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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Summary (300/300 words)

Background
Childhood obesity is a global public health issue, which has prompted governments to invest in prevention programs. This study evaluated the effectiveness of parent-focused early childhood obesity prevention interventions globally.

Methods
We conducted a systematic review and individual participant data meta-analysis (PROSPERO: CRD42020177408). We searched databases and trial registries from inception until September 30, 2024, for randomised controlled trials commencing before 12 months of age examining parent-focused behavioural interventions to prevent obesity in children, compared with usual care, no intervention, or attention control. Individual participant data were checked, harmonised, and assessed for integrity and risk of bias. The primary outcome was body mass index (BMI) z-score at age 24±6 months, with 33 pre-specified behavioural and anthropometric secondary outcomes. We conducted intention-to-treat two-stage random effects meta-analysis to examine effects overall and for pre-specified subgroups. Certainty of evidence was assessed using Grading of Recommendations Assessment, Development, and Evaluation.

Findings
Of 19,990 identified records, 47 trials were completed and eligible. Of these, 18 assessed our primary outcome, BMI z-score. We obtained individual participant data for 17 (n=9128) out of these 18 trials (n=9383), representing 97% of eligible participants. Of these 9128 participants, 4549 (51%) were boys, 4415 (49%) girls and 164 had unknown sex. We found no evidence of an effect of interventions on BMI z-score at age 24±6 months (mean difference -0.01 [95% CI -0.08, 0.05], high certainty evidence, τ^2=0.01, n=6505, 2623 missing), and no evidence of effects for most secondary outcomes. Findings were robust to pre-specified sensitivity analyses (e.g. different analysis methods, missing data), and there was no evidence of differential intervention effects for pre-specified subgroups including priority populations and trial-level factors.

Interpretation
These findings indicate that examined parent-focused behavioural interventions are insufficient to prevent obesity at age 24±6 months. This highlights a need to re-think childhood obesity prevention approaches.

Funding
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Panel: Research in context

Evidence before this study

While there have been numerous reviews of childhood obesity prevention trials, few have focused on infancy, and many are narrative. A Cochrane review evaluating obesity prevention interventions in children aged 0-18 years found that combined diet and physical activity interventions led to a small reduction in body mass index z-score in children aged 0-5 years (mean difference −0.07 (95% CI −0.14, −0.01). However, this review was limited by reliance on published aggregate data, precluding outcome harmonisation and in-depth subgroup analyses. Recent updates to this review only examined interventions in age groups older than 2 years. The Early Prevention of Obesity in Children (EPOCH) Collaboration conducted an individual participant data prospective meta-analysis of four Australian/New Zealand randomised controlled trials. They found that parent-focused behavioural interventions for the prevention of early childhood obesity resulted in a small reduction in body mass index z-score at age 18-24 months, compared to usual care (-0.12 standard deviations; (95% CI −0.22 to, −0.02)). However, this difference was no longer statistically significant when accounting for missing data, and there was insufficient power for subgroup analyses. More studies in a global context were needed to confirm this finding and explore differential effects across key subgroups, including obesity-vulnerable priority populations (e.g. individuals with lower education or income levels, immigrants), with sufficient statistical power. We searched databases and trial registries from their inception up to September 30, 2024, without language restrictions, to identify randomised controlled trials evaluating the effectiveness of obesity prevention interventions commencing antenatally or during infancy. The search strategy included terms related to weight (e.g. “obes*”, “overweight”, “body mass index”, “adiposity”), behavioural interventions (e.g. “behavio?r*”, “diet*”, “physical activity”, “sleep”, “feeding”) , children, parents and families (e.g. “child”, “infan*”, “pregnan*”, “prenatal”, “parent$), and study design (e.g. “randomi#ed”)

Added value of this study

This is the largest systematic review with individual participant data meta-analysis in the field to date, including 31 trials set across 10 countries with 28,825 participants. Out of 18 eligible completed trials that assessed our primary outcome (BMI z-score at 24±6months), we obtained individual participant data for 17, including 9128 participants (97% of eligible participants). We employed rigorous data checking, harmonisation, integrity and risk of bias assessments enhanced by the availability of individual participant data and collaboration with trial representatives to create a global dataset. Access to original data enhanced statistical power and enabled advanced and complex analyses, including examination of important obesity-vulnerable subgroups. The resulting high-quality TOPCHILD dataset provided robust evidence to address our research questions. Here we report findings for the primary outcome, BMI z-score, and for 33 pre-specified secondary anthropometric and behavioural outcomes.

Implications of all the available evidence

This large individual participant data meta-analysis provides evidence that existing approaches to parent-focused behavioural interventions delivered up to 12 months of age are insufficient to impact BMI z-score at 24±6 months of age or key obesity-related behavioural outcomes covering diet, feeding, physical activity, sleep and parenting. These findings underscore the need to re-think current behavioural approaches to prevent obesity in early childhood.

MAIN TEXT (3498/3500)

Introduction

The United Nations' Sustainable Development Goals identify prevention of non-communicable diseases as a core priority.[1] Overweight and obesity in childhood are risk factors for non-communicable disease across the life course,[2,3] and represent major public health challenges which threaten recent health improvements contributing to increased life expectancy in many countries.[4] Globally, around 37 million children under 5 years already live with overweight or obesity.[2] High body mass index (BMI) in infancy and very early childhood strongly predicts lifelong overweight and obesity.[4-6] Obesity in childhood tracks into adulthood,[7,8] and is linked to increased risk of short and long-term negative health consequences.[9,10] This large burden on health and social care systems has significant economic consequences for individuals and society.[11,12] Obesity prevalence rates are increasing disproportionately among socially disadvantaged populations.[2,13]

To prevent obesity, many argue it is imperative to intervene early, when biology is most amenable to change, before overweight or obesity first develop in early childhood and obesity-conducive behaviour patterns are established .[4] Consequently, the World Health Organization (WHO) report of the Commission on Ending Childhood Obesity[1] recommends a life-course approach to reduce the risk of obesity, starting during preconception and pregnancy, and continuing throughout infancy and early childhood up to adolescence. The WHO also highlights the need to '*provide guidance on, and support for, healthy diet, sleep and physical activity in early childhood'*[4] for parents/caregivers, making early parent-focused interventions a key strategy for obesity prevention.

Previous evidence syntheses of early obesity prevention interventions targeting child dietary, activity, and/or sleep behaviours have yielded mixed and inconclusive results. A systematic review assessing behavioural, educational, or quality improvement-based obesity prevention interventions in children younger than 2 years found no intervention improved child weight status.[14] The latest Cochrane review to examine the broader age group of children 0-5 years[15] found that combined diet and physical activity interventions led to a small reduction in body mass index (BMI) z-score (mean difference −0.07; 95%CI −0.14 to −0.01; 16 trials, n=6261, τ^2=0.01, random effects, moderate certainty). To put this into perspective, an effect of ≥0.2 BMI z-score units is generally considered clinically meaningful.[16] Across these reviews, heterogeneity of interventions and reliance on published data limited the ability to conduct meaningful comparisons and sufficiently powered subgroup analyses. An individual participant data prospective meta-analysis of four Australian and New Zealand trials (commencing between 2007-2009) sought to address this, finding a small effect on BMI z-score at age 2 years (adjusted mean difference −0.12; 95%CI −0.22, −0.02; 4 trials, n=2196, heterogeneity p value=0.09, fixed effects),[17] although this effect dissipated at longer term follow-up and when accounting for missing data.[18]

We have since identified a plethora of completed, ongoing or planned randomised trials examining the impact of parent-focused interventions commencing before 12 months of age for primary prevention of childhood obesity. Such interventions are highly varied in their content, timing, dose and populations reached.[19,20] Additionally, many of these programs focused on weight-related behavioural outcomes and were thus underpowered to detect a difference in anthropometric outcomes like BMI. Uncertainty around the effectiveness of such interventions

has put policymakers in a challenging position, resulting in decisions to implement potentially resource-intensive programs based on limited evidence.[21-23]

Individual participant data meta-analyses are the gold standard for combining randomised trial data.[24] They enable harmonisation of outcome measures that are otherwise too heterogenous to be synthesised in aggregate form, increasing statistical power (e.g. calculating BMI z-scores using a consistent reference population). They also allow examination of subgroup effects, that is, effect modification of intervention effects for different populations (such as whether interventions work better for families with low socioeconomic position), with improved power and reduced risk of aggregation bias,[25] enabling us to understand what works for whom.[26] This is important, since childhood obesity prevention is a health equity issue,[5] whereby families experiencing socioeconomic disadvantage are disproportionately affected by early childhood obesity and face greater barriers to accessing preventive interventions.[19,27] For instance, children living in the most socioeconomically disadvantaged areas of England are twice as likely to start school with obesity and three times as likely to start school with severe obesity compared to those from higher socio-economic backgrounds.[28] We conducted a systematic review and individual participant data meta-analysis to assess 1) whether parent-focused interventions commencing antenatally or in the first year after birth are effective in improving BMI z-score and behavioural outcomes at two years of age, and 2) whether effectiveness varies across subgroups defined by individual-level or trial-level characteristics.

Methods

Detailed methods were pre-specified in a published protocol,[29] a Prospectively Registered Systematic Reviews with Health Related Outcomes (PROSPERO) registration record (CRD42020177408), and a statistical analysis plan that was uploaded to Open Science Framework (OSF) a priori (appendix pp 8-119). Minor protocol deviations with justifications (e.g. limited data availability) are described in appendix pp 20-21. We followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)-IPD and PRISMA 2020 reporting guidelines (appendix pp 120-127).[30,31] Consumer representatives supported protocol development and interpretation of results (appendix pp 7). The study protocol was approved by The University of Sydney Human Research Ethics Committee (approval number 2020/273).

Search strategy and selection criteria

We included individual and cluster randomised controlled trials comparing parent-focused behavioural interventions for early childhood obesity prevention with usual care, no intervention, or attention control, that assessed at least one weight-related outcome. We classified attention controls as those designed to match the intervention for contact time but with content not intended to affect key study outcomes (e.g. general home safety information). We excluded quasi-randomised studies and those with active controls such as enhanced usual care or alternative interventions (i.e. those designed to specifically impact the same outcomes as the experimental intervention) as our aim was to assess overall (rather than comparative) effectiveness and including these trials could dilute effect estimates. Eligible participants were parents/caregivers and their infant(s). Interventions could commence before or after birth, but needed to include intervention exposure between birth and 12 months of age. For trials including children both under and over 12 months of age at baseline, only data from children under 12 months were included. Eligible interventions focused on primary prevention of obesity in children and targeted at least one modifiable child behaviour related to obesity risk (i.e. early feeding, diet, physical activity, sleep). There were no date or language restrictions.

We systematically searched databases (MEDLINE, Embase, CENTRAL, CINAHL, PsycInfo) from inception to Feb 27, 2023, and clinical trials registries (ClinicalTrials.gov, WHO International Clinical Trials Registry Platform) from inception to Mar 28, 2023 (both searches updated Sep 30, 2024), according to recommended guidelines[32] (appendix pp 128-136). We also consulted collaborators, and hand-searched conference abstracts and reference lists of relevant reviews.

Two reviewers independently screened each study, with conflicts resolved by a third. Trialists were consulted if uncertainties remained. Principal Investigators of all eligible trials were invited to join the Transforming Obesity Prevention for Children (TOPCHILD) Collaboration, give feedback on the protocol and statistical analysis plan, share their individual participant data, and contribute to a complementary intervention coding project.[20,33]

Data collection, management and analysis

Definitions of all outcomes, covariates and subgroups were pre-specified in the statistical analysis plan (appendix pp 41-67). Our primary outcome was BMI z-score at age 24±6 months, using WHO Child growth standards.[34] We chose this continuous measure as our primary outcome given it is a strong predictor of lifelong obesity,[4-6] is commonly used in this age group,[15,17] and is considered the most feasible option for large-scale, population-level monitoring of obesity.[35,36] We pre-specified several subgroups (appendix pp 56-62) at the individual level (e.g. maternal education status, household income, parity) and at the intervention/trial level (e.g. mode of intervention delivery, duration, setting) to assess differential treatment effects for our primary ooutcome.[28]

Prespecified key secondary outcomes (appendix pp 39-41) were duration of exclusive breastfeeding up to 6±2 months, and each of the following at age 24±6 months: daily vegetable consumption, screen time, physical activity, sleep duration, and parent feeding practices domain of control (restriction). Other prespecified secondary outcomes (n=27, appendix pp 39-41) included other measures related to weight status, feeding, dietary intake, activity, sleep, parent/carer behaviours and adverse events. To harmonise variables and outcomes, trial-level data were mapped, compared, and discussed at domain-specific outcome harmonisation workshops involving content and methods experts (see appendix for further details pp 38-39, 234-235 and an illustrative example pp 38-39, 115-117, 234-235) .

De-identified individual participant data were supplied by trial representatives for published and unpublished studies according to a pre-specified data collection form (appendix pp 225-230). To ensure high-quality datasets, we conducted rigorous pre-specified processing and cleaning procedures (appendix pp 22-25).

Using trial publications, registration records, and individual participant data, two reviewers independently assessed trial integrity with the IPD Integrity Tool,[37] conducted data quality checks according to a pre-specified checklist derived from a scoping review,[38] and assessed risk of bias for the primary outcome and secondary outcome categories using the Cochrane Risk of Bias 2 Tool (ROB2, appendix pp 137-143).[39] Discrepancies were resolved by a third reviewer, or by consulting trialists or advisors.

Once finalised, individual participant data from all trials were merged into a single dataset. If individual participant data were not obtained for a trial, aggregate data were extracted from published records by two reviewers, with conflicts adjudicated by a third. We followed a prespecified checklist[40] to determine whether to include published aggregate data when individual participant data were unavailable (appendix p 144).

Certainty of evidence was assessed by two reviewers using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach[41] for the primary outcome and key secondary outcomes.

All analyses were prespecified in a time-stamped statistical analysis plan (appendix pp 8-119) and conducted using R version 4.4.1[42] or Stata (release 18)[43] for floating subgroup analyses ('metafloat' package).[25] All analyses were intention-to-treat following the principles of White et al.,[44] including all eligible randomised participants for whom data were available.

Analysis for all outcomes was conducted using a complete case two-stage approach . assuming random effects in generalised linear mixed models. In accordance with the decision-tree pre-specified in our analysis plan (appendix p 70) and best-practice guidance,[45] we favoured a two-stage over a one-stage approach to overcome concerns around model stability, convergence issues, and to minimise the risk of aggregation bias. For cluster randomised trials, correlated data were accounted for by adding random intercepts within trials. We adjusted for sex, as a fixed (common) effect. For continuous outcomes, we estimated mean differences. For binary outcomes and count outcomes, we estimated risk ratios or rate ratios (i.e. log link) or, if binary outcome models failed to converge, odds ratios (i.e. logit link). For binary outcomes, when no events were recorded in a trial for either control or intervention groups, that trial wasn't included for that outcome in line with best practice recommendations.[46] For breastfeeding duration outcomes, we estimated hazard ratios using Cox regression models to account for infants still breastfeeding at study end. To account for multiplicity issues, outcomes were interpreted as patterns of evidence in consideration of clinical plausibility, rather than focusing on any single statistically significant result.[47] Our complete statistical model and example code are available in appendix pp 231-233.

Heterogeneity was examined by inspecting forest plots, tau-squared (τ^2, i.e. the estimated variance of true effect sizes across studies in a random-effects meta-analysis) and 95% prediction intervals (PI, the range within which the treatment effect in a future trial from a similar population is expected to fall), and by conducting a common effects sensitivity analysis. Individual-level subgroup analyses (i.e. effect modification analyses) were performed for the primary outcome by examining within-trial treatment-by-covariate interactions with common effects to avoid aggregation bias.[48] Trial-level subgroup analyses were conducted for continuous variables using two-stage random effects meta-regressions, with a single moderator. Trial-level subgroup analyses for categorical variables were compared with a Q_m test to assess whether the moderator coefficients significantly differ from the null. Prespecified sensitivity analyses for the primary outcome included different analysis methods (one-stage model with a random treatment effect stratified by trial and centre, two-stage fixed effects model, incorporation of aggregate data where individual participant data were unavailable, exclusion of trials with high risk of bias, integrity concerns, significant conflict of interest, >40% missing data, or low adherence (trial-level) and multiple imputation (appendix pp 72-74). Multiple imputation was conducted using the mice package in R (appendix p 72).[49]

Role of the funding source

The funder of this study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

We identified 19,990 records from database and registry searches (Figure 1). Of these, 8030 were duplicates, and 10,737 were excluded after title and abstract screening. For the remaining 1223 records, we reviewed full text reports and identified 47 eligible and completed trials (appendix pp 145-179). Of these, 18 trials assessed the primary outcome for the meta-analysis of BMI z-score at 24±6 months and thus were eligible for our primary outcome analysis. We obtained individual participant data for 17 of these 18 trials, representing 9128/9383 (97%) of total eligible participants. Of these 9128 participants, 4549 (51%) were boys, 4415 (49%) girls and 164 had unknown sex. We did not include aggregate data for the one trial without individual participant data following pre-specified decision rules (appendix pp 68-70, 144). The 17 trials in the primary outcome analysis were set across eight countries (all high-income).[50] Of these, five trials (29%) targeted families with low socio-economic position, two (12%) targeted families from culturally and linguistically diverse backgrounds or ethnic minority groups and the remaining 10 (59%) targeted a global population.[19] Median eligible sample size was 533 (IQR 270-698). Interventions in 5/17 (29%) trials commenced during pregnancy; postnatal interventions commenced at a median child age of 3.91 months (IQR 1.66, 5.75). Mean maternal pre-pregnancy BMI was 25.34 (SD 5.45) and mean age at birth was 30.38 (SD 5.36) years. Mean child birthweight was 3418.54 (SD 529.83) grams. Baseline characteristics were balanced, and missing data for the primary outcome (n=2623) were evenly distributed between intervention (28%) and control (29%) groups. See appendix pp 180-182 for trial and participant characteristics.

There was no evidence that the intervention had an effect on the primary outcome BMI z-score at 24±6 months of age, with a mean difference of -0.01 (95%CI -0.08 to 0.05, p=0.15, high certainty of evidence, τ^2=0.01, n = 6505, 2623 missing, 95%PI –0.07 to 0.14) (Table 2, Figure 2). Results were consistent across all prespecified sensitivity analyses, including a complete case analysis excluding the four trials with more than 40% missingness (MD -0.02 [95%CI -0.09, 0.04, [p=], τ^2=0.00, 13 trials, n=6170, 1808 missing), multiple imputation for missing outcome data (MD -0.02 [95%CI -0.08, 0.04], τ^2=0.00, 17 trials) and excluding trials with high risk of bias (appendix pp 190-195, 205). Risk of bias was rated high for seven of 17 trials including 3246 (36%) participants (due to missing data), some concern for four trials including 2364 (26%) participants, and low for six trials including 3518 (39%) participants. There was no evidence that the effect on BMI z-score differed according to any of the 19 individual or trial/intervention-level subgroup characteristics (i.e. no evidence of effect modification, including infant sex), except for a minor increase in intervention effect by 0.01 for every 100-gram increase in birthweight (interaction MD 0.01; 95%CI 0.00, 0.02) (Tables 3-4). There was no evidence of publication bias based on visual inspection of the funnel plot and Egger's test (p=0.91; appendix p 189).

For secondary outcomes, 47 completed trials were eligible, with 34 providing individual participant data. Three were excluded due to integrity issues relating to missing data and randomisation, leaving 31 trials contributing data to secondary outcomes (n=28,825 participants). Albeit not all trials collected all outcomes. The number of trials and participants per outcome are shown in Table 2.Mean maternal pre-pregnancy BMI was 25.6 (SD 5.7) and mean age at birth was 26.7 (SD 5.7) years. Mean child birthweight was 3,422 (SD 465) grams. Baseline characteristics were balanced, with missing data evenly distributed across intervention and control groups (appendix pp 182-183).

For key secondary outcomes (Table 2), there was no evidence that the intervention had an effect on duration of exclusive breastfeeding at 6±2 months of age, or on daily vegetable intake, physical activity or sleep duration at 24±6 months of age. Small improvements were seen in

screen time at 24±6 months of age, with an average decrease of 9 minutes and 36 seconds per day in the intervention group compared to control (9 trials, n=3650, MD -9.60, 95%CI -13.72, -5.47, moderate certainty).

For the remaining 27 secondary outcomes across the categories of anthropometry, feeding, diet, movement, sleep, parent practices and adverse events, there were no differences between the intervention and control groups, except for a few isolated small effects (appendix pp 187-188). Risk of bias was rated high for most secondary outcomes (such as diet and physical activity), due to self-reporting and missing data. For anthropometric secondary outcomes, 9/29 trials had low risk of bias due to objective, blinded measurements, while six had some concerns, and 14 were rated high risk of bias due to missing data (appendix p 138).

Discussion

This large individual participant data meta-analysis of randomised controlled trials found no evidence of effectiveness of early childhood obesity prevention interventions for our primary outcome BMI z-score and most secondary outcomes around infant feeding, movement, diet, and sleep. There was a high certainty of evidence for the primary outcome, which included 97% of eligible participants from 17/18 identified trials and was robust across subgroups and sensitivity analyses. Our findings align with previous reviews, which reported no effect[14] or only very small effects below the threshold of clinical significance.[15,17] Despite the 17 trials being set in eight countries and targeting a range of different populations, the findings were quite homogenous, with little heterogeneity across trials. Certainty of evidence varied for secondary outcomes and data were available from 31/44 identified trials (85% of randomised participants).

This is the most comprehensive review of early obesity prevention interventions to date. We employed gold-standard methods for meta-analysis, including rigorous checks of data quality, integrity, and risk of bias. Availability of individual participant data enabled harmonisation of outcomes with heterogeneous definitions and measurement methods (e.g. portion sizes of fruits and vegetables across different countries, appendix pp115-117), and inclusion of three unpublished studies and several unpublished outcomes, thereby increasing statistical power to provide the most reliable and precise effect estimates. The collection of individual participant data also enabled exploration of potentially differential effects across key individual and trial-level characteristics, addressing whether these interventions work exclusively or better in some populations than others.

Limitations should be considered. Seven of the 17 trials contributing to the primary outcome were rated as high risk of bias due to missing data and/or imbalanced missingness across intervention and control groups (appendix p 137). However, pre-specified sensitivity analyses excluding trials with high risk of bias or high levels of missingness did not change the result. Although BMI z-score is a surrogate measure of clinical adiposity, it is an acceptable and commonly used measure for large-scale monitoring of obesity risk[35,36] and is strongly predictive of lifelong obesity.[4-6] Further, other measures of body composition were analysed as secondary outcomes (e.g. overweight, obesity, waist circumference) and findings were consistent with our primary outcome. Only 3/6490 children had severe underweight (appendix pp. 187-188). We were unable to analyse some pre-specified outcomes and subgroups (e.g. fidelity of, and adherence to interventions, ethnicity) due to excessive heterogeneity in whether and how these were assessed. These challenges highlight the need in future trials for use of core outcome sets, core outcome measurement sets,[51-55] prospective approaches to evidence synthesis,[56]

and a standardised approach for collecting key sociodemographic variables to advance health equity.

Interventions in this study were designed carefully by world-leading experts in the field. Some were grounded in behaviour change theories, while others were based on pilot work and consultation with various stakeholders.[20] The lack of evidence supporting the effectiveness of these interventions is surprising and discouraging. There are several potential explanations.

First, since the included landmark interventions were designed, new approaches have been developed to identify promising behaviour strategies (e.g. stronger application of behaviour change theory and co-design science)[57] and target outcomes,[20] such as targeting more 'stop behaviours'.[58] Incorporating this knowledge into the development of new interventions could be one promising avenue for future research (for example, in the Greenlight Plus trial[59] the intervention group had a reduction in BMI z-score of 0.19 (95%CI −0.36 to −0.01), but was not eligible for TOPCHILD due to an active comparator).[59] Importantly, any future research should report results in the context of clinical significance to aid interpretation. However, it could be argued that the interventions included in this study were already quite diverse, and subgroup analyses did not show that any intervention types (e.g. setting, dose) worked better than others. Future work will combine detailed intervention deconstruction with individual participant data to further explore potential differences in effectiveness between intervention features.[20]

Second, interventions may be targeting the wrong age group. While there is a strong theoretical case for starting interventions early, one challenge is that such interventions rely on indirect causal pathways.[60] That is, they aim to improve child weight status by changing the behaviour of parents, who then need to influence their child's behaviour. Our consumer panel highlighted that the first year of life can be overwhelming and stressful for parents, leaving them with limited capacity to absorb new content or engage in behavioural interventions. It is also possible that any potential effects on behaviour fade out too quickly to have a lasting impact on child weight status. Once children enter broader social settings beyond the family (e.g. early child care, school), more direct interventions via a settings approach may improve reach and effectiveness.[61]

Third, the interventions may not have effectively reached priority populations, who are most in need of support. Families experiencing socioeconomic disadvantage and those from minority groups are disproportionately affected by childhood obesity and also often face the greatest barriers to accessing interventions.[19,27] This inequity, also referred to as the 'prevention dilemma',[62] underscores the need for implementation strategies to address systemic barriers. A TOPCHILD sub-study found that although around half of the included interventions targeted priority populations, their success in reaching these groups varied.[19] This lack of reach aligns with our findings for key secondary outcomes, which showed that on average outcome values for both intervention and control groups were close to or met recommendations. For instance, on average, children in both groups exceeded minimum physical activity and sleep recommendations). Yet, the observed BMI z-scores were above the population median (i.e. >0) in both groups. Notably, we did not find the anticipated differential intervention effects across priority populations, with relevant subgroup analyses (e.g. income, education, employment, immigration status) showing consistent null results. This suggests the interventions were not effective for any population, including priority populations.

Fourth, the included interventions employed downstream approaches that require a high degree of individual agency, relying on families to be able and willing to make positive

behavioural changes.[63] Yet, obesity is predominantly driven by upstream environmental and socio-economic factors that are beyond the capacity of the individual to change.[64,65] Recognising this, the WHO Commission on Ending Childhood Obesity[4] advocated for a coordinated, whole-system, life-course approach incorporating upstream, low-agency interventions. Such interventions place less onus on individuals and instead focus on transforming obesogenic environments for all populations, thereby mitigating social inequities through addressing disparities in individuals' capacity to make healthier choices.[66] Examples of upstream interventions include policies to improve access to healthy foods, providing social support for parents (e.g. paid parental leave), increasing green spaces, and regulating unhealthy food marketing.[61,63,64] Supporting this, a recent system dynamics model in an Australian context[67] found that among five intervention scenarios for child obesity prevention, early interventions targeting mothers of children aged less than one year had the lowest potential impact on reducing obesity prevalence. In contrast, upstream interventions with high coverage over the life course and low individual agency, including a sugar-sweetened beverage tax and child sports vouchers, demonstrated the greatest potential impact. Synergistic effects were observed when combined with setting-based interventions across the life course, including childcare and school-based programs.

Fifth, interventions may need more time to be effective, and measuring outcomes at 24 months may have been too early. Yet, an individual participant data meta-analysis of four Australasian early obesity prevention trials found no evidence of intervention effects for weight-related outcomes at follow up at 3.5 or 5 years of age,[18] making this explanation less plausible. We will further examine BMI z-scores at these later timepoints once more trials have completed follow-up.

This study is the most comprehensive individual participant meta-analysis in the field to date. Using rigorous, gold standard methods, we found no evidence that parent-focused obesity prevention interventions impact child BMI z-score at age 24±6 months or most secondary outcomes. Our findings indicate that current early, behavioural, parent-focused interventions alone are insufficient to address childhood obesity.

Contributors

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 conceptualization, and methodology. KDH, MB, JLT, RL, AGF, CH, COS, KKO, LK, JKL, AML, MM, LMW, EO, NØ, CP, IMP, EMP, FER, EAR, 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.

Data sharing

The TOPCHILD collaboration has obtained permission to use but does not own all data used in these analyses. Where possible, individual participant data collected for this study, including a data dictionary, will be made available following a moderated access process, whereby a proposal needs to be approved by the original data custodians (i.e., the trial investigators) and a cross-institutional data access agreement needs to be signed. The statistical analysis plan and protocol are already publicly available. Please contact KEH (kylie.hunter@sydney.edu.au) or the TOPCHILD collaboration (topchild.study@sydney.edu.au) to request data access.

Declaration of interests

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 (393112, 1003780) and Centre for Research Excellence (1101675, 2006999). 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). declares they are the recipient of a grant from NIH. MJM declares support for their included trail 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. EAR 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 included 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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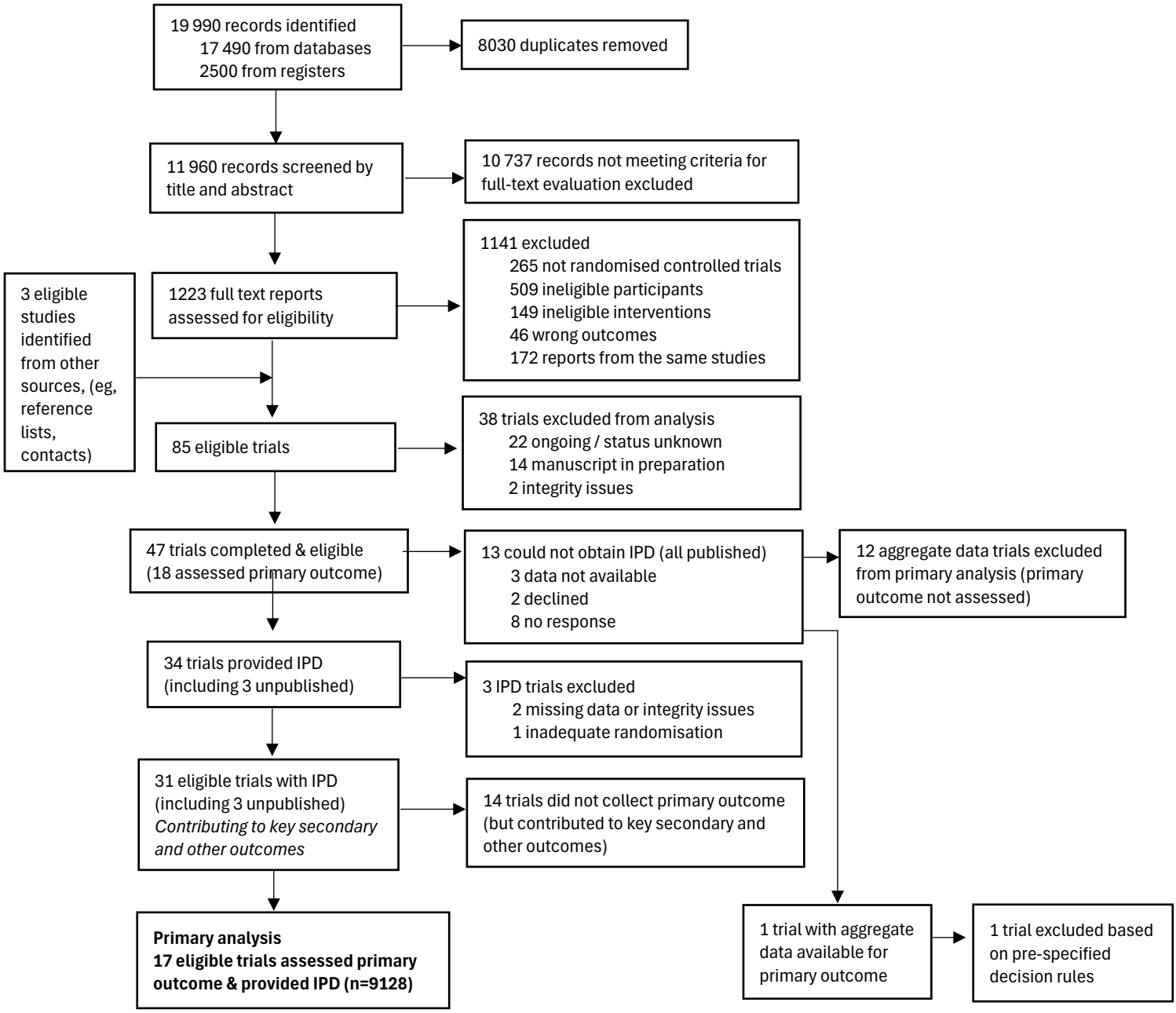

Figure 1. Trial selection diagram

IPD = individual participant data

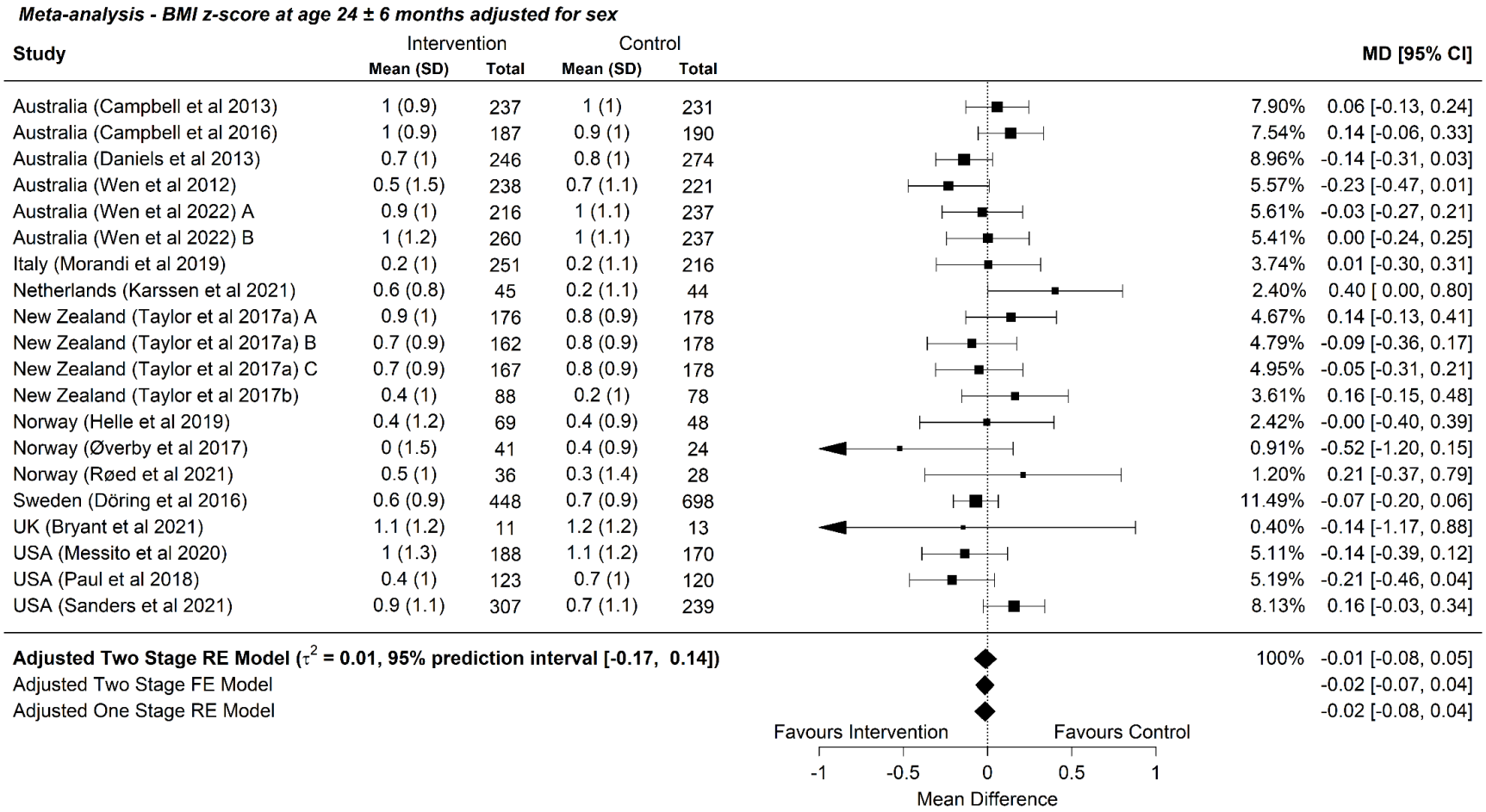

Figure 2. Forest plot for the primary outcome of BMI z-score at age 24±6 months

BMI=body mass index, SD=standard deviation, MD=mean difference, CI=confidence interval, RE=random effects, FE=fixed effects. There are two multi-arm trials: Australia (Wen et al 2022) and New Zealand (Taylor et al 2017a). Each arm is indicated by A, B, C after the study name . The black squares capture the intervention effect estimate. The 95% CIs around this estimate are represented by the black line. Lines with arrows indicate confidence intervals that extend beyond the scale of the plot. The Adjusted Two Stage RE Model (bolded) presents the primary analysis. τ^2 is the variance of the between study effects. The prediction interval represents the range within which the treatment effect in a future trial from a similar population is expected to fall. The adjusted Two Stage FE Model and the Adjusted One Stage RE model are sensitivity analyses.

Table 1. Characteristics of included studies (n=31)

Trials contributing to primary +/- secondary outcome analysis (n=17)								
Trial ID	**Dates**	**Sample size[a]**	**Unit of randomisation**	**Participants**	**Intervention period**	**Intervention/s (n)**	**Control (n)**	**Primary outcome/s**
Australia (Campbell et al 2013)[68]	2008/2010	Actual: 542 Eligible: 542	Cluster	First-time parent regularly attending first-time parent group Parent groups were eligible if >6 or 8 parents enrolled in areas of low socioeconomic position	Start: In the first 6 months End: Finishes by 24 months	6 x 2-h sessions delivered within pre-existing mothers' groups (3, 6, 9, 12, 15, 18 months) 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)[69]	2011/2020[b]	Actual: 514 Eligible: 514	Cluster	First-time parents with infants aged 3-4 months regularly attending a parents group in disadvantaged areas	Start: In the first 6 months End: Finishes by 36 months	6 x 1.5 h group-sessions (3, 6, 9, 12, 15, 18 months), then quarterly newsletters for additional 24 months 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 age 18 and 36 months
Australia (Daniels et al 2013)[70]	2008/2009	Actual: 698 Eligible: 698	Individual	First-time mothers of healthy term infants	Start: In the first 6 months End: Finishes by 24 months	2 education peer support modules (6 fortnightly sessions each) at age 4-7 and 13-16 months at community health venues Behaviours targeted: Food provision and parent feeding practices, Movement practices (346)	Usual care plus quarterly newsletter on general child health messages excluding sleep, food and activity (352)	Food intake, food preferences, and feeding behaviour
Australia (Wen et al 2012)[71]	2007/2010	Actual: 667 Eligible: 667	Individual	Women aged 16 or over, expecting their first child, between 24-34 weeks pregnancy	Start: During pregnancy End: Finishes by 24 months	8 home visits (antenatal, 1, 3, 5, 9, 12, 18, 24 months); 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 follow-up sessions plus three mail outs (330)	BMI at 2 years of age
Australia (Wen et al 2022)[72]	2017/2020	Actual: 1155 Eligible: 1155	Individual	Women aged 16 or over in their third trimester that can communicate in	Start: During pregnancy End: Finishes by 12 months	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,	Usual care comprising at least one nurse visit for general support at home and possible multiple home visits for	BMI, breastfeeding duration, and timing of introduction of solids

				English, Chinese or Arabic		10, 12–15, 15–18, 18–24 months) (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)	vulnerable families from the local health districts (385)	
Italy (Morandi et al 2019)[73]	2014/2017	Actual: 529 Eligible: 529	Cluster (paediatrician)	Healthy full-term newborns	Start: In the first 6 months End: Finishes by 24 months	Intensive education: At each well visit until child age 2 years, parents provided with oral and written information on obesity-protective behaviours for their children. Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (278)	Usual education about nutrition and lifestyle, during their child's first 2 years of life (251)	BMI at two years of age
Netherlands (Karssen et al 2021)[74]	2018/2019[b]	Actual: 357 Eligible: 270	Individual	Parents with an infant aged 7-11 months who have low or medium educational attainment	Start: In the first 12 months End: Finishes by 48 months	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)[75]	2009/2017	Actual: 802 Eligible: 802	Individual	Women aged over 16 before 34 weeks' gestation. Infants excluded if they are not full-term	Start: During pregnancy End: Finishes by 24 months	Arm 1 Food activity and breastfeeding (FAB): mix of 7 home visits and group based sessions promoting breastfeeding, healthy eating, physical activity (1 week, 3, 4, 7, 9, 12, 18 months) (214) Arm 2 (Sleep): 2 home visits (antenatal, 3 weeks) targeting prevention of sleep problems, as well as a sleep treatment program if requested (6–24 months) (209) Arm 3: FAB and sleep	Usual care: First 4 week midwife home visits; Well Child (Plunkett) nurse: 8 visits in 5 years (214)	Weight at 6, 12 and 24 months of age; BMI at 24 months of age

						Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices, Sleep health practices (210)		
New Zealand (Taylor et al 2017b)[76]	2012/2016	Actual: 206 Eligible: 206	Individual	Pregnant women aged 16 or over, before 34 weeks' gestation. Able to communicate in English or Te Reo Maori Infants excluded not full-term	Start: During pregnancy End: Finishes by 12 months	Baby-Led Introduction to Solids (BLISS): lactation consultant support (3 face-to-face, 2 telephone; 10-60 min each) up to age 6 months and 3 personalized face-to-face contacts (5.5, 7, 9 months) Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices (105)	Usual "Well Child" care, usually consists of 6-7 home or clinic visits (from 6 week to 2 years of age) from trained health professional (101)	BMI at 12 months
Norway (Helle et al 2019)[77]	2015/2021	Actual: 533 Eligible: 533	Individual	Parent and 5.5 month-old child	Start: In the first 6 months End: Finishes at 12 months	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 months (264)	Child eating behaviour, food intake, mealtime routines, maternal feeding practices
Norway (Øverby et al 2017)[78]	2012/2015	Actual: 110 Eligible: 110	Individual	Parents and 4-6 month-old infant attending selected public health clinics	Start: In the first 6 months End: At 6 months	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 (56)	Parents receive a booklet containing recipes for homemade foods for infants (54)	Food intake at 6, 15 and 24 months of age
Norway (Røed et al 2021)[79]	2015/2022	Actual: 298 Eligible: 237	Individual	Infants close to 12 months and one of their parents	Start: In the first 12 months End: Finishes by 24 months	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 Behaviours targeted: Food provision and parent feeding practices (148)	Usual care at the community child health centres (150)	Child diet quality and food variety, assessed at inclusion, 18, 24, and 48 months

Sweden (Döring et al 2016)[80]	2008/2015	Actual: 1369 Eligible: 1148	Cluster (child health care centres)	First-time mothers and their children recruited at child health care centres at 9-10 months of age	Start: In the first 12 months End: Finishes by 48 months	9 sessions: 1 group (11 months), 6 individual (8-9 months, 1, 1.5, 2, 3, 4 years), 2 individual telephone (2.5, 3.5 years) delivered by nurse focusing on healthy food habits and physical activity. Behaviours targeted: Food provision and parent feeding practices, Movement practices (601)	Usual care: regular age-related health checkups of Swedish child health services (768)	BMI and waist circumference of children at age 4 & their mothers
UK (Bryant et al 2021)[81]	2017/2019	Actual: 117 Eligible: 28	Cluster (Children's Centres)	Mothers, fathers or other carers and at least 1 child aged 6 months - 5 years	Start: In the first 6 months to 5 years End: Finishes by 18 months to 6 years depending on start age	8-week Health, Exercise, Nutrition for the Really Young (HENRY) 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 (47)	Wait list control (70)	Feasibility, child BMI z-score
USA (Messito et al 2020)[82]	2012/2020	Actual: 533 Eligible: 533	Individual	Latina mother with a singleton uncomplicated pregnancy fluent in English or Spanish	Start: During pregnancy End: Finishes by 36 months	Starting Early Program (StEP): 15 sessions: 2 individual (3rd trimester; postpartum), 13 group (1, 2, 4, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33 months), 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
USA (Paul et al 2018)[83]	2012/2023	Actual: 291 Eligible: 291	Individual	Full term singleton infants born to primiparous mothers	Start: In the first 6 months End: Finishes by 36 months	Responsive parenting: 4 home visits by research nurses (age 3, 16, 28, 40 weeks), annual research center visits until 3 years; 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 age 3 years
USA (Sanders et al 2021)[84]	2010/2014	Actual: 865 Eligible: 865	Cluster (trial sites)	Infant presenting for 2 mo well-child check-up, caregiver able to	Start: age 2 months End: 18 months	Greenlight toolkit- low literacy booklets that reviewed dietary, physical activity, sleep, and screen	Attention placebo- Injury prevention counselling according to The Injury	Percent of children with

				speak Spanish or English		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)	Prevention Program by the American Academy of Pediatrics (406)	overweight or obesity at 2 years
Other trials contributing to secondary outcomes only (n=14)								
Trial ID	**Dates**	**Sample size[a]**	**Unit of randomisation**	**Participants**	**Intervention period**	**Intervention/s (n)**	**Control (n)**	**Primary outcome/s**
Belarus (Kramer et al 2001)[85]	1996/1998	Actual: 17046 Eligible: 17046	Cluster (hospital and associated outpatient clinic)	Full-term singleton infants weighing at least 2500 g and their healthy mothers who intended to breastfeed	Start: At birth End: At 12 months of age	Breastfeeding promotion and support according to the WHOs Baby Friendly Hospital Initiative at hospital and follow up visits. Behaviours targeted: Infant feeding practices (8865)	Usual care (8181)	Breastfeeding (any and duration), gastrointestinal infection, respiratory tract infection and atopic eczema during the first 12 months of life
Brazil (Sangalli et al 2021)[86]	2008/2010	Actual: 715 Eligible: 715	Cluster (healthcare centre)	Pregnant women in their third trimester attending health centres predominantly serving low-income families	Start: During pregnancy End: Finishes by 24 months	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 (373)	Usual care (363)	Exclusive breastfeeding at 4 months
UK (Lakshman et al 2018)[87]	2011/2015	Actual: 669 Eligible: 669	Individual	Parents (mainly mothers) and their infants (aged 2 to 14 weeks) who are formula-fed	Start: In the first 6 months End: Finishes by 6 months	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 months 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.	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 age 12 months

						Behaviours targeted: Infant feeding practices (340)		
UK (McEachan et al 2016)[88]	2012/2012	Actual: 120 Eligible: 120	Individual	Pregnant women with overweight/obesity (BMI ≥25) at 10–12 weeks' gestation and infants from birth	Start: During pregnancy End: Finishes by 12 months	Healthy and Active Parenting Programme for early Years (HAPPY) aimed to promote breastfeeding, promote healthy eating and habits, and promote physical activity: delivered through 12 group sessions (6 antenatal, 6 postnatal). The intervention was developed to be culturally appropriate for key groups (White British and South Asian Origin women).Behaviours targeted: Infant feeding practices, Food provision and parent feeding practices, Movement practices (59)	Usual care (61)	Child weight
USA (de la Haye et al 2019a)[89]	2018/2022	Actual: 50 Eligible: 50	Individual	Mother-child dyads enrolled in home visitation programs; Mothers facing poverty, housing instability, lack of social and material support, lack of transportation and limited education and literacy Infants aged between birth to 24 months	Start: During pregnancy End: Finishes by 2 years	Home visitation program (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)[90]	2014/2015	Actual: 87 Eligible: 85	Individual	Pregnant women with overweight or obesity (body mass index ≥25), Medicaid insured, owned a smartphone	Start: During pregnancy End: Finishes by 12 months	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 Children's Hospital of Philadelphia Care Network (42)	Feasibility

USA (Linares et al 2019)[91]	2016/2018	Actual: 39 Eligible: 39	Individual	Immigrant hispanic pregnant women who intended to breastfeed and their infant	Start: During pregnancy End: At 6 months of age	Early Childhood Obesity Risk-Reduction Program in Hispanics (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 old
USA (Palacios et al 2018)[92]	2016/2016	Actual: 202 Eligible: 202	Block	Caregivers of healthy term infants 0-2 months participating in the WIC Program in Puerto Rico and Hawaii	Start: In the first 6 to 12 months End: Finishes by 6 to 12 months depending on start age	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
USA (Paul et al 2011)[93]	2006/2009	Actual: 160 Eligible: 160	Individual	Mother-newborn dyads, primiparous, singleton, gestational age ≥ 34 weeks	Start: In the first 6 to 12 months End: Finishes by 6 to 12 months depending on start age	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. 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)	Usual care (41)	Weight-for-length percentile at age 1 year

USA (Rybak et al 2023)[94]	2021/2022	Actual: 65 Eligible: 65	Individual	Mothers of singleton infants born > 2500 g, at 37- 42 weeks' gestation, English speaking, attending a primary care practice primarily serving minority groups and low-income populations	Start: At 1 month well-child visit End: At 6 month well-child visit, but final data collected at 9 months	A strengths-based responsive parenting intervention, Teaching Healthy Responsive parenting during Infancy to promote Vital growth and rEgulation (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 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)	A socioemotional development and positive parenting intervention matched for time, attention, and level of provider, but did not contain the specific active ingredients of the THRIVE intervention related to infant feeding, sleep, and regulation (32)	Feasibility (enrolment), acceptability (retention and adherence)
USA (Stough et al 2018)[95]	2018/2020[b]	Actual: 34 Eligible: 32	Individual	Parent and infant born > 38 weeks' gestation, above 10th percentile of length-for-weight, aged 2-3 months	Start: At 4 months of age End: At 9 months of age	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 age 3 & 9 months
USA (Thomson et al 2018)[96]	2013/2016	Actual: 82 Eligible: 54	Individual	Pregnant women at least 18 years of age, < 19 weeks pregnant and their infant from birth, residing in a rural region with high rates of infants with low birth weight, preterm infants, child poverty and childhood overweight/obesity	Start: During pregnancy End: At 12 months of age	Parents as Teachers Experimental arm will receive the enhanced nutrition and physical activity lessons and materials which will follow the 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	Parents as Teachers curriculum, home visits, optional group sessions (monthly), developmental screenings and resource network for families. To increase parental knowledge of child development, improve parenting, early detection of developmental delay, prevent abuse and	Maternal: gestational weight gain, weight retention, dietary intake, physical activity; Infant: dietary at 12 months of age

						feeding practices, Movement practices, Sleep health practices (24)	increase child reading (30)	
USA (Trak-Fellermeier et al 2019)[97]	2013/2015	Actual: 31 Eligible: 31	Individual	Women with overweight/obesity, singleton pregnancy <16 weeks' gestation and their infant from birth, residing in Puerto Rico	Start: During pregnancy End: 6 days post-birth	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)[98]	2013/2017	Actual: 430 Eligible: 429	Individual (stratified)	Primiparous and multiparous non-Hispanic Black mothers enrolled at 28 weeks' pregnancy; infants from birth to 15 months	Start: During pregnancy End: 15 months	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 practices, Movement practices, Sleep health practices (215)	Attention-control received maternal advice on injury prevention (214)	Infants' mean weight-for-length z-score at 15 months of age

BMI=body mass index, SMS=short message service, h=hours, min=minutes, WHO=World Health Organisation, WIC=Women, Infants and Children (a program that supports high-risk, low-income populations)

[a] Actual sample size represents the total number of participants randomised in the trial. Eligible sample size represents the total number of participants randomised in the trial that met eligibility criteria for TOPCHILD, e.g. UK (Bryant et al 2021) randomised 117 children aged 6 months to 5 years. Of these, 28 participants were randomised before age 12 months and thus were eligible for TOPCHILD.

[b] Main results unpublished at time of analysis

Allocation ratio was 1:1 for all trials

Table 2. Primary and key 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 τ^2 (95% PI)	GRADE
Primary outcome								
BMI z-score at age 24 ±6 months	17	6505	0.71 (1.08)	0.72 (1.05)	z-score	Mean difference -0.01 (-0.08, 0.05)	0.01 (-0.17, 0.14)	High
Key secondary outcomes								
Duration of exclusive breastfeeding assessed at 6 ±2 months	5	1653	12.22 (9.32) Median (95% CI)[c] 13 (10, 13)	10.69 (8.86) Median (95% CI)[c] 12 (8.69, 13)	weeks	Hazard ratio 0.86 (0.74, 1.00)	0.01 (0.65, 1.14)	Moderate
Vegetable intake per day at age 24 ±6 months	12	4616	117.18 (90.06)	107.48 (84.09)	grams	Mean difference 3.11 (-0.64, 6.85)	0.00 (-0.64, 6.85)	Moderate
Screen time per day at age 24 ±6 months	9	3650	59.58 (69.98)	72.36 (69.98)	minutes	Mean difference -9.60 (-13.72, -5.47)	0.00 (-13.72, -5.47)	Moderate
Physical activity per day at age 24 ±6 months	1	314	252.59 (137.46)	276.60 (150.13)	minutes	Mean difference -24.14 (-57.17, 8.90)	NA	Very low
Combined sleep duration per night and day at age 24 ±6 months	10	3839	12.68 (1.53)	12.69 (1.57)	hours	Mean difference 0.06 (-0.02, 0.15)	0.002 (-0.06, 0.18)	Moderate
Parent feeding practices: Control (Restriction) score ≥3 at age 24 ±6 months	2	545	81/269 (30%)	91/276 (33%)	domain score ≥3 events[d]	Risk Ratio 0.90 (0.72, 1.13)	0.00 (0.72, 1.13)	Low

SD=standard deviation, CI=confidence interval, τ^2 =tau-squared (i.e. the estimated variance of true effect sizes across studies in a random-effects meta-analysis), PI=prediction interval (i.e. the range within which the treatment effect in a future trial from a similar population is expected to fall), GRADE= Grading of Recommendations Assessment, Development, and Evaluation, BMI=body mass index, IQR=interquartile range, NA=Not applicable

[a] Means are crude estimates not adjusting for clustering by trial or centre

[b] For multi-arm trials, the "approximate adjustment" method was used to avoid unit-of-analysis errors that can be introduced when using the same control group for two different comparisons [99]

[c] Survival analysis performed for this outcome, thus survival median with 95% CI is reported

[d] Event defined as "Regular use" of feeding practice, i.e. domain score ≥3[100]

Note values are rounded to 2 decimal places

Table 3. Subgroup analyses by individual-level characteristics for the primary outcome of BMI z-score at age 24±6 months

Continuous individual-level factors				
Covariate	**Number of studies**	**Number of participants**	**Unit of measurement**	**Pooled interaction effect (95% CI)**
Birthweight	16	6222	100 grams	0.01 (0.00, 0.02)
Gestational age at birth	7	3751	weeks	0.02 (-0.01, 0.06)
Maternal / birthing parent weight status	15	6048	kg/m^2	-0.00 (-0.02, 0.01)
Weighted standardised household income*	6	2301	0 = earning median >0 = earning more than median <0 = earning less than median	0.14 (-0.07, 0.36)
Categorical individual-level subgroups				
Covariate	**Number of studies**	**Number of participants**	**Floating subgroup-specific intervention effect (95% CI)**	**Pooled interaction effect (95% CI)**
Any formal childcare attendance at 0-12 months	4	1335		
No	4	1156	-0.05 (-0.20, 0.09)	(reference)
Yes	4	179	0.08 (-0.48, 0.64)	0.14 (-0.48, 0.75)
Any formal childcare attendance at 12-24 months	4	1025		
No	4	266	-0.02 (-0.37, 0.34)	(reference)
Yes	4	759	-0.08 (-0.24, 0.07)	-0.07 (-0.43, 0.29)
Partner status	13	4714		
In a partnership (married, de facto, living with partner)	13	4418	-0.01 (-0.08, 0.07)	(reference)
Single (single, divorced, widowed)	12	296	-0.20 (-0.48, 0.07)	-0.19 (-0.48, 0.09)
Parity/first-time parent	12	5335		
First-time parent	12	4225	-0.05 (-0.13, 0.03)	(reference)
Already has at least 1 other child	8	1110	0.06 (-0.10, 0.22)	0.11 (-0.07, 0.29)
Parent/carer immigration status	7	3636		
Primary parent/carer born in trial country	7	2512	0.01 (-0.11, 0.13)	(reference)
Primary parent/carer born outside trial country	7	1124	-0.02 (-0.21, 0.18)	-0.03 (-0.30, 0.25)
Infant sex	17	6505		
Male	17	3287	0.01 (-0.07, 0.10)	(reference)
Female	17	3218	-0.04 (-0.12, 0.04)	-0.05 (-0.16, 0.05)
Ambiguous/other	0	0	-	-
Carer education	12	4848		
Low education	9	414	0.09 (-0.26, 0.44)	0.11 (-0.24, 0.46)
High school graduate	12	994	0.02 (-0.12, 0.16)	0.03 (-0.13, 0.20)
Non-university tertiary education or incomplete university	10	776	-0.04 (-0.18, 0.11)	-0.02 (-0.19, 0.16)
University graduate or postgraduate	12	2664	-0.02 (-0.10, 0.06)	(reference)
Carer employment	15	5598		
Any employment (including paid leave)	15	2738	0.03 (-0.07, 0.12)	(reference)
Unemployed (includes retired, student without employment, unpaid leave, home duties, charity work)	15	2860	-0.04 (-0.13, 0.06)	-0.06 (-0.19, 0.06)

BMI=body mass index, CI=confidence interval, kg=kilograms, m^2=metres squared.
For continuous subgroups, the pooled interaction effect is the difference in intervention effect after a one unit increase in the covariate, assuming a linear relationship between the intervention and BMI z-score across all levels of the covariate (e.g. the intervention increases BMI z-score by 0.01 for every 100-gram increase in birthweight). For categorical subgroups, the pooled interaction is the difference in intervention effect between the comparator and reference subgroup (e.g. the intervention reduces BMI z-score by 0.19 for those without a partner compared to those who do have a partner.) A result is statistically significant if the 95% confidence interval of the pooled interaction effect does not include zero. Floating subgroup-specific intervention effects can be interpreted as the intervention effect that is specific to their respective subgroup (e.g. the intervention reduces BMI z-score by 0.01 and 0.20 for those with and without a partner respectively. Note: if the pooled interaction effect is not significant, the subgroup-specific intervention effects are not interpreted as *statistically different*.

* For each participant, weighted standardised household income was calculated as follows:

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

Table 4. Subgroup analyses of trial-level characteristics for the primary outcome of BMI z-score at age 24±6 months

Categorical trial-level characteristics				
Covariate	**Number of studies**	**Number of participants**	**Test of subgroup differences χ^2**	**P value**
Setting - home - community - combination	17	6505	0.57	0.75
Face to face delivery - yes - no	17	6505	0.96	0.33
Intervention mode - Individual - Group - Both	17	6505	3.47	0.18
Intervention onset - antenatal - postnatal	17	6505	0.32	0.57
Continuous trial-level characteristics				
Covariate	**Number of studies**	**Number of participants**	**Unit of measurement**	**Meta-regression slope estimate (95% CI)**
Intervention duration	15	6263	hours	-0.010 (-0.023, 0.004)
Development of country	17	6505	Human development index	-0.70 (-6.43, 5.04)
Intervention end	15	6239	months	0.0005 (-0.0056, 0.0066)

BMI=body mass index, CI=confidence interval

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