02/2025
- P = 0.73



Pre-specified sensitivity analyses for secondary outcomes

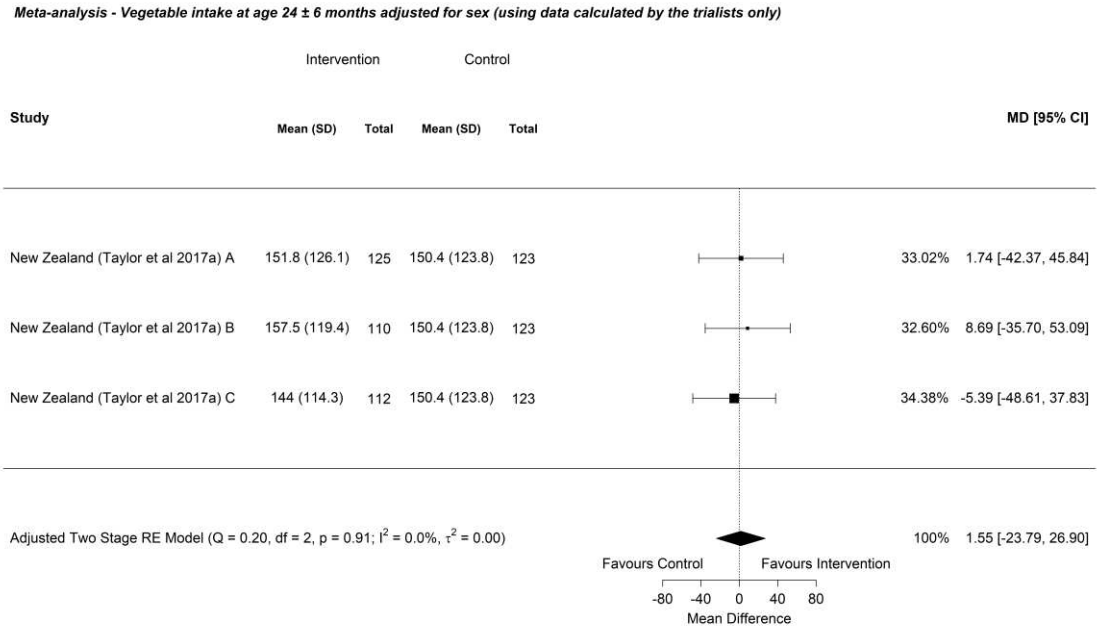
Duration of exclusive breastfeeding (from birth until 6 ± 2 months of age): Excluding data from trials where continuous estimates were derived from categorical data

- Version: 05/02/2025
- P = 0.10



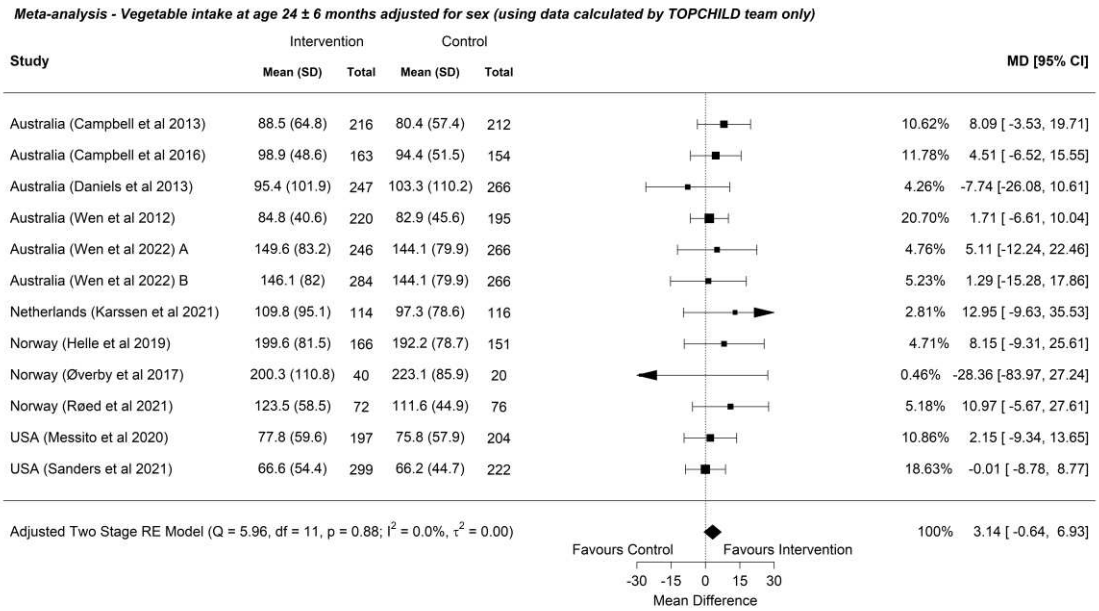
Vegetable intake per day at age 24 ± 6 months: Excluding data from trials where continuous estimates were derived from categorical data

- Version: 19/02/2025
- P = 0.90



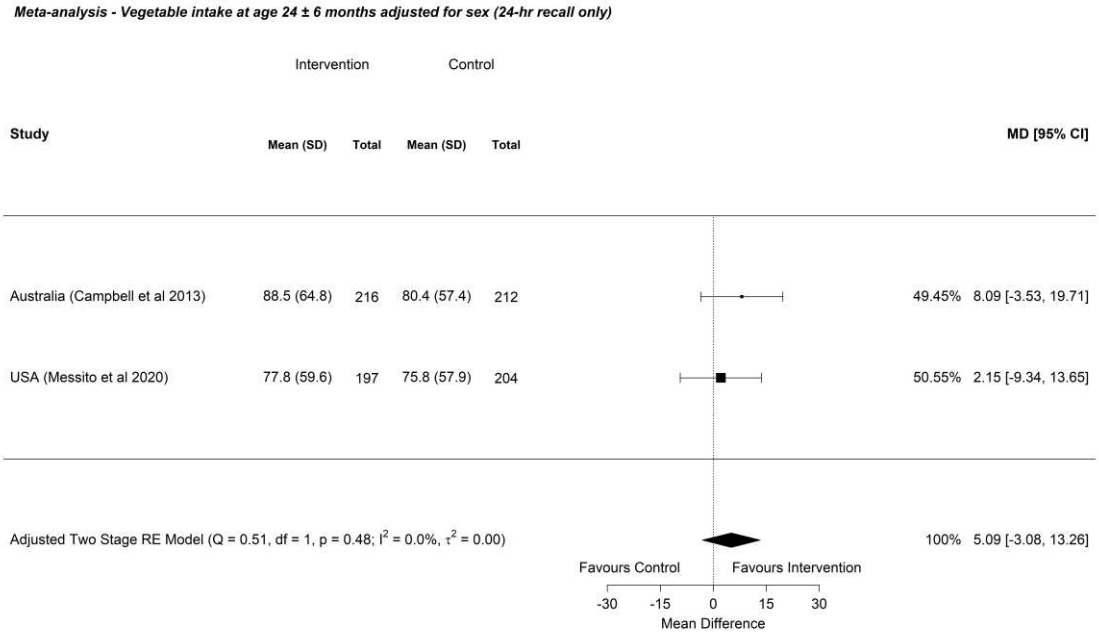
Vegetable intake per day at age 24 ± 6 months: including only trial data that were converted from categorical to continuous format

- Version: 19/02/2025
- P = 0.10



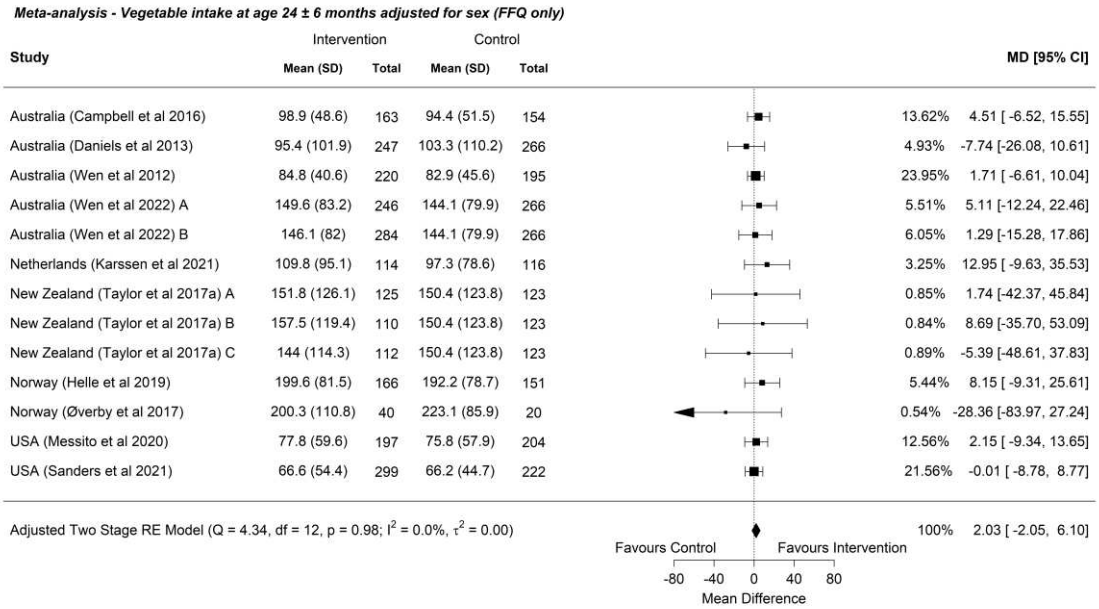
Vegetable intake per day at age 24 ± 6 months: including 24-hr recall data only

- Version: 05/02/2025
- P = 0.22



Vegetable intake per day at age 24 ± 6 months: including Food Frequency Questionnaire (FFQ) data only

- Version: 05/02/2025
- P = 0.33

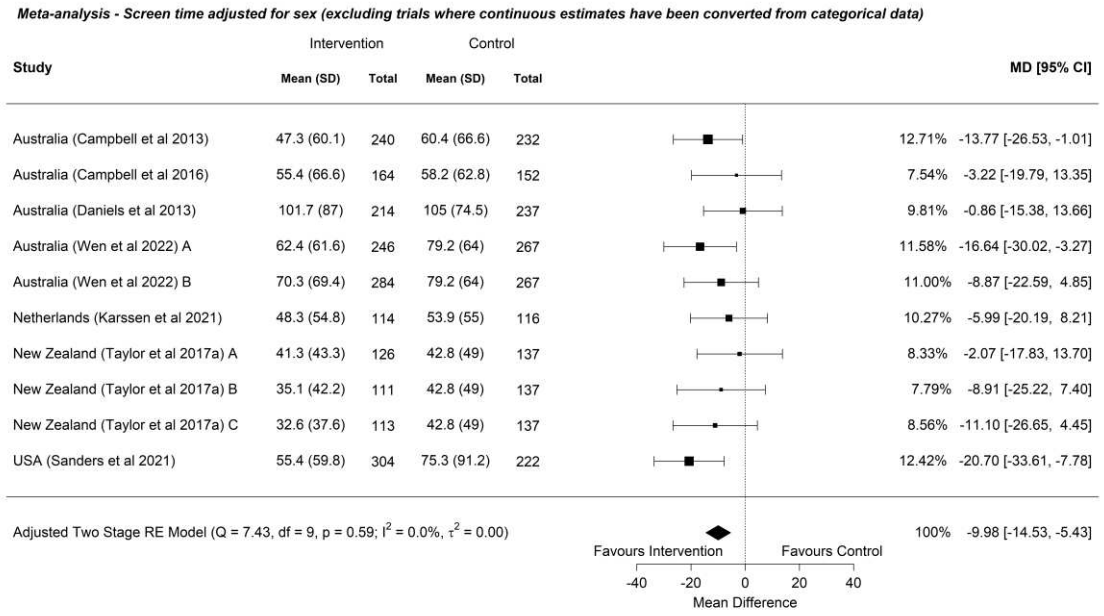


Self-reported physical activity at age 24 ± 6 months: Excluding data from trials where continuous estimates were derived from categorical data

- Only 1 trial (Australia Campbell et al 2016) provided data for this outcome, hence the sensitivity analysis does not differ to the main analysis and has not been included here.

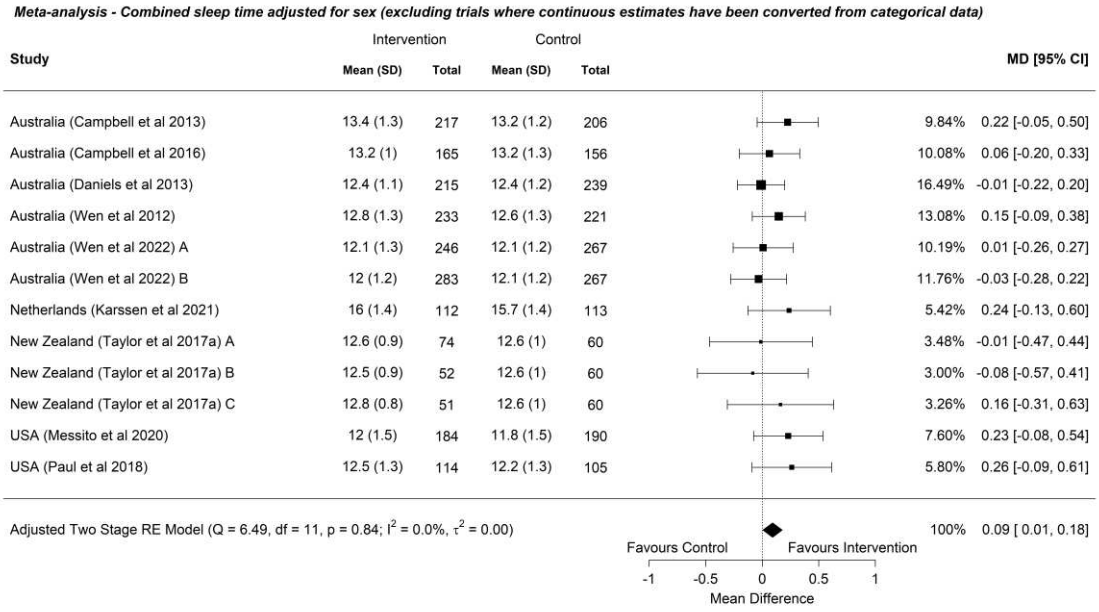
Screen time at age 24 ± 6 months: Excluding data from trials where continuous estimates were derived from categorical data

- Version: 05/02/2025
- P < 0.01



Combined sleep time at age 24 ± 6 months: Excluding data from trials where continuous estimates were derived from categorical data

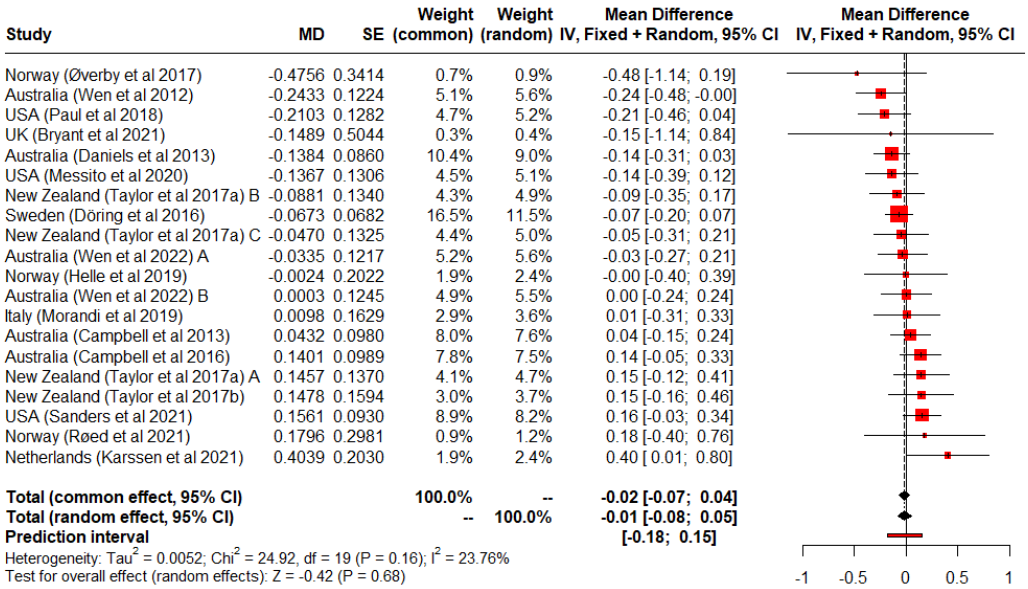
- Version: 05/02/2025
- P = 0.03



Post-hoc sensitivity analyses

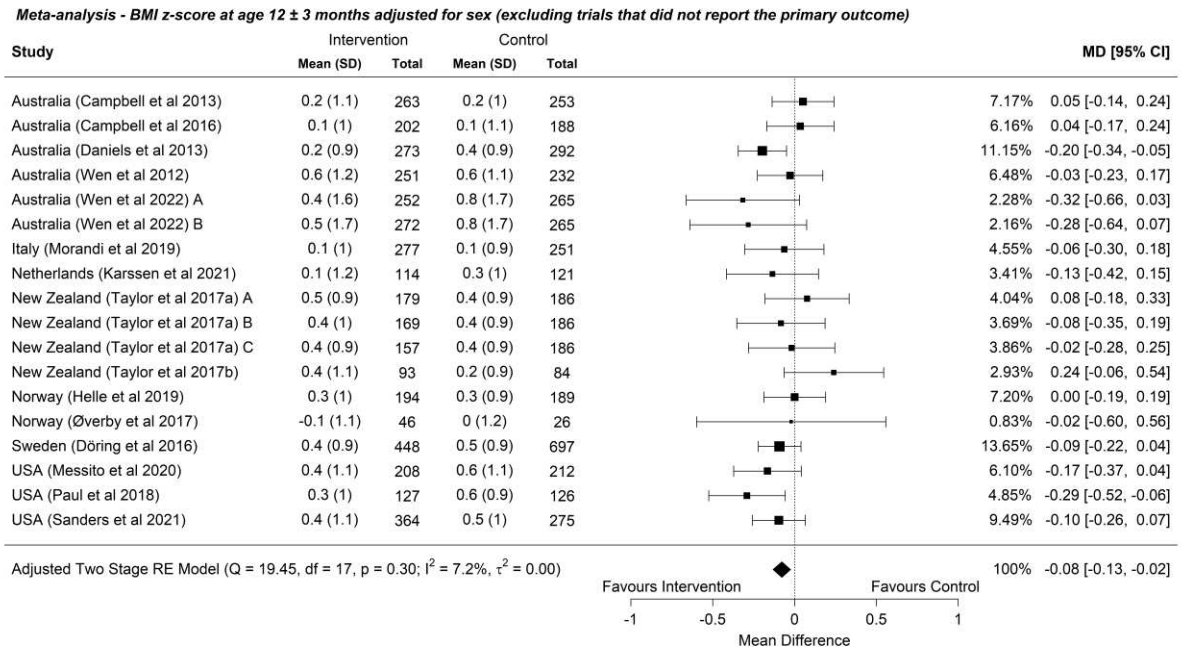
BMI z-score at age 24 ± 6 months without adjusting for sex

- Version: 19/02/2025
- P = 0.68



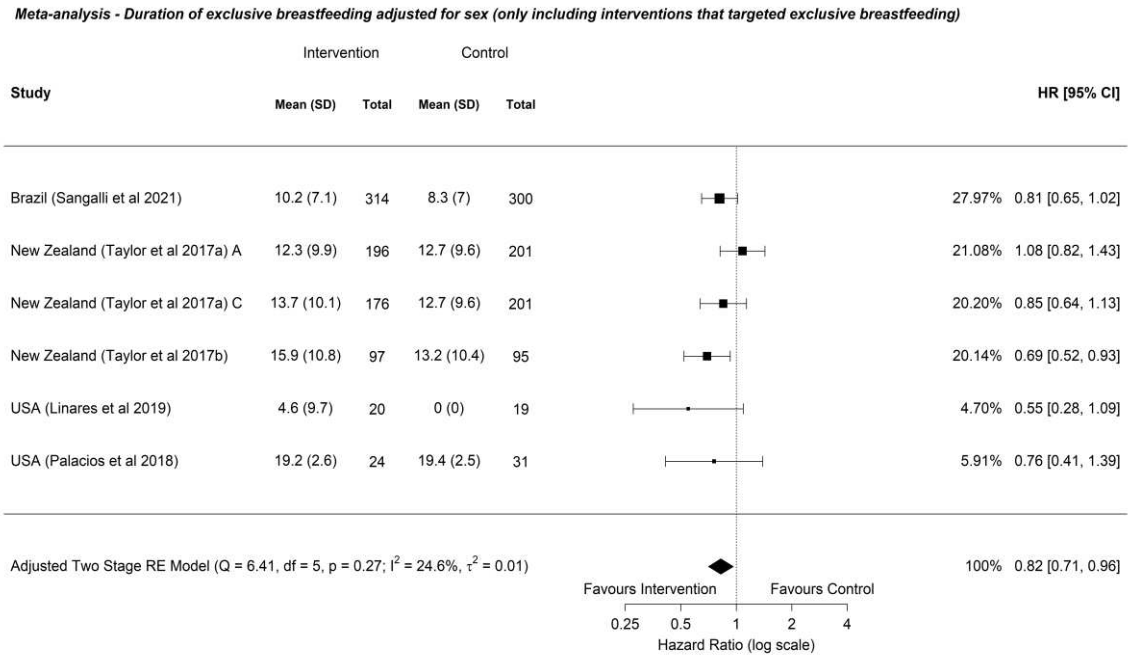
BMI z-score at age 12 ± 3 months: Excluding trials that did not report the primary outcome

- Version: 05/02/2025
- P < 0.01 (conclusions remain the same)



Duration of exclusive breastfeeding (from birth until 6 ± 2 months of age): Excluding data from trials where interventions did not target this outcome

- Version: 05/02/2025
- P = 0.01

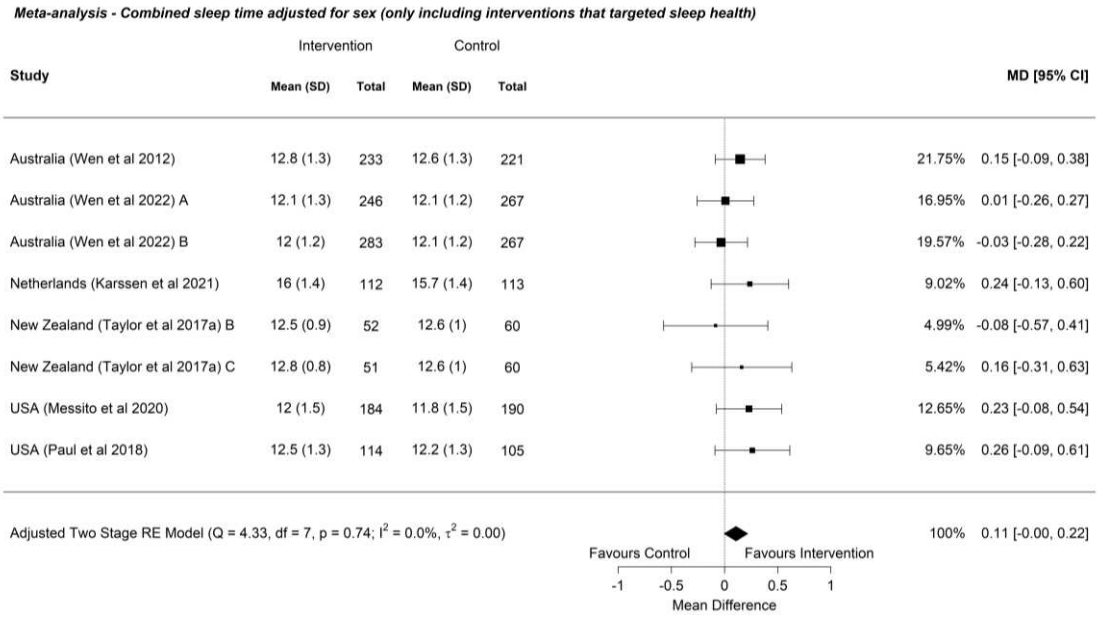


Self-reported physical activity at age 24 ± 6 months: Excluding data from trials where interventions did not target this outcome

- Only 1 trial (Australia Campbell et al 2016) provided data for this outcome, hence the sensitivity analysis does not differ to the main analysis and has not been included here.

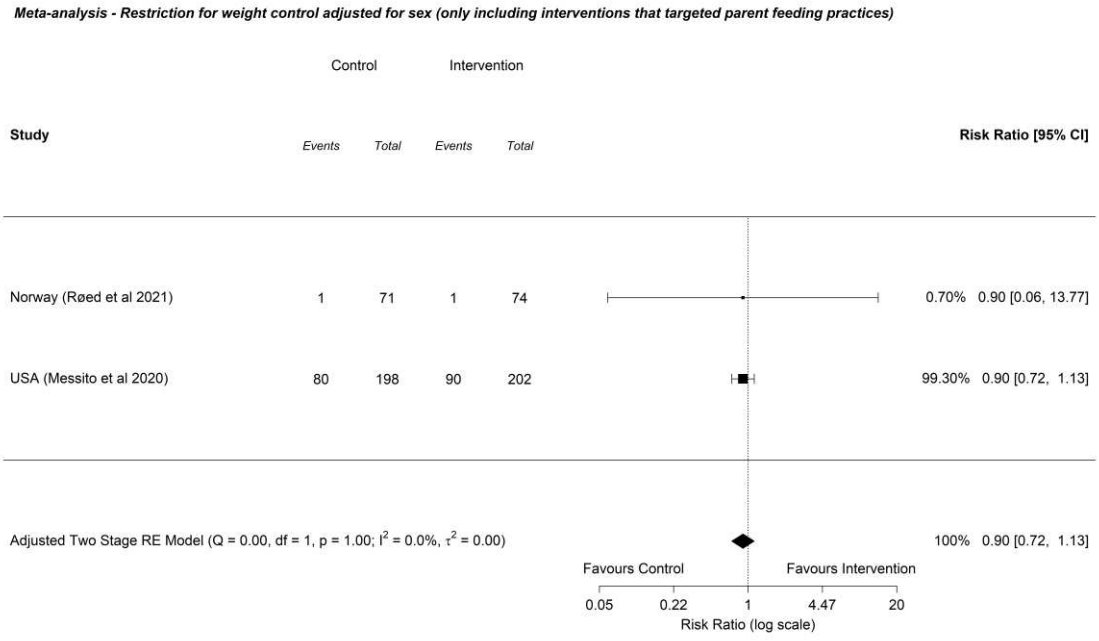
Combined sleep time at age 24 ± 6 months: Excluding data from trials where interventions did not target this outcome

- Version: 05/02/2025
- P = 0.05



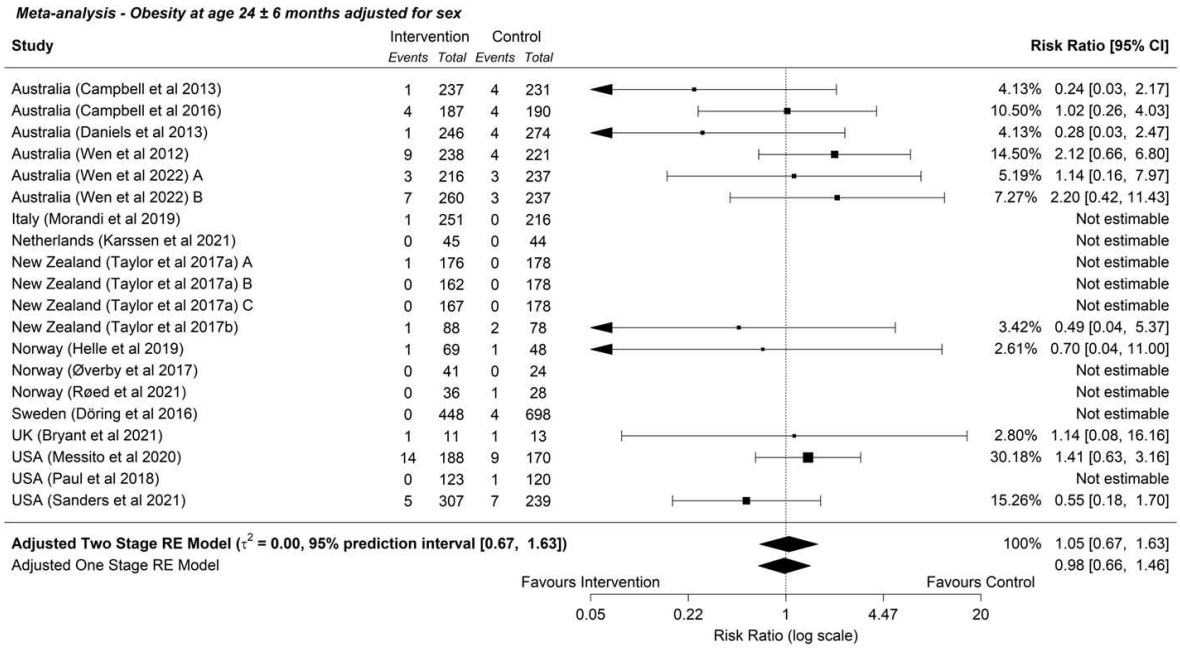
Control (Restriction) at age 24 ± 6 months: Excluding data from trials where interventions did not target this outcome

- Version: 05/02/2025
- P = 0.38



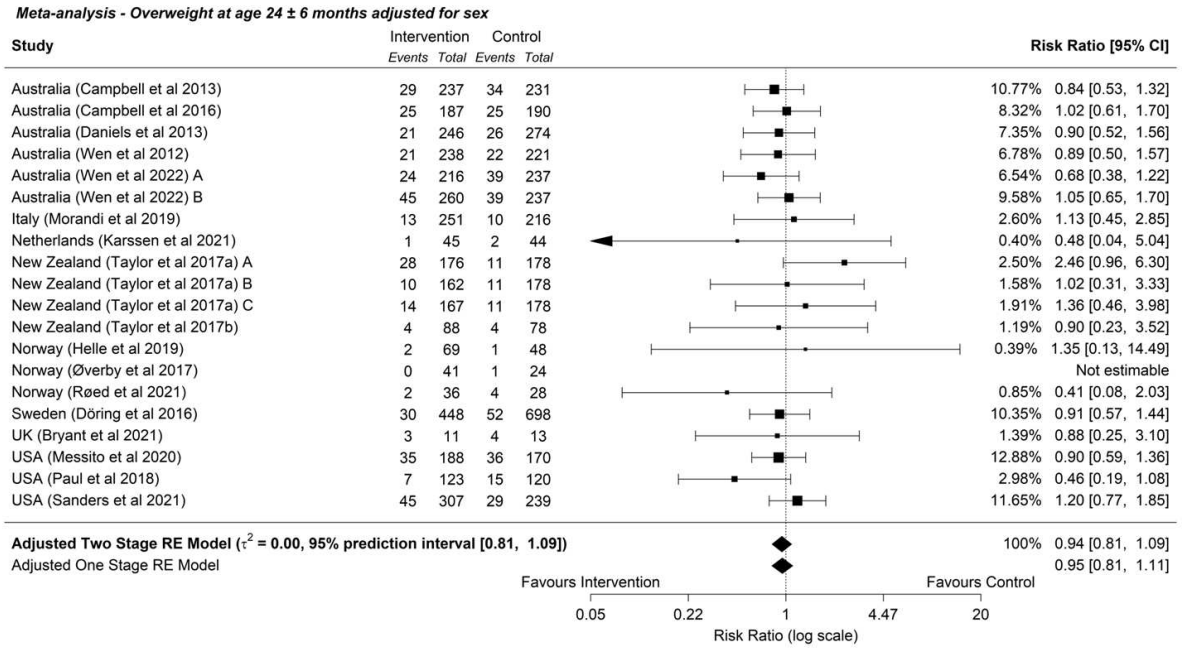
Obesity at age 24 ± 6 months: Using a one-stage model to include trials with zero events in a single arm

- Version: 17/04/2025
- P (one stage model) = 0.92
- Trials with zero events in both arms were excluded from the one-stage model as per recommended practice (Riley RD, Burke DL, Morris T. Chapter 8: One-stage versus Two-stage Approach to IPD Meta-Analysis: Differences and Recommendations. In: Riley RD, Tierney JF, Stewart LA, eds. Individual Participant Data Meta-Analysis: A Handbook for Healthcare Research: John Wiley & Sons Ltd; 2021: 199-217.)



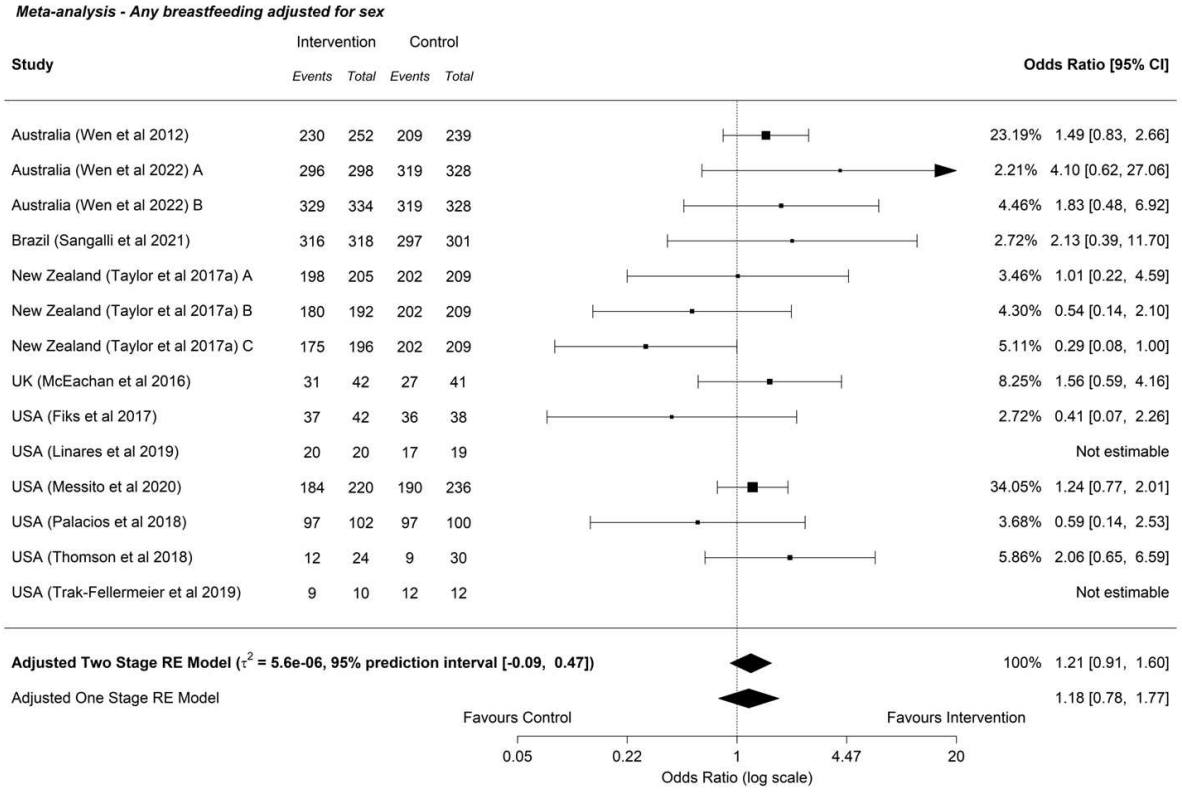
Overweight at age 24 ± 6 months: Using a one-stage model to include trials with zero events in a single arm

- Version: 17/04/2025
- P (one stage model) = 0.51



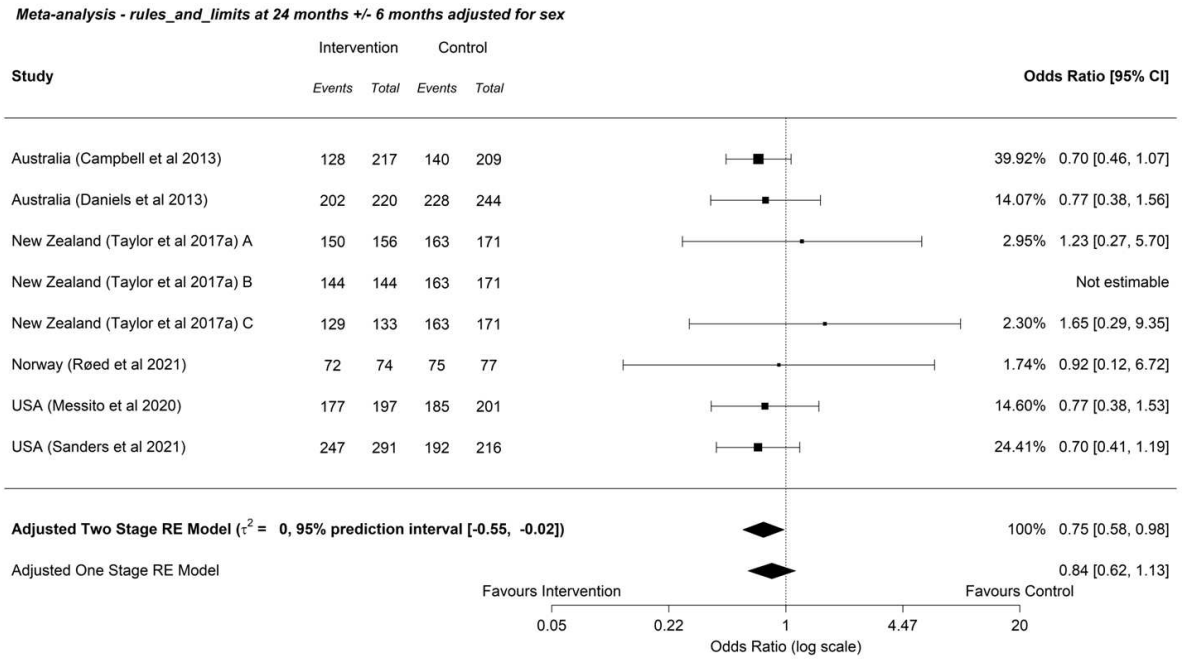
Any breastfeeding at age 24 ± 6 months: Using a one-stage model to include trials with zero non-events in a single arm

- Version: 17/04/2025
- P (one stage model) = 0.44



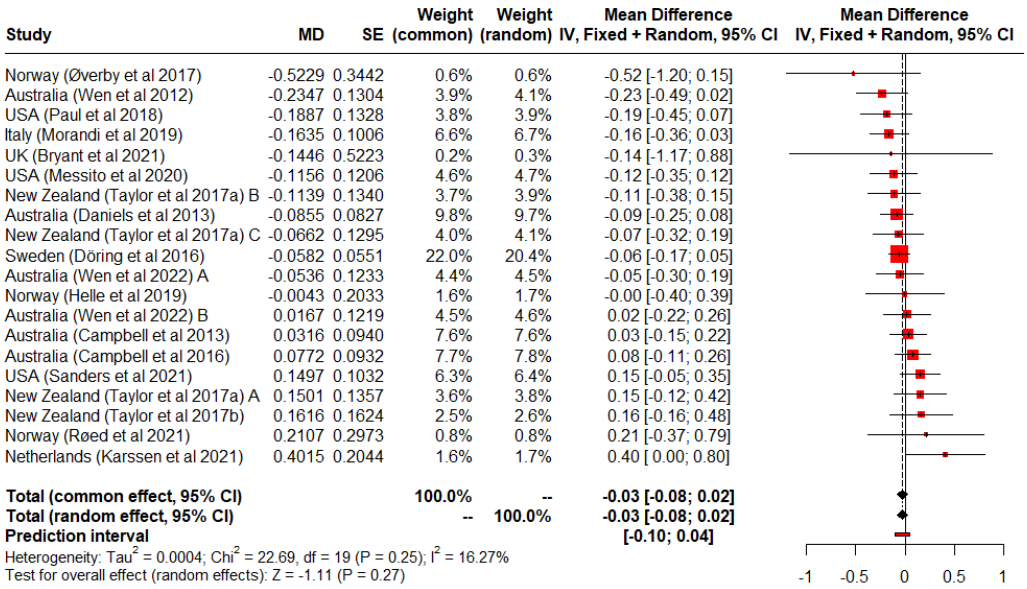
Parent feeding practices – Structure (Monitoring and rules) at age 24 ± 6 months: Using a one-stage model to include trials with zero non-events in a single arm

- Version: 17/04/2025
- P (one stage model) = 0.24



Multiple imputation of the primary outcome BMI z-score at age 24 ± 6 months (using predictors with 60% useable cases)

For multiple imputation we employed the MICE package in R. We used predictive mean matching for imputing the outcome ZBMI. We imputed separate datasets for each intervention in each trial. Imputing split group has been suggested to minimise bias in the case of mispecified analysis models (1). In each dataset we created 30 imputations and 15 iterations. Predictors included in the imputation model were determined using quickpred and met the following criteria: a correlation of ≥0.2 with ZBMI (as recommended by (2)) , a minimum of 60% usable cases, and were removed in the case of causing logged events due to multicollinearity or constancy. We also only included variables that would plausibly predict ZBMI in the selection process.



References

(1) Sullivan, T. R., White, I. R., Salter, A. B., Ryan, P., & Lee, K. J. (2018). Should multiple imputation be the method of choice for handling missing data in randomized trials?. *Statistical methods in medical research*, *27*(9), 2610-2626.

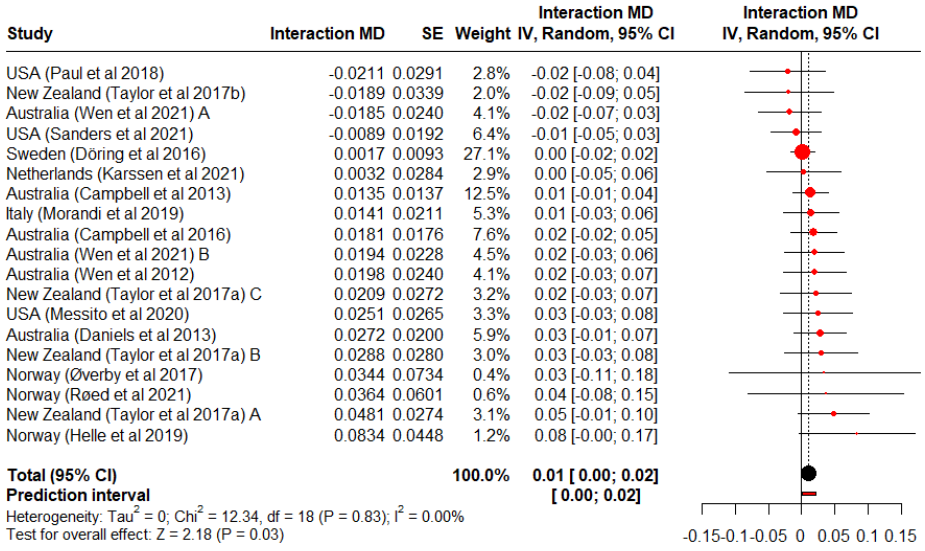
(2) Mainzer RM, Nguyen CD, Carlin JB, Moreno-Betancur M, White IR, Lee KJ. A comparison of strategies for selecting auxiliary variables for multiple imputation. Biometrical Journal. 2024 Jan;66(1):2200291.

K: Subgroup analyses

Pre-specified individual-level subgroup analyses for the primary outcome

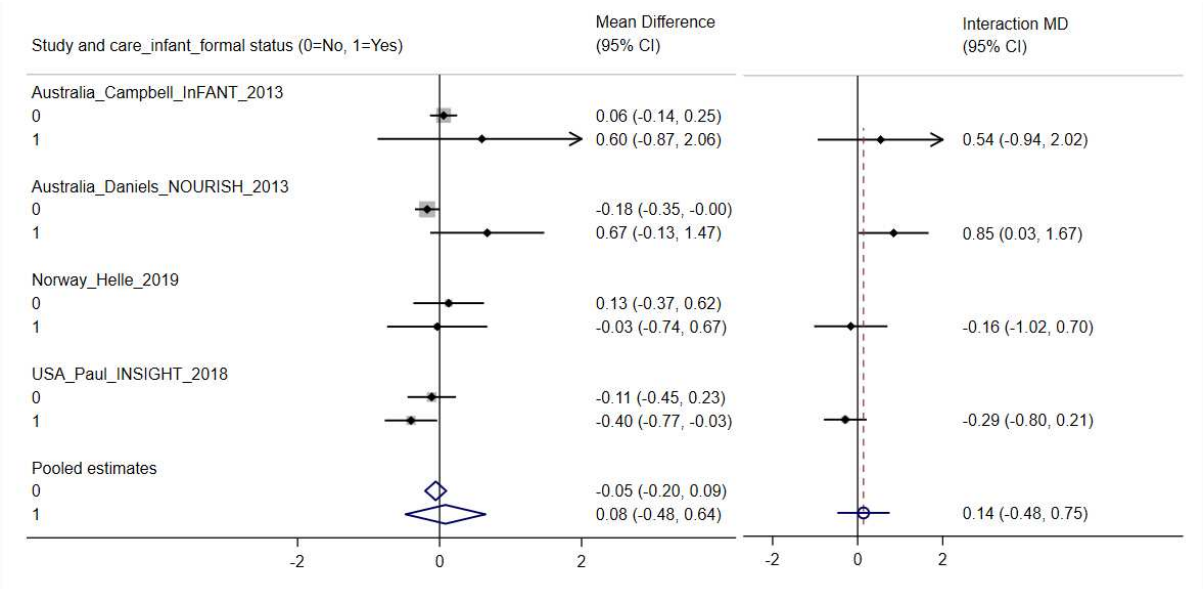
Birthweight

- Version: 25/11/2024



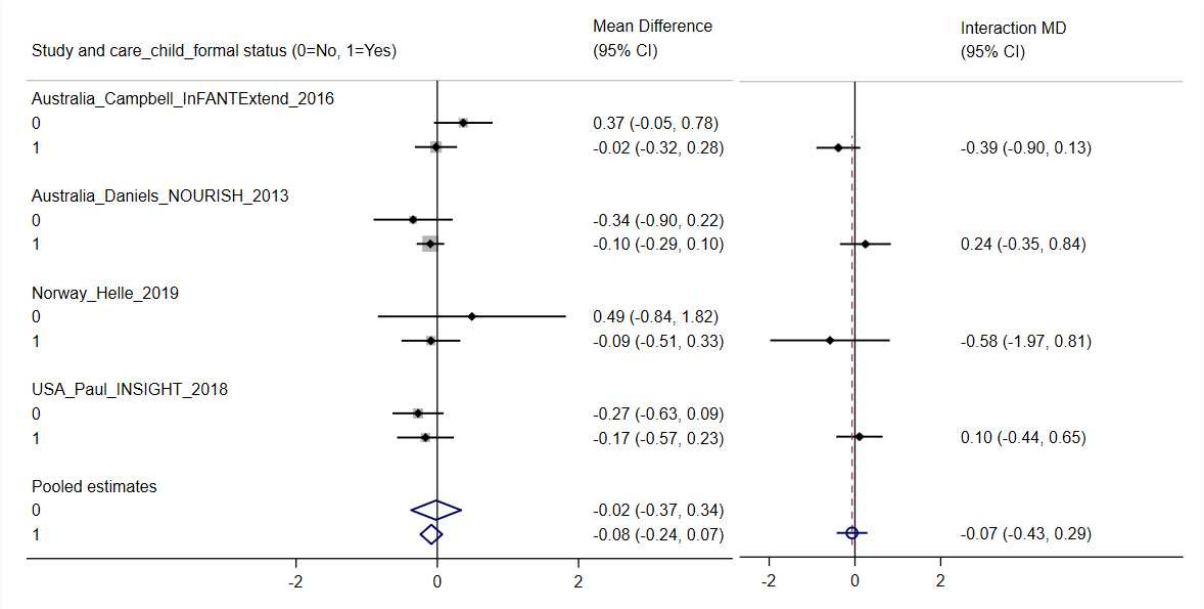
Any formal childcare attendance at 0-12 months

- Version: 21/10/2024



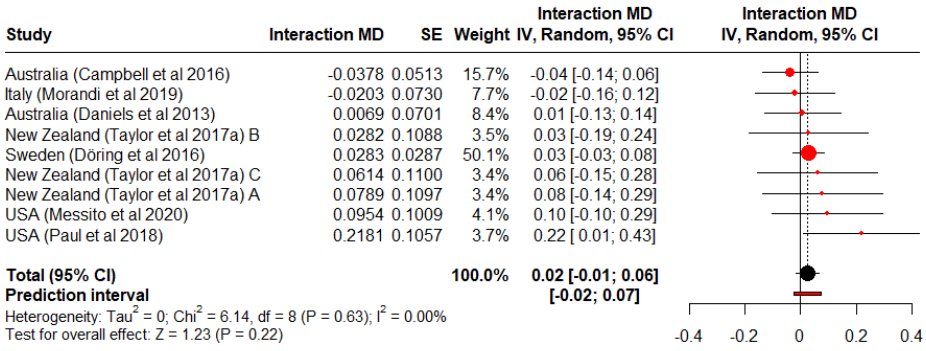
Any formal childcare attendance at 12-24 months

- Version: 21/10/2024



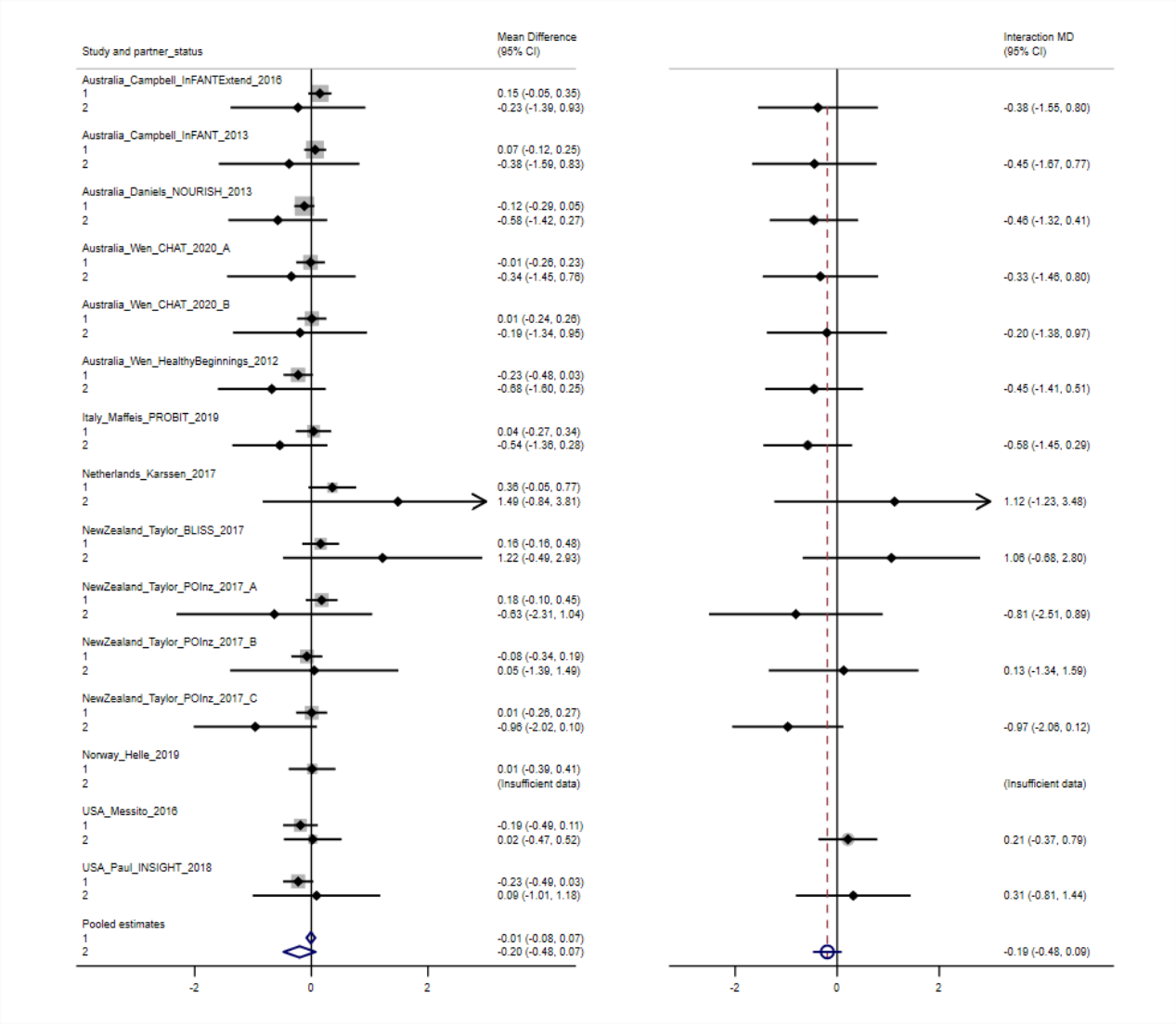
Gestational age at birth

- Version: 21/10/2024



Partner status

- Version: 21/10/2024
- Categorised as:
  - 1 = in a partnership (married, de facto, living with partner)
  - 2 = single (single, divorced, widowed)

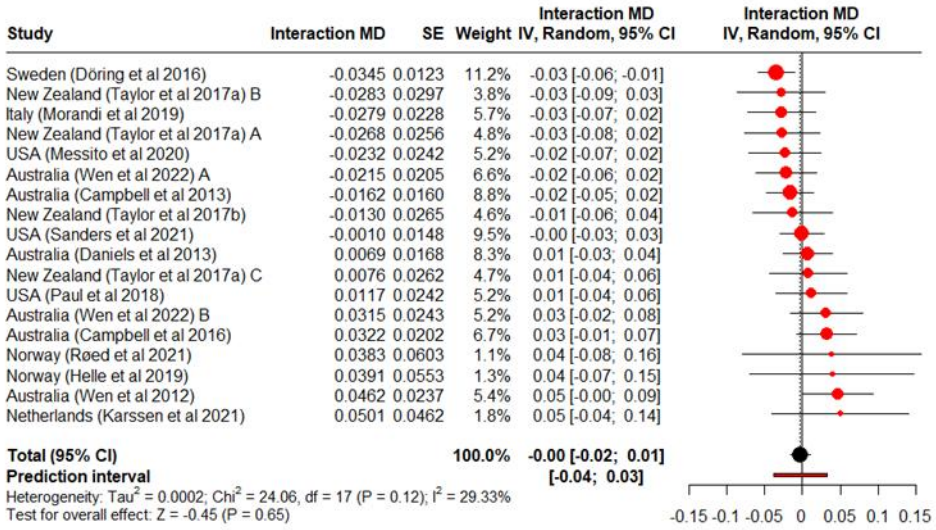


Household composition

Insufficient data.

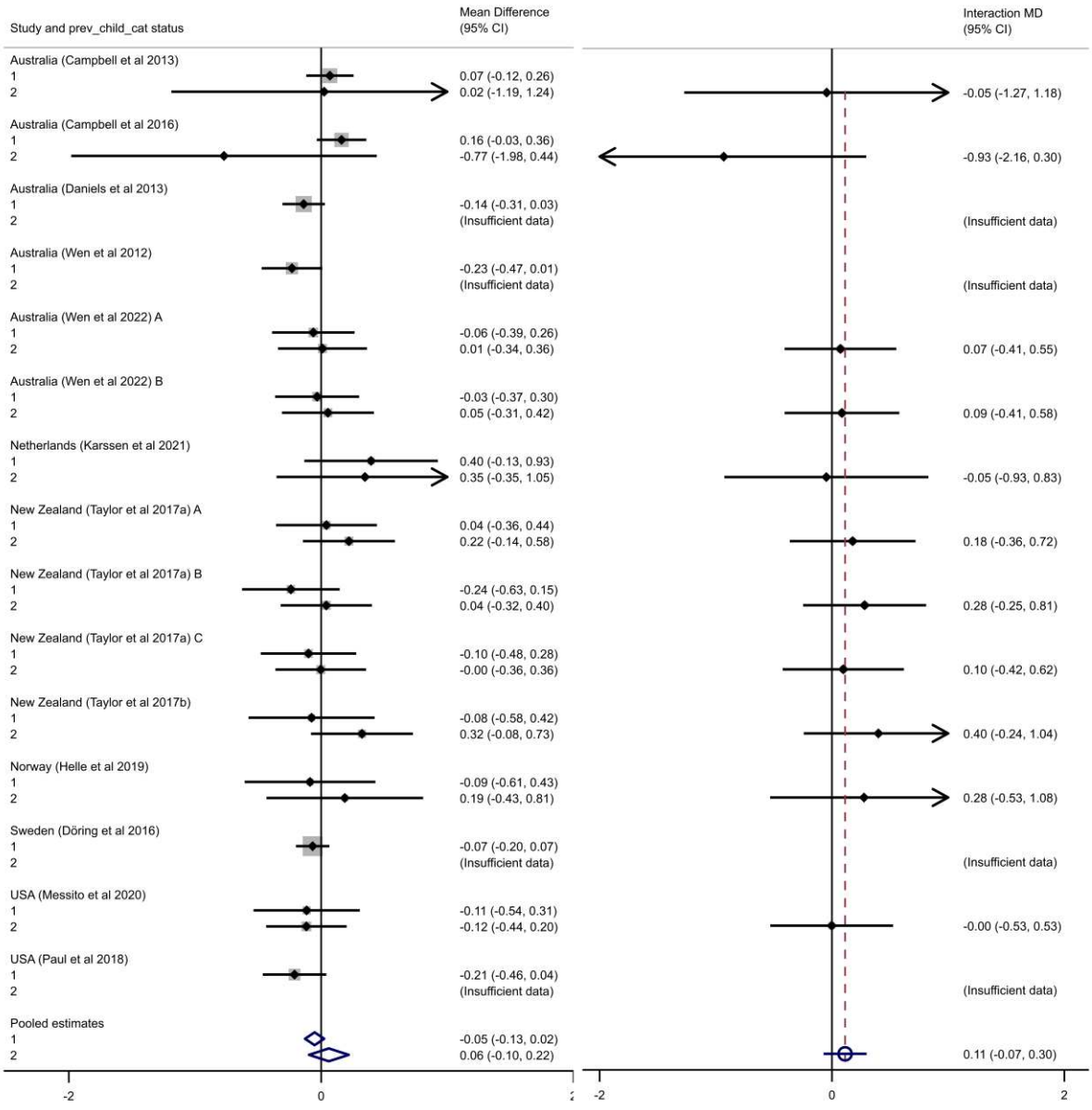
Maternal/birthing parent weight status

- Version: 17/04/2025
- Defined as the pre-pregnancy body mass index of the mother/birthing parent.



Parity/first-time parent

- Version: 17/04/2025
- Categorised as:
  - 1 = first-time parent
  - 2 = already had at least 1 other child

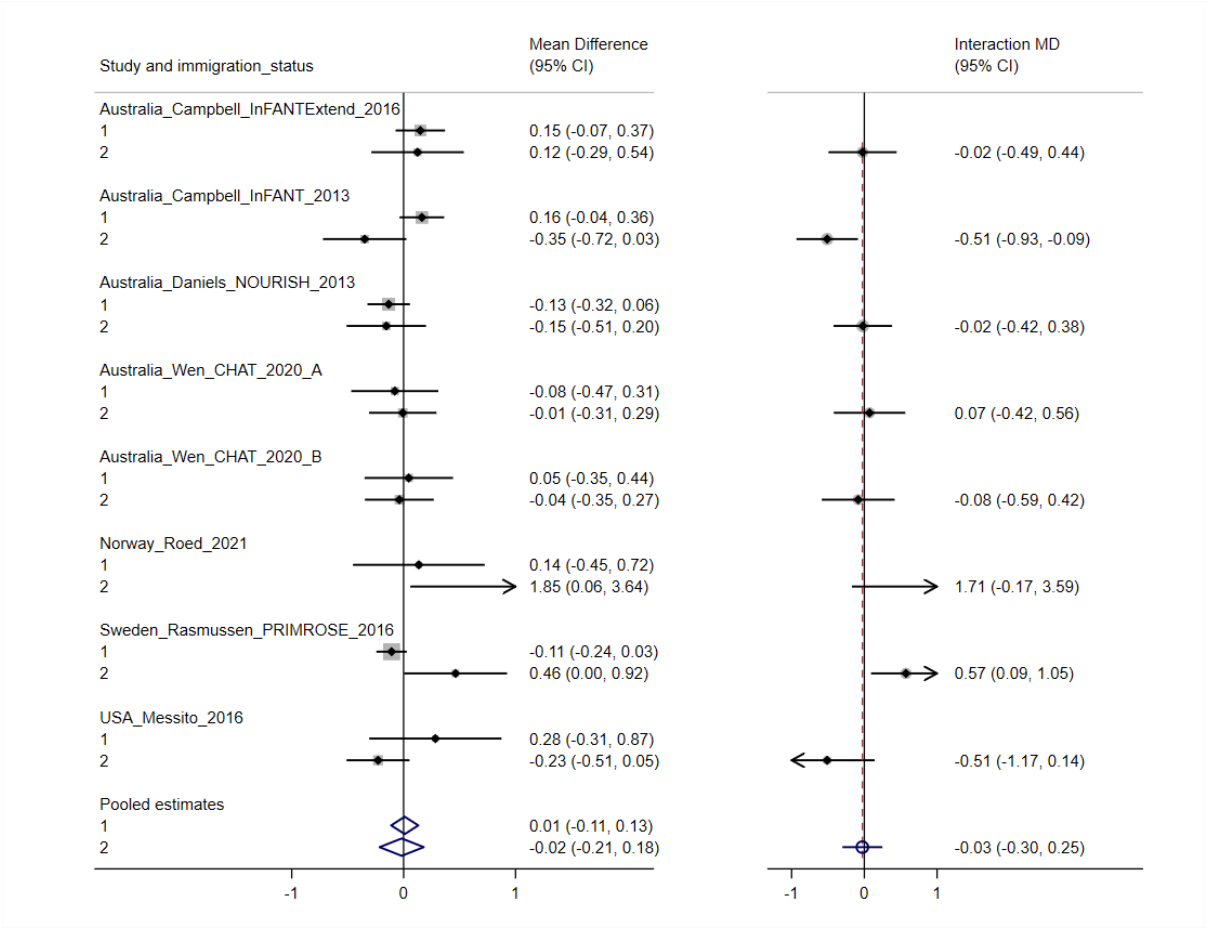


Race/ethnicity

Data too heterogenous to harmonise; added immigration status instead.

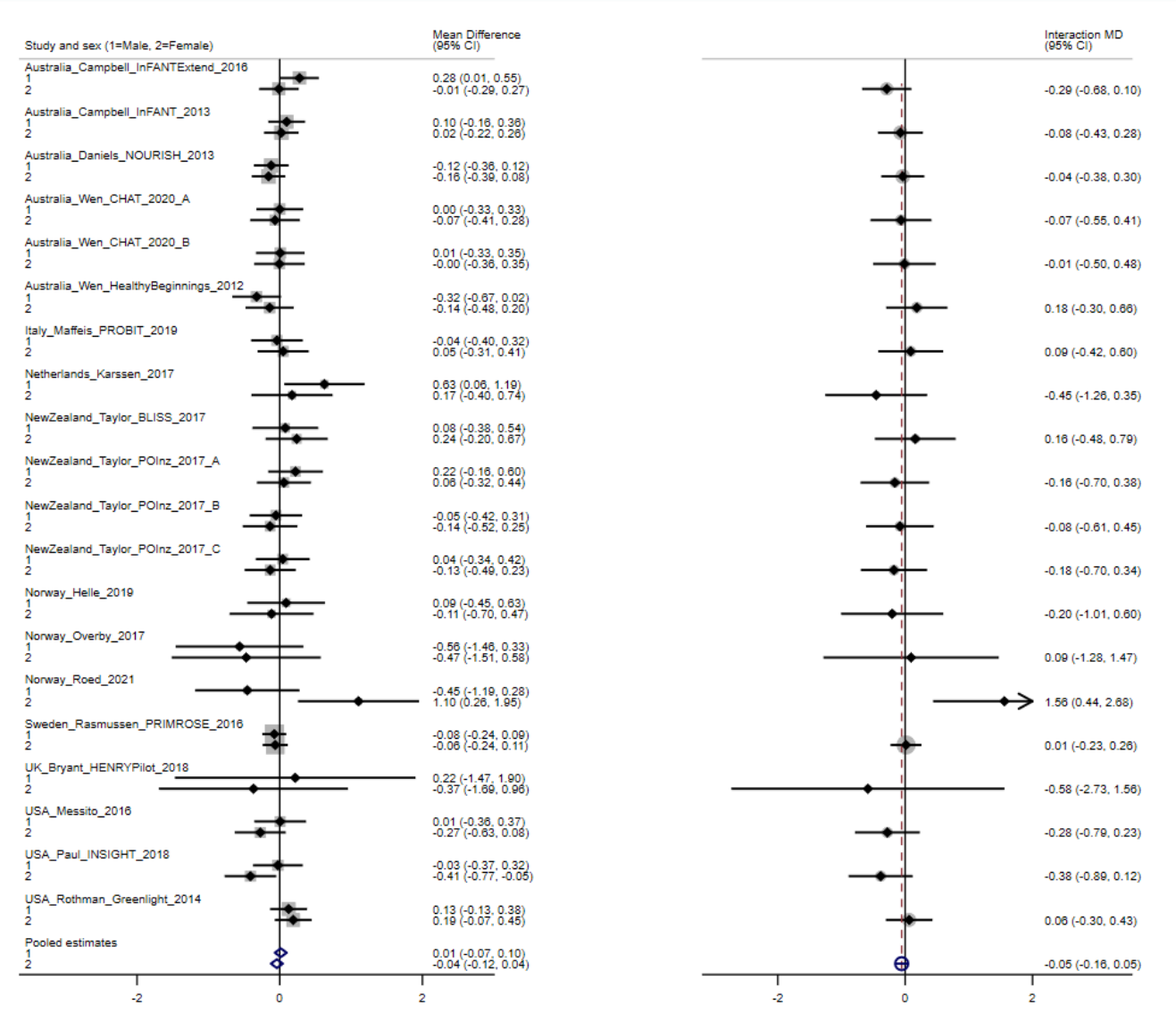
Parent/carer immigration status

- Version: 21/10/2024
- Categorised as:
    - 1 = primary parent/carer born in study country
    - 2 = primary parent/carer born outside study country



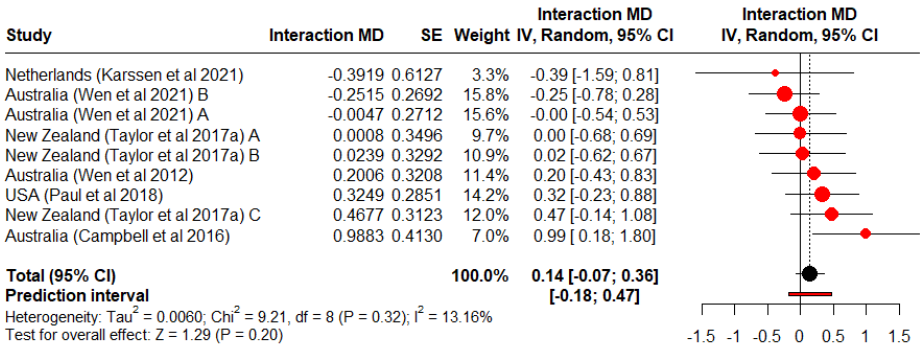
Infant sex

- Version: 21/10/2024
- Categorised as:
  - 1 = Male
  - 2 = Female
  - 3 = Ambiguous/other (data not available)



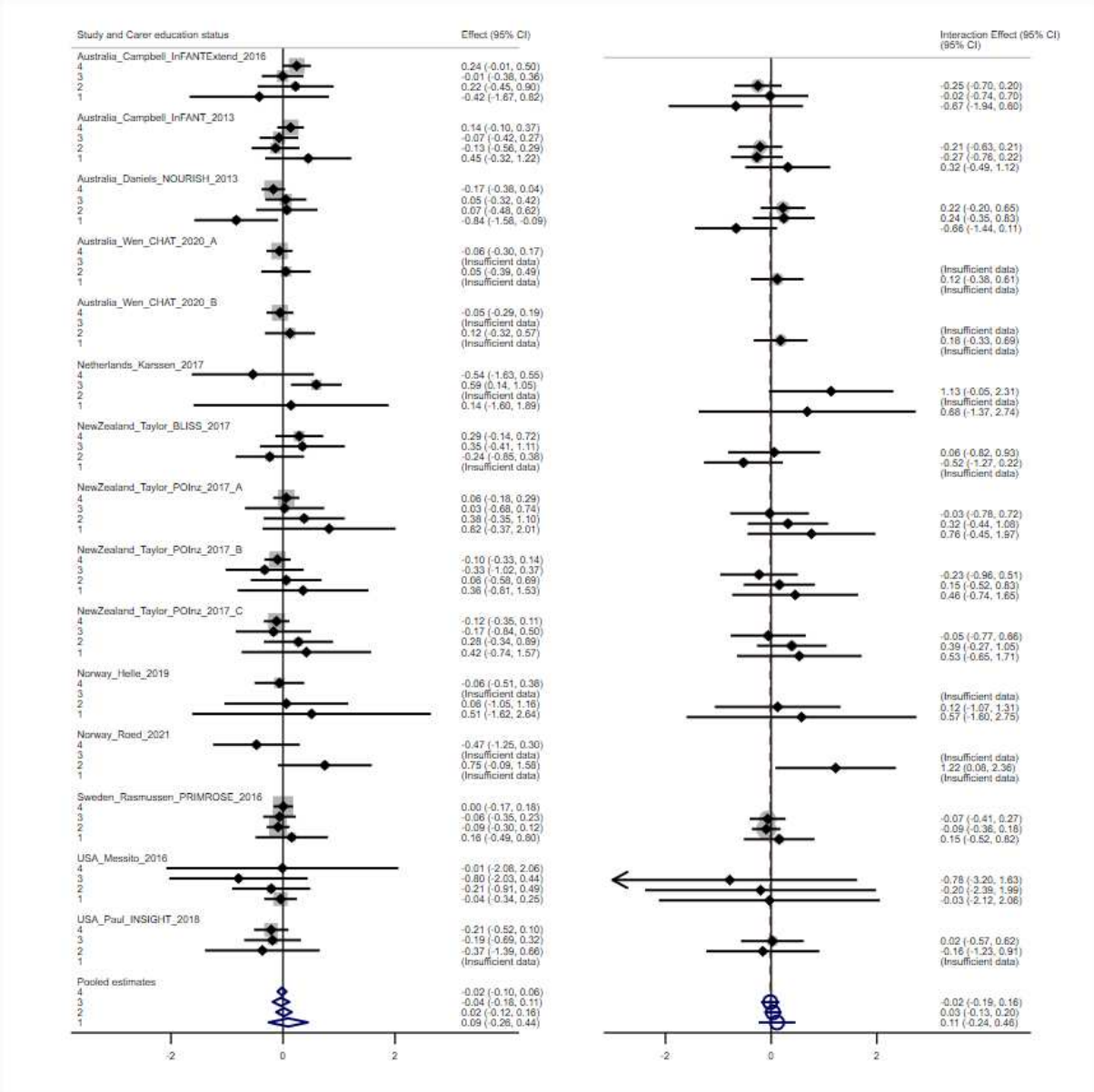
Socioeconomic position – weighted standardised household income

- Version: 21/10/2024



Socioeconomic position – carer education

- Version: 21/10/2024
- Categorised as:
    - 1 = low education (little/no formal education, or some school but did not finish high school)
    - 2 = high school graduate
    - 3 = non-university tertiary education or qualification or incomplete university
    - 4 = university graduate or postgraduate



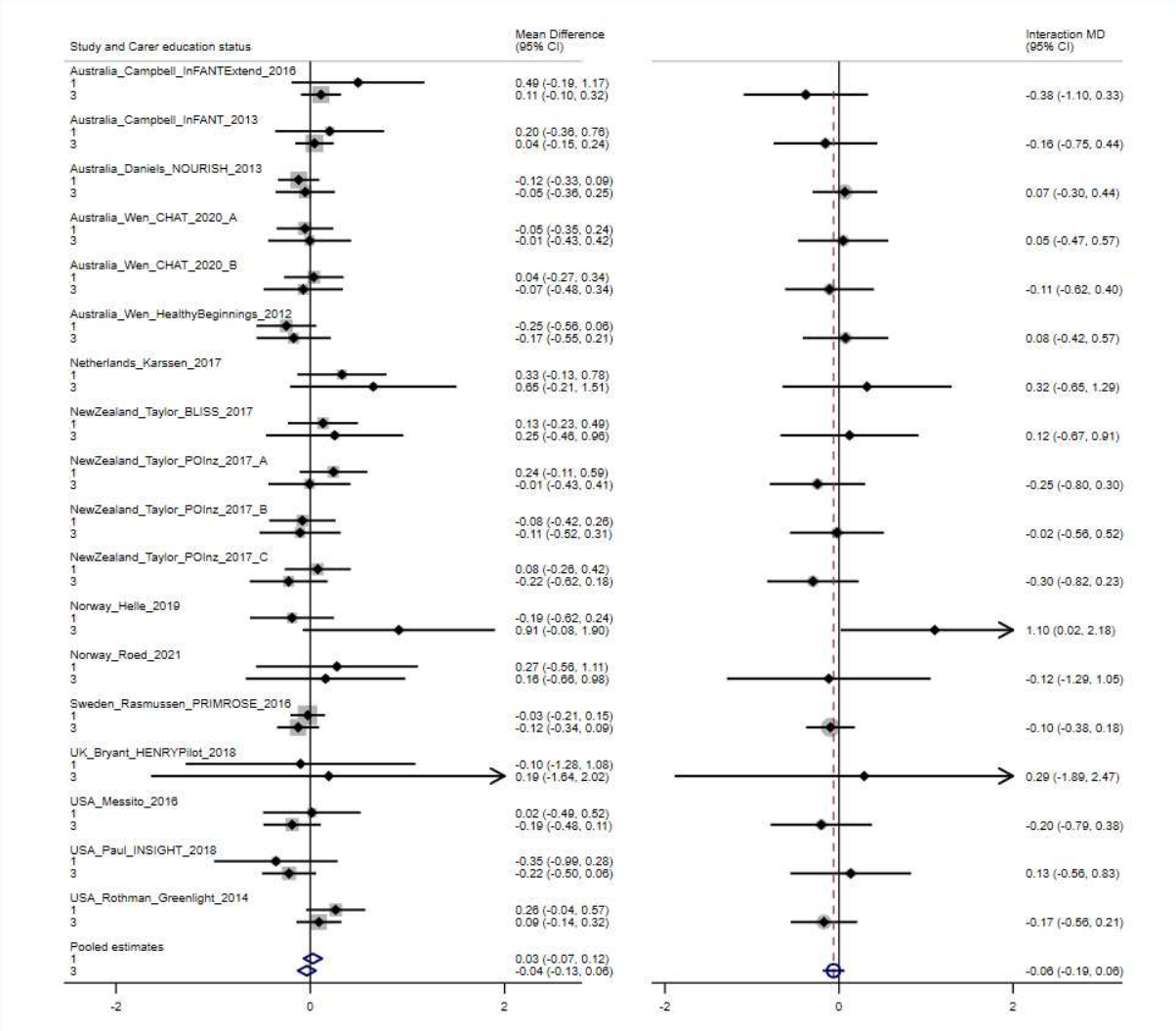
Socioeconomic position – carer employment status

- Version: 21/10/2024

  Categorised as:

- 1 = any employment (including paid leave)*
- 3 = unemployed (includes returned, student without employment, unpaid leave, home duties, charity work).

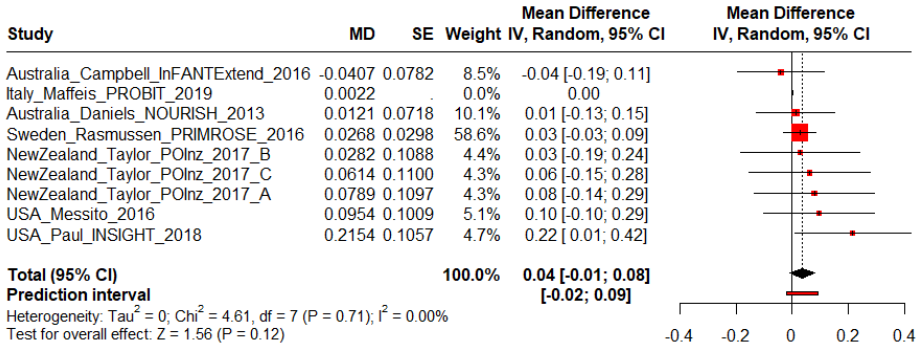
*Note: full time employment and part time employment have been collapsed into one category (any employment), therefore there is no longer a category 2.



Post-hoc individual-level subgroup analysis for the primary outcome

Child age at enrolment (continuous)

- Version 19/02/2025
- P = 0.12

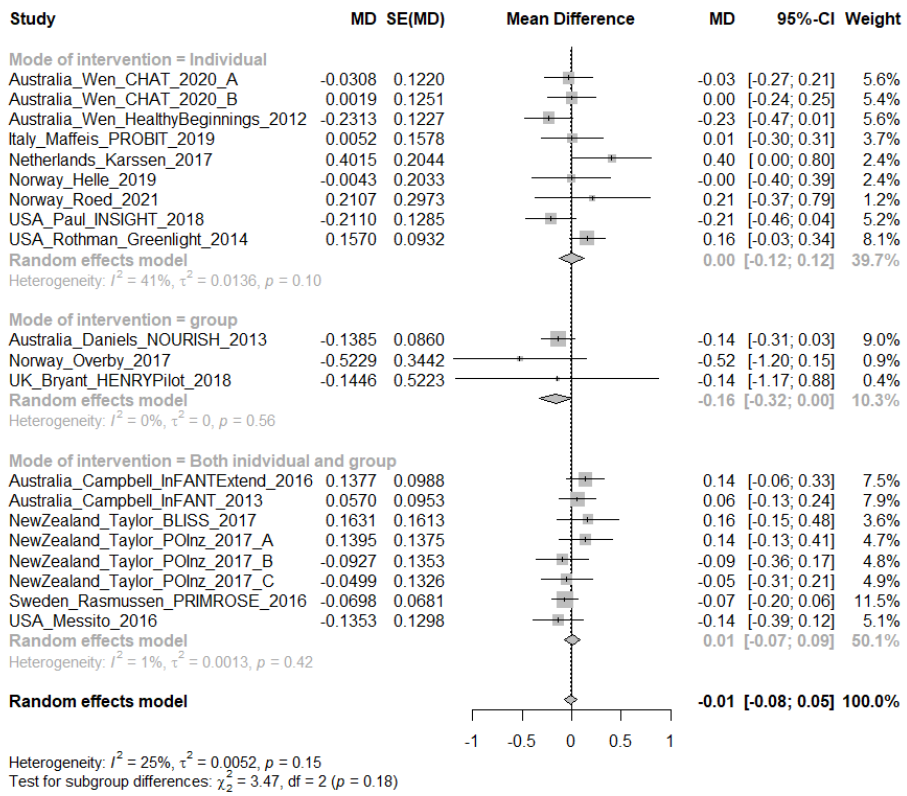


Pre-specified intervention/trial-level subgroup analyses for the primary outcome

Intervention delivery mode (individual vs group)

Categorised as:

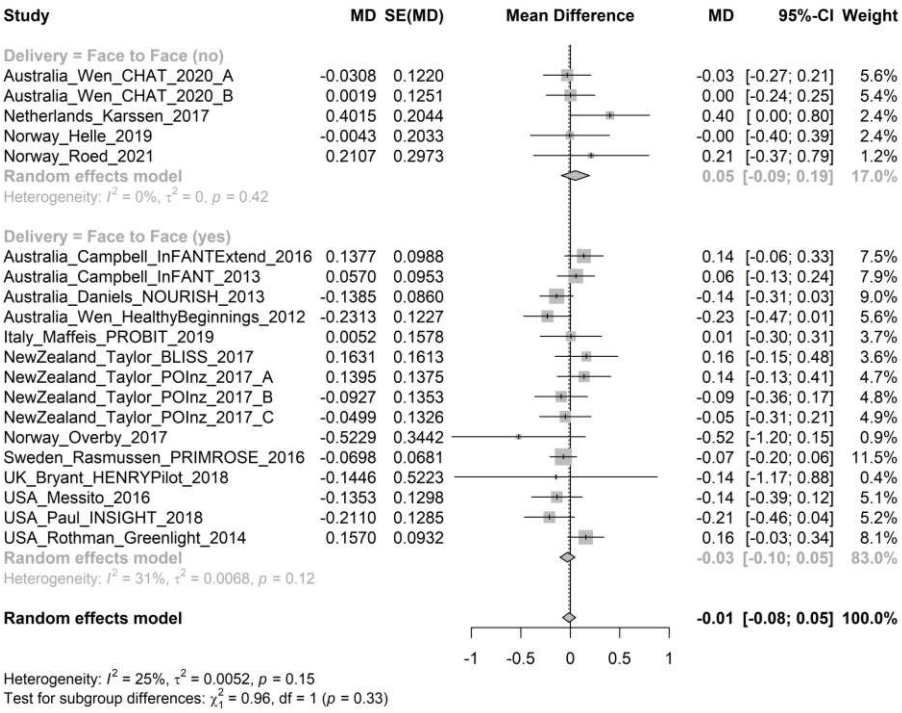
- Individual
- Group
- Both individual and group



Intervention delivery mode (any face-to-face component)

Categorised as:

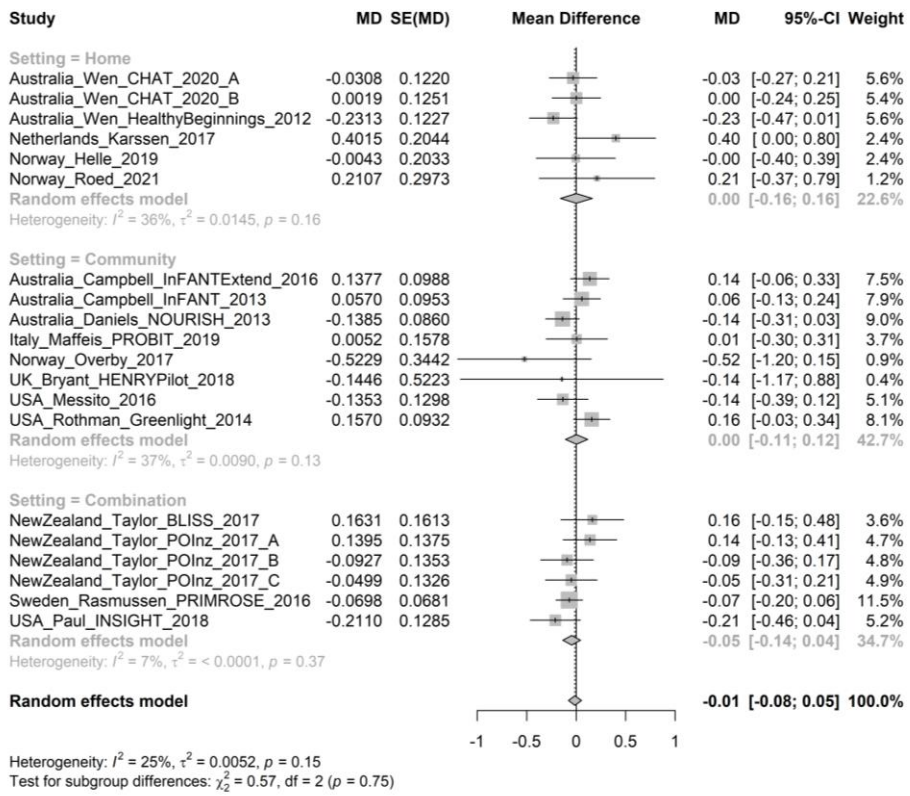
- Face to face
- All other modes



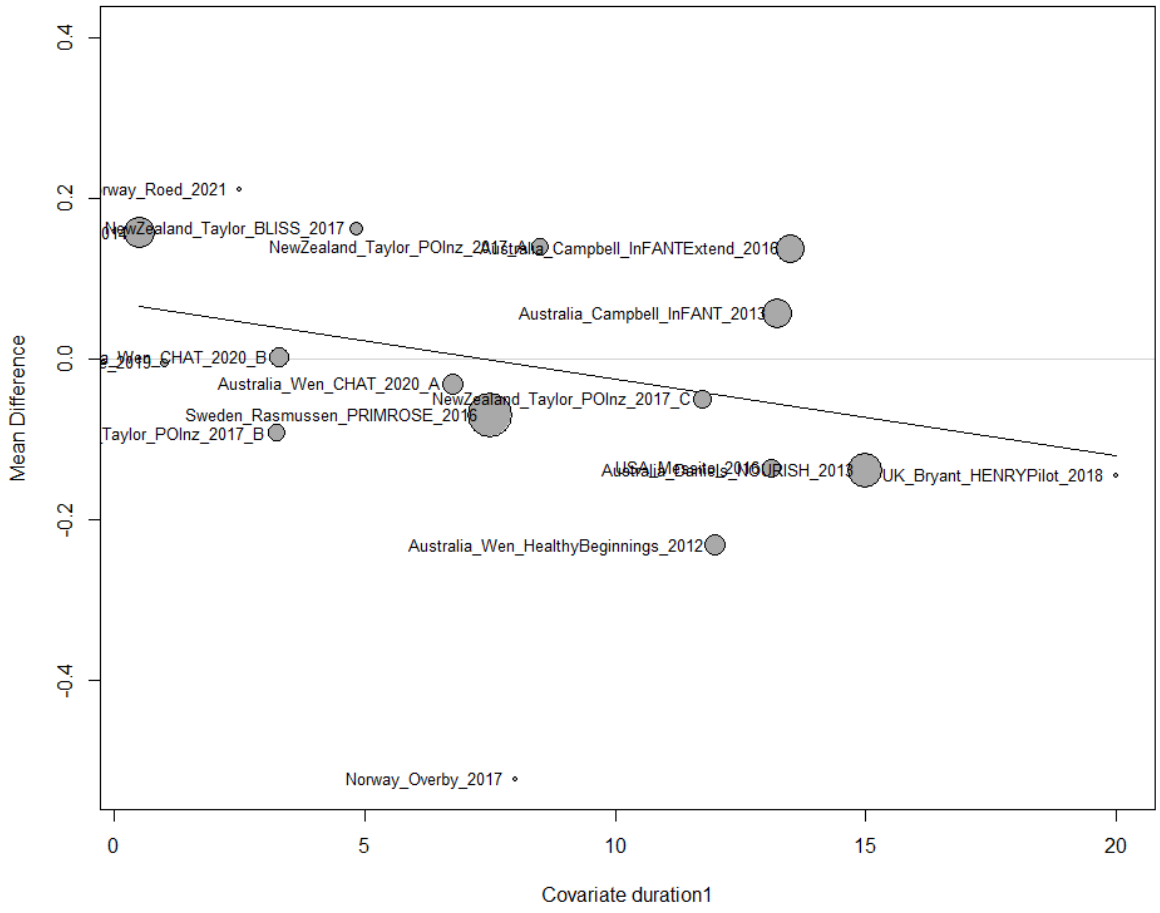
Intervention setting

Categorised as:

- At participants home
- In community setting, such as hospital
- A combination of home and community



Intervention dose/intensity



Term	Estimate	se	p	95% CI
Duration - total number of hours of intervention delivery intended to be received by participants (calculated using an average of the minimum and maximum duration)	-0.0095	0.0069	0.1666	-0.0230, 0.0040

Test for Residual Heterogeneity: QE(df = 15) = 16.3559, p-val = 0.36
Test of Moderators: QM(df = 1) = 1.9134, p-val = 0.17

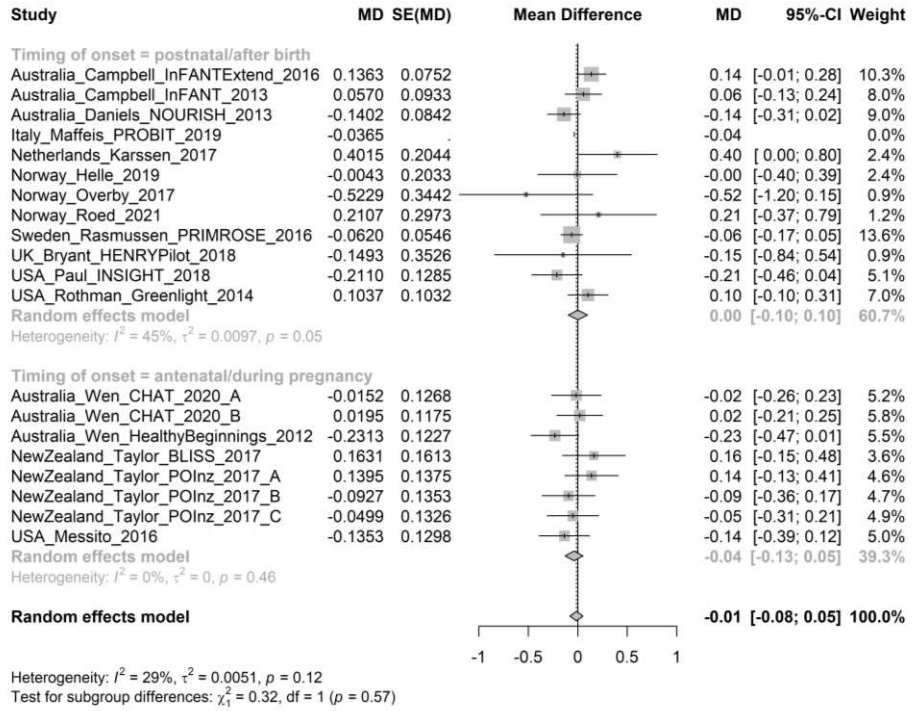
Fidelity

Not enough variation in data to analyse.

Timing of intervention onset

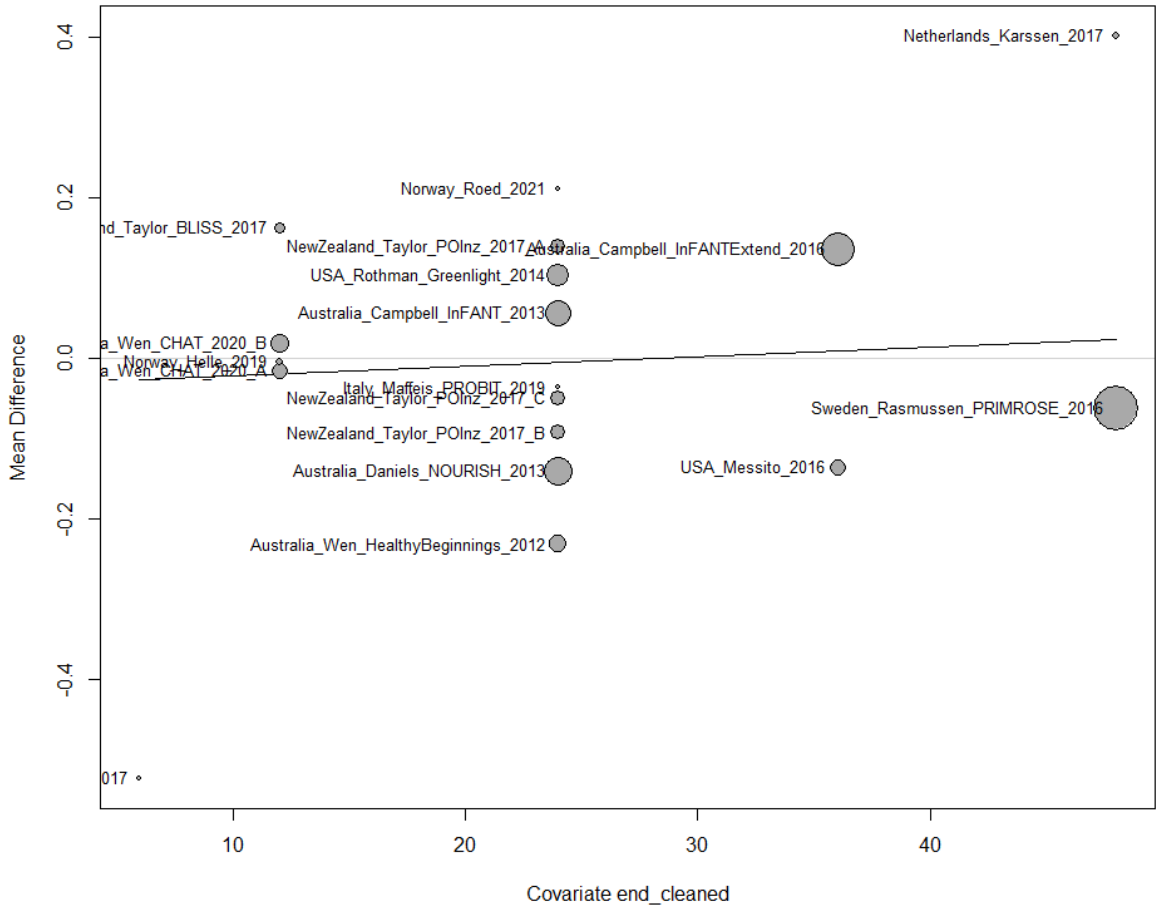
Categorised as:

- Postnatal (after birth)
- Antenatal (during pregnancy)



Timing of intervention completion

Mean difference by completion of intervention in months

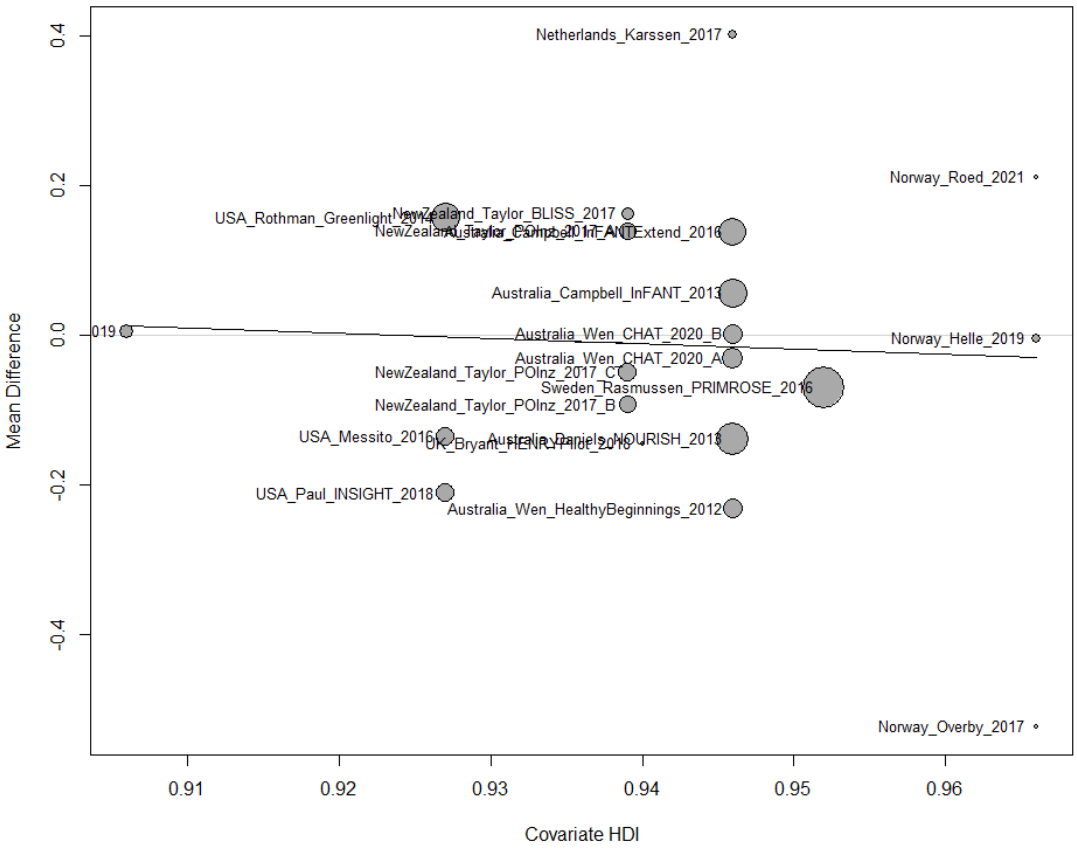


Term	Estimate	se	p	95% CI
Timing of intervention end (months)	0.0012	0.0031	0.6982	-0.0049, 0.0073

Test for Residual Heterogeneity: QE(df = 15) = 22.6729, p-val = 0.091

Test of Moderators: QM(df = 1) = 0.1504, p-val = 0.70

Current level of background care in the community/country



Term	Estimate	se	p	95% CI
Human development index (HDI)	-0.6959	2.9264	0.8120	-6.4315, 5.0398

Test for Residual Heterogeneity: QE(df = 18) = 24.9986, p-val = 0.13

Test of Moderators: QM(df = 1) = 0.0565, p-val = 0.81

Behavioural ± other intervention type

Insufficient data; only one trial had an additional non-behavioural intervention

L: Data collection form

TOPCHILD
Transforming Obesity Prevention for CHILDren

Data provision form

Trial name:	
Trial registration number:	
Citation(s) for any trial publications or abstracts (if applicable):	
Name of person completing this form:	
Email address of person completing this form:	

Information about the design of your trial	
What method was used to generate the random allocations in the trial?	☐ Simple (such as coin toss) ☐ Random number tables ☐ Permuted blocks ☐ Minimisation ☐ Other, please specify:
What, if any, stratification factors were used?	
What proportions was the trial designed to have in each arm?	*Example: 1:1*
What method was used to conceal the random allocation?	☐ Opaque, sequentially numbered, sealed envelopes ☐ Central randomisation by phone/fax/computer ☐ Other, please specify:

CONSORT flow diagram - http://www.consort-statement.org/consort-statement/flow-diagram	
Please provide a CONSORT flow diagram for your trial, or indicate where it can be found	☐ Provided as email attachment ☐ Copy and pasted below ☐ Available at (please specify, e.g. publication citation, website, etc.):

COVID-19 impact on your trial	
If relevant, please briefly describe any impacts of the COVID-19 pandemic on the conduct of your trial, e.g. relating to timeline or intervention delivery	

Definitions used in your trial, including assessment tools and timepoint(s) where applicable *****Note: we have provided some examples below in grey to guide you. Please replace with your trial's specific definition***** ***If available, please provide your trial's coding form, data dictionary, case report forms (CRFs) and/or questionnaires.***	
Term **(variable name)**	**Definition/measures/coding used in your trial**
Study centre (centre)	*Example: variable levels are coded as follows:* *1 = Royal Prince Alfred Hospital* *2 = Eunice Kennedy Shriver National Institute of Child Health & Human Development* *3 = Dunedin Hospital*
Ethnicity/race of child (ethnicity)	*Example: variable levels are coded as follows:* *1 = White* *2 = Mixed* *3 = Asian* *4 = Black/African* *5 = Hispanic* *6 = Other*
Small for gestational age (SGA)	*Example: birth weight < 10th percentile for gestational age*
Large for gestational age (LGA)	*Example: birth weight > 90th percentile for gestational age*
Type of childcare (care_type)	*Example: variable levels are coded as follows:* *1 = Long day care centre* *2 = Family day care* *3 = Cared for by family at home* *4 = Other*
Body mass index z-score (ZBMI)	*Example: determined in accordance with WHO growth standards*
Body fat percentage/adiposity (adiposity)	*Example: body fat percentage measured by DEXA scan*
Child overweight (overweight)	*Example: body mass index z-score of > 2 standard deviations above the WHO reference*
Child obesity (obesity)	*Example: body mass index z-score of > 3 standard deviations above the WHO reference*
Exclusive breastfeeding (bf_exclusive)	*Example: no other food or drink, not even water, except breast milk (including milk expressed or from a wet nurse); but allows the infant to receive oral rehydration solution, drops/ syrups of vitamins, minerals and medicines*
Energy intake (energy_kj), (energy_cal)	*Example: average daily energy intake in kj assessed using 3 day dietary recall*
Fruit consumption (fruit)	*Example: grams of fruit consumed per day assessed using the Food Frequency Questionnaire (FFQ)*
Vegetable consumption (veg)	*Example: grams of vegetables consumed per day assessed using the Food Frequency Questionnaire (FFQ)*

Fruit & vegetable consumption (fruit_veg)	*Example: Combined grams of fruit & vegetables consumed per day assessed using the Food Frequency Questionnaire (FFQ)*
Energy dense nutrient poor food consumption (EDNP)	*Example: Combined grams of foods high in saturated fats, trans-fatty acids, free sugars and/or salt consumed per day assessed using the Food Frequency Questionnaire FFQ*
Sugar-sweetened beverage consumption (SSB)	*Example: Combined millilitres of fruit juice, fruit drink, cordial/squash/syrup, soft or fizzy drinks, energy drinks, diet drinks and/or flavoured milk consumed per day assessed using the FFQ*
Screen time (screen)	*Example: Self-reported: 'Currently, on average, how many hours per day does your child spend sitting watching TV, videos, DVDs, playing computer games, or on the internet for pleasure? (may include portable & non-portable devices, e.g. TV, iPad)*
Restrained time (restrained)	*Example: Assessed using question 'Currently, on average, how many hours per day does your child spend restrained, e.g. in prams/strollers, high-chairs, or strapped on a caregiver's back or chest?'*
Physical activity (self-report) (PA_report)	*Example: Assessed using question 'On a usual day, how much time (in hours and minutes) would your child participate in active play, which may include light activities such as standing up, moving around and playing or more vigorous activities such as running, jumping, skipping, hopping, climbing, dancing, playing ball etc.?*
Physical activity (device assessed) (PA_device)	*Example: Daily physical activity assessed using an ActiGraph accelerometer attached by specially made belts to the child's waist and worn over 5 consecutive 24-hr periods. Measured as counts/minute.*
Tummy time / Prone play (tummy)	*Example: Assessed by question 'Over the last week about how much time (in hours & minutes) did your baby spend in tummy time (on their stomach while awake)?*
Sleep duration (day) (sleep_day)	*Example: Assessed using question from the Brief Infant Sleep Questionnaire (BISQ): How much time does your child spend in sleep during the DAY (between 7 in the morning and 7 in the evening)? Hours: _____ Minutes: _____*
Sleep duration (night) (sleep_night)	*Example: Assessed using question from the Brief Infant Sleep Questionnaire (BISQ): How much time does your child spend in sleep during the NIGHT (between 7 in the evening and 7 in the morning)? Hours: _____ Minutes: _____*
Sleep quality (sleep_qual)	*Example: Self-report: 'How many times does your child usually wake during the night? [refers to your child's normal routine over the last 2 weeks]'* *0=Does not wake up during the night* *1=Wakes 1-2 nights per week* *2=Wakes 3-4 nights per week* *3=Wakes 5-6 nights per week* *4=Wakes 7 nights per week*
Gestational weight gain (GWG)	*Example: the amount of weight gain between conception and birth (in kg) as reported in medical records*
Household income (income)	*Example: Assessed by question: Before tax is taken out, what is your approximate household income, from all sources, over the last 12 months in Australian dollars?*
Adults in household (household_adults)	*Example: where adults are defined as anyone aged 15 years or above*
Children in household (household_children)	*Example: where children are defined as anyone aged <15 years. Includes the enrolled child/children.*

Equivalised household income (HIED)	*Example: derived by dividing total household income by the 'modified OECD' equivalence scale, which equals the sum of those in household, whereby first adult=1 point, each additional person ≥15 years =0.5 points, and each child <15 =0.3 points*
Marital status (marital_status)	*Example: What is your current marital status?* *1=Living in a registered marriage* *2=Living in a de facto relationship* *3=Separated* *4=Divorced* *5=Widowed* *6=Single*
Education (carer_education)	*Example: assessed using the question 'What is your highest level of education you have completed?'* *0=No formal qualifications* *1=Elementary/primary school graduate* *2=High school graduate (or equivalent)* *3=Trade/apprenticeship/technical certificate/ diploma (e.g. hairdresser, chef)* *4=University Bachelor's degree* *5=Master's degree/Graduate Diploma* *6=Doctorate/PhD*
Employment (carer_employment)	*Example: What is your current employment status?* *0=on maternity/paternity leave* *1=employed full-time* *2=employed part-time* *3=casually employed* *4=unemployed* *5=student* *6=retired* *7=home duties full-time* *8=other* *NA=missing*
Occupation (carer_occupation)	*Example: assessed using the question 'What is the level of your most recent occupation?'* *0=never employed* *1=manager* *2=professional* *3=academic* *3=administrative* *4=manual skilled* *5=manual unskilled* *6=hospitality* *7=other*
Socioeconomic position (SEP)	*Example: SEP is derived from a composite of education, occupation and income, according to the methods of (Singh-Manoux et al. 2002) (UK)* *1=Low* *2=Medium*

	3=High
Socio-economic index of home neighbourhood (SEI_area)	*Example: Based on an Australian government SEIFA classification system – see https://www.abs.gov.au/websitedbs/censushome.nsf/home/seifa* *1=SEIFA 1 (most disadvantaged)* *2=SEIFA 2* *3=SEIFA 3* *4=SEIFA 4* *5=SEIFA 5 (most advantaged)*
Immigration status (immigration_status)	*Example: Self-reported by participant as:* *1=First generation (born outside study country)* *2=Second generation (born in study country to at least 1 foreign-born parent)* *3=Third generation (born in study country to parents both born in study country, but with at least one foreign born grandparent)* *4=Fourth generation or higher*
Language proficiency (lang_prof)	*Example: Self-reported for national or nationally dominant language as:* *1=very well* *2=well* *3=not very well* *4=not at all*
Health literacy (health_literacy)	*Example: Based on score achieved in health activities literacy scale:* *1=Possess very limited to restricted literacy proficiencies* *2=Below average proficiency of those graduating from high school* *3=Can integrate information from relatively long/dense text; minimum level literacy* *4=High proficiency associated with challenging tasks in test* *5=Highest proficiency associated with challenging tasks in test*
Other measure of socioeconomic position (SEP_other)	*Example: What are your current household arrangements?* *1=Paying rent or board in private rental* *2=Paying rent or board in public rental / Department of Housing* *3=Paying off your home* *4=Fully own your home* *5=Living rent free* *6=Purchasing under a rent buy scheme* *7=Other, please specify _____*
Carer physical activity (carer_PA)	*Example: Carer physical activity, quantified as the average duration of moderate to vigorous physical activity per week, assessed by self-report questionnaire*
Carer diet (carer_diet)	*Example: Carer average daily energy intake diet in kilojoules (kj)*
Carer sleep (carer_sleep)	*Example: Carer average sleep duration per night (in hours). Self-report was the measurement tool.*
Carer stress (carer_stress)	*Example: Overall, how do you think you are coping with life at present? 0=Not at all, 1=A little, 2=Fairly well, 3=Very well, 4=Extremely well, -9=missing*
Other measures of intervention compliance (Compliance)	*Example: Participant attended at least 80% of the prescribed intervention sessions* *0=no* *1=yes*

Parenting style (parent_style)	*Example: Self-reported using the Parenting Style Questionnaire (PSQ):* *1=Strict* *2=Balanced* *3=Uninvolved* *4=Permissive* *5=Disciplinarian*
Parent feeding practices (parent_feeding)	*Example: assessed using Comprehensive Feeding Practices Questionnaire (CFPQ), subscale 'Food as Reward'* *1=low tertile* *2=middle tertile* *3=high tertile*
Parenting self-efficacy (self_efficacy)	*Example: parenting question from Longitudinal Study of Australian Children (LSAC):* *1=Not very good* *2=A person who has some trouble being a parent* *3= Average parent* *4=Above average* *5=Very Good*
Reason participant excluded from analyses (reason_excluded)	*Example: variable levels are coded as follows:* *1=infant moved location and could no longer participate* *2=infant fell ill due to reasons unrelated to this study*

Any additional comments

Please return this form to topchild.study@sydney.edu.au *

M: Statistical models

First stage models:

Generalised linear model for trials with no clustering

$$g(E[y_{ij}]) = \hat{\alpha}_i + \hat{\theta}_i x_{ij} + \hat{\beta}_i z_{ij}$$

- $E[y_{ij}]$ = expected response for infant j in trial i
- $g(.)$ = link function:
  - Identity function for continuous outcomes
  - Log function for binary and count outcomes (or logit function for binary outcomes when log function does not converge)
- x_{ij} = treatment allocation for infant j in trial i (intervention = 1; control = 0)
- z_{ij} = sex at birth for infant j in trial i (male = 1; female = 2)
- $\hat{\alpha}_i$ = estimated response for male infants from the control group in trial i
- $\hat{\theta}_i$ = estimated intervention effect in trial i
- $\hat{\beta}_i$ = estimated female effect in trial i

Generalised linear mixed model for trials with cluster randomisation

$$g(E[y_{ikj}]) = \hat{\alpha}_{ik} + \hat{\theta}_i x_{ikj} + \hat{\beta}_i z_{ikj}$$

$$\hat{\alpha}_{ik} \sim N(\alpha_i, \tau_{ik}^2)$$

- $E[y_{ij}]$ = expected response for infant j in cluster k within trial i
- $g(.)$ = link function:
  - Identity function for continuous outcomes
  - Log function for binary and count outcomes (or logit function for binary outcomes when log function does not converge)
- x_{ikj} = treatment allocation for infant j in cluster k within trial i (intervention = 1; control = 0)
- z_{ikj} = sex at birth for infant j in cluster k within trial i (male = 1; female = 2)
- $\hat{\alpha}_{ik}$ = estimated response for male infants from the control group in cluster k within trial i (assumed normal with mean α_i and between-cluster variance τ_{ik}^2)
- $\hat{\theta}_i$ = estimated intervention effect in trial i
- $\hat{\beta}_i$ = estimated female effect in trial i

Cox proportional hazards model for trials with no clustering (for analysing breastfeeding duration outcomes)

$$h_{ij}(t) = h_{0i}(t) exp\,(\hat{\theta}_i x_{ij} + \hat{\beta}_i z_{ij})$$

- $h_{ij}(t)$ = hazard rate over time t for infant j in trial i
- $h_{0i}(t)$ = baseline hazard over time t for infants in trial i
- x_{ij} = treatment allocation for infant j in trial i (intervention = 1; control = 0)
- z_{ij} = sex at birth for infant j in trial i (male = 1; female = 2)
- $\hat{\theta}_i$ = estimated intervention effect in trial i

- $\hat{\beta}_i$ = estimated female effect in trial i

Mixed effects Cox proportional hazards model for trials with cluster randomisation (for analysing breastfeeding duration outcomes)

$$h_{ikj}(t) = h_{0i}(t)\exp\left(\hat{\alpha}_{0ik} + \hat{\theta}_i x_{ikj} + \hat{\beta}_i z_{ikj}\right)$$
$$\hat{\alpha}_{0ik} \sim N\left(0, \tau_{ik}^2\right)$$

- $h_{ij}(t)$ = hazard rate over time t for infant j in cluster k within trial i
- $h_{0i}(t)$ = baseline hazard over time t for infants in trial i
- $\hat{\alpha}_{0ik}$ = random effect on the baseline hazard due to the kth cluster within trial i (assumed normal within mean 0 and between-cluster variance τ_{ik}^2)
- x_{ikj} = treatment allocation for infant j in cluster k within trial i (intervention = 1; control = 0)
- z_{ikj} = sex at birth for infant j in cluster k within trial i (male = 1; female = 2)
- $\hat{\theta}_i$ = estimated intervention effect in trial i
- $\hat{\beta}_i$ = estimated female effect in trial i

Second stage model:

Random effects meta-analysis (inverse variance weighting)

$$\hat{\theta} = \frac{\sum_{i=1}^{S} \hat{\theta}_i w_i}{\sum_{i=1}^{S} w_i}$$

$$var\left(\hat{\theta}\right) = \frac{1}{\sum_{i=1}^{S} w_i}$$

$$w_i = \frac{1}{s_i^2 + \hat{\tau}^2}$$

- $\hat{\theta}$ = estimated summary intervention effect
- $\hat{\theta}_i$ = estimated intervention effect in trial i (obtained from first stage models)
- S = number of trials
- w_i = weight of trial i
- s_i^2 = variance of treatment effect estimate of trial i (assumed known)
- $\hat{\tau}^2$ = estimated between-trial variance of treatment effect

Example code

Example code – for primary outcome ZBMI (24 months) main effect

```
# variables============================================================

#ZBMI = primary outcome ZBMI at 24 months

#Group = treatment assignment

#Sex = sex

#Center = center (for multi-centre trials cluster randomised by center)

#Df = data frame of variables above

#modelling first stage=================================================

library(lme4) # for mixed effect models

# For cluster randomised trials we ran linear mixed effect models

Trial_i <- lmer(ZBMI ~ group + sex + (1|centre),

data = df)

# For all other trials we ran simple linear models

Trial_i <- lm(ZBMI ~ group + sex,

data = df)

#modelling second stage================================================

# trial estimates are then synthesised with a random effect model

library(metafor) # package for second stage synthesis via a random effect model

rma1 <- rma(yi, #treatment effects

Sei, # standard errors of each trial

#test="knha" Knapp-Hartung method not used due homogeneity concerns and because the number of studies was not low

Data = df_combining _trialestimates

)
```

N: Outcome harmonisation process

The outcome harmonisation process was described in the statistical analysis plan (pp 38-39 of this supplement). The TOPCHILD data dictionary developed by the steering group is available as an appendix to the analysis plan (pp 77-84 of this supplement). In Table 1 below, we provide an example variable map for the outcome daily vegetable intake. Variable maps and a collated list of questions were shared with experts and advisors prior to harmonisation workshops.

Table 1: Example outcome harmonisation map for vegetable intake in grams per day

Trial_id	Outcome: vegetable intake in grams/day	Timepoint(s)
Trial_EG1	DQ_veg_T3,T4,T5 About how many serves of vegetables does your child usually eat per day? Do not include potatoes, hot chips or fried potato. (1 serve=1⁄2 cup cooked vegetables or 1 cup salad vegetables) [0=My child does not eat vegetables, 1=Less than one serve/day, 2=1 serve/day, 3=2 serves or more/day]	18 months/3.5 years/5 years
Trial_EG2	Grams of vegetables consumed per day assessed using the Food Frequency Questionnaire (FFQ)	18 months and 3 years
Trial_EG3	B092_2,3,4 (Freq Vegies day): Please circle how often your child had each of the following food/drink items in the past 24 hours 0=Nil, 1=Once, 2=Twice, 3=3 Times, 4=4 Times, 5= 5+ Times Vegetables (raw or cooked) e.g.: salad in sandwich + vegetables at evening meal = twice B094_2,3,4 (Freq Vegies wk): How many days in the last week did your child have some vegetables (raw or cooked)? None 1 2 3 4 5 6 every day	18 months, 3.5 and 5 years
Trial_EG4	Not collected	Not applicable
Trial_EG2	Grams of fruit consumed per day assessed using 2-day dietary recall	2 years
Trial_EG7	How often does your child currently eat the following? Cut fruit, berries and/or vegetables (tick off for frequency and amount, or just frequency if the answer is “seldom/never”) 1. Carrot, 2. Rutabaga, 3. Cauliflower, broccoli, 4. Frozen Vegetable Mix, 5. Salad ("råkost" in Norwegian), 6. Spinach, 7. Cucumber, 8. Tomato, 9. Peas, 10. Corn, 11. Bell peppers 1=Never/not tried, 2= <1 time per wk, 3= 1-2 times per wk, 4= 3-4 times per wk, 5= 5-6 times per wk, 6= 1 time a day, 7= 2 times a day, 8= 4 times a day, 9= >4 times a day	12 months, 24 months
Trial_EG8	Not available	Not applicable
Trial_EG9	Vegetable serving equivalents computed from 24-hour dietary recalls reported by the infants’ mothers at each monthly home visit for postnatal months (PM) 1-12 and based on the USDA Food Patterns Equivalent Database.	postnatal months 1-12

Legend	
	Variable is available; no transformation required
	Available variable can be harmonised to required format
	Variable not collected or not available

We conducted six harmonisation workshops in total, including one per each of the following variable/outcome domains: demographics, anthropometry, diet, physical activity, parent feeding practices and sleep. Each workshop was attended by 3-10 TOPCHILD collaborators with specific expertise or interest in the domain. Some collaborators also provided feedback by email. While contrasting views were sometimes raised, after careful discussion at workshops and email follow-up, we were able to resolve any disagreements.

Some example questions that were discussed are shown in Table 2 below, with all decisions and rules clearly documented and applied to re-code datasets in preparation for analyses.

Table 2: Example harmonisation questions and decisions for workshops

Question/issue	**Decision / notes / actions**
Variable: bf_duration (Duration of any breastfeeding, in weeks)	
Can age stopped breastfeeding be used as a proxy for breastfeeding duration? i.e. can we assume bf started at (or close to) birth?	Yes, age stopped breastfeeding can be used as a proxy for breastfeeding duration, i.e. assume bf started at (or close to) birth and that it occurs continuously.
Variable: bf_exclusive (Duration of exclusive breastfeeding, in days)	
If we only have exclusive breastfeeding yes/no at different data collection points, how can we code for this variable? e.g. if Mother 123 answers 'yes' to exclusive breastfeeding at 1,2 and 3 months, but 'no' at 4 months, how should we code the duration? 3 months? 3.5 months? NA?	Take the last 'yes' Consider sensitivity analyses comparing half-way between the interval with conservative (last yes)
Variable: fruit (Fruit consumed, grams/day)	
Confirming that we should code this variable as 'NA' if we only have fruit and vegies *combined*?	Yes, code grams fruit/day as NA if only have fruit and veg combined
Variable: veg (Vegetables consumed, grams per day)	
1. Can we assume that 'portions' are equivalent to 'servings'?	No, portions=what people eat, serving=what is recommended