INPLASY

Parent-only versus parent–child behavioral treatment for pediatric obesity: a protocol for a redesigned update and meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - No support.

Review Stage at time of this submission - An earlier, broader version of the review had undergone literature searching, study screening, data extraction, risk-of-bias assessment, and preliminary statistical synthesis before the present registration. Following an independent methodological audit, substantial conceptual and data-handling issues were identified, including heterogeneity in intervention comparability, ambiguity between direct child-attendance effects and broader treatment-package effects, and inconsistencies in trial-level population and outcome handling. The review has therefore been substantially redesigned. At the time of this registration, the formal V2 eligibility reassessment, re-screening, data re-extraction, revised risk-of-bias assessment, and V2 statistical synthesis have not yet been undertaken.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202680112

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 August 2026 and was last updated on 31 August 2026.

INTRODUCTION

Review question / Objective Primary objective: Among children and adolescents with overweight or obesity receiving behavioral weight-management treatment, does direct child participation provide additional benefit for child weight outcomes compared with parent-only treatment when intervention arms are otherwise sufficiently comparable in treatment content, dose, duration, and delivery structure?

Secondary objective: To compare broader parent-only and parent–child behavioral weight-management treatment packages when intervention content, dose, duration, provider, booster support, or delivery structure are not fully matched.

Additional objectives are to compare treatment engagement and outcome-assessment retention and to summarize relevant behavioral outcomes, including physical activity and dietary or energy-intake outcomes, when sufficiently comparable data are available.

Rationale Parents are central agents of behavior change in pediatric obesity treatment, but family involvement can be delivered through different treatment configurations. Some randomized trials compare parent-only and parent–child interventions that are closely matched apart from

direct child attendance, whereas other trials simultaneously differ in treatment intensity, content, duration, provider, booster support, or delivery structure. Pooling these intervention architectures without distinction may obscure two different clinical questions: whether direct child attendance itself adds benefit, and whether broader parent-only treatment packages differ from parent–child packages in real-world practice. An independent methodological audit of an earlier review identified this distinction as a major source of conceptual and analytical heterogeneity. This redesigned protocol therefore prespecifies separate synthesis of attendance-isolated or closely matched comparisons and broader treatment-package comparisons.

Condition being studied Pediatric overweight and obesity. Childhood obesity is a chronic, multifactorial condition associated with adverse cardiometabolic, musculoskeletal, and psychosocial outcomes. Behavioral weight-management treatment commonly involves parents or caregivers, but the optimal degree of direct child participation remains uncertain.

METHODS

Search strategy The following databases will be searched from inception to the final V2 search date: MEDLINE via PubMed, Embase via embase.com, the Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Library, PsycINFO via ProQuest, and CINAHL via EBSCOhost. ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) will be searched for completed, ongoing, or unpublished potentially eligible randomized trials. Reference lists of included reports and relevant systematic reviews will be checked, and forward citation searching of included primary trial reports will be performed where feasible.

Search concepts will combine controlled vocabulary and free-text terms for pediatric overweight/obesity, children/adolescents, parents/caregivers/family-based interventions, and randomized trials. The V2 searches will retain the previously developed high-sensitivity search structure, with syntax adapted to each database. No language restrictions will be applied. Search strategies will be validated against a prespecified set of known eligible randomized trials indexed in the respective databases. Following protocol registration, all database searches will be rerun and the final search date documented.

Participant or population Children and adolescents younger than 18 years with overweight or obesity, as defined by the original trial investigators using recognized age- and sex-specific anthropometric criteria. Studies restricted to obesity secondary to conditions that substantially alter growth, appetite regulation, body composition, or weight trajectory will be excluded when the treatment question is not comparable with general pediatric obesity treatment.

Intervention A parent-only or caregiver-only behavioral weight-management intervention in which the parent or caregiver is the principal direct participant in the core treatment program. Eligible components may include dietary behavior change, physical activity, parenting practices, behavioral modification, self-monitoring, goal setting, and modification of the family environment. Children may undergo measurement, research assessments, routine clinical care, or activities unrelated to the core behavioral weight-management intervention; such contact alone will not disqualify the study.

Comparator A parent–child or family-based behavioral weight-management intervention in which the child directly participates in the active core treatment. Intervention comparability will not be required for review-level eligibility; instead, eligible comparisons will be classified prospectively according to treatment content, dose, duration, delivery/provider, child component, and additional support.

Study designs to be included Randomized controlled trials, including individually randomized and eligible cluster-randomized trials. Multi-arm randomized trials will contribute only relevant eligible comparisons, with appropriate handling to avoid double-counting shared comparator groups.

Eligibility criteria Inclusion criteria: randomized controlled trials enrolling participants younger than 18 years with overweight or obesity; at least one eligible parent-only/caregiver-only behavioral weight-management arm; at least one comparator involving direct child participation in active behavioral weight-management treatment; and at least one prespecified child weight-status, engagement/retention, or relevant behavioral outcome.

Exclusion criteria: prevention-only studies; non-randomized studies; child-only interventions without an eligible parent-only arm; studies without an eligible direct-child-participation comparator; adult-only populations; studies restricted to

secondary/syndromic obesity when not clinically comparable with general pediatric obesity treatment; and reports that contain no usable information beyond another report of the same trial. Protocols, follow-up reports, and secondary analyses will be linked within trial families and used to supplement primary trial reports rather than counted as independent trials.

Information sources MEDLINE/PubMed, Embase, CENTRAL, PsycINFO, CINAHL, ClinicalTrials.gov, WHO ICTRP, reference-list checking, forward citation searching, trial protocols and registrations, supplementary materials, and additional reports belonging to the same randomized trial family. Study authors may be contacted when essential eligibility or numerical data remain unclear after all available trial-family sources are reviewed.

Main outcome(s) Primary outcome: child BMI z-score/BMI-SDS. Outcomes will be analyzed at prespecified clinically meaningful time points: treatment end, short/intermediate follow-up when available, and longest eligible follow-up. For outcomes measured on a common scale, mean differences with 95% confidence intervals will be preferred. Treatment-end and follow-up outcomes will not be pooled across fundamentally different time points. The primary quantitative synthesis will focus on attendance-isolated/closely matched randomized comparisons.

Additional outcome(s) Other weight-related outcomes may include BMI, body weight, percentage overweight, waist circumference, and body-composition measures. Engagement outcomes will be treated as distinct constructs: treatment initiation, intervention adherence, intervention completion, and outcome-assessment retention. Treatment completion and outcome-assessment retention will not be treated as interchangeable. Physical activity, dietary behavior, and energy-intake outcomes will be synthesized quantitatively only when constructs, instruments, scoring directions, and assessment times are sufficiently comparable; otherwise they will be summarized narratively. Adverse events will be summarized when reported.

Data management Records will be managed in a structured review database and trial-level master dataset. The unit of evidence will be the randomized trial rather than the publication. Each trial will receive a unique trial_id, and each associated publication will receive a report_id. Multiple reports from the same randomized cohort will be linked as a trial family. Data will be stored in separate trial-level, intervention-comparability, outcome-level, engagement, risk-of-bias, and discrepancy-log tables. One reviewer will enter data into the master dataset and a second reviewer will independently verify all randomized denominators, numerical outcome data, intervention characteristics, and trial-family links against the original source reports. Material discrepancies will be resolved by discussion and documented.

Quality assessment / Risk of bias analysis Risk of bias will be assessed using Cochrane RoB 2 for randomized trials and will be result-specific, with primary emphasis on the BMI z-score/BMI-SDS result contributing to the primary synthesis. The five RoB 2 domains will be assessed and an overall judgment of low risk, some concerns, or high risk will be assigned. Two reviewers will independently assess the primary result, with disagreements resolved by consensus and, if necessary, adjudication by a third reviewer. Supporting quotations and source locations will be retained in a master RoB dataset that will serve as the single source for manuscript text, figures, sensitivity analyses, and GRADE judgments.

Strategy of data synthesis Eligible comparisons will first be classified using a prespecified six-domain intervention-comparability framework covering core treatment content, planned dose, treatment duration, delivery/provider, child component, and additional support. Tier 1 (attendance-isolated/closely matched) comparisons will form the primary evidence set. Tier 2 (package-level) comparisons will contribute to a broader secondary synthesis. Tier 3 (borderline/indirect) comparisons will not enter the primary synthesis and will be considered for broader synthesis only according to prespecified comparability rules, not observed effect size.

Random-effects meta-analysis will be the primary quantitative model. Mean difference will be used for continuous outcomes measured on the same scale; standardized mean difference may be used when conceptually comparable outcomes are measured using different instruments. Risk ratios will be used for appropriate binary outcomes. Statistical heterogeneity will be described using I-squared and tau-squared where applicable, interpreted together with clinical and methodological heterogeneity. Prediction intervals will be considered when the number of studies permits meaningful interpretation. Multi-arm trials will be handled to avoid double counting. Missing standard deviations may be derived from standard errors, confidence intervals, test statistics, or P values using standard methods and will be

explicitly labelled as derived. A non-significant between-group difference will not be interpreted as formal equivalence unless a defensible equivalence/noninferiority margin has been prespecified and appropriately analyzed.

Subgroup analysis Subgroup analyses will be limited and clinically motivated because the expected number of randomized trials is small. Potential subgroup factors include preschool versus school-aged populations, treatment intensity, treatment duration, and intervention comparability. Exploratory meta-regression will generally be avoided unless the final evidence base is unexpectedly large enough to support reliable estimation.

Sensitivity analysis Prespecified sensitivity analyses will include: (1) attendance-isolated/closely matched comparisons versus the broader eligible evidence set; (2) exclusion of results judged at high risk of bias; (3) random-effects versus fixed-effect models where appropriate; and (4) alternative reasonable data-selection decisions, such as endpoint versus change data, alternative eligible follow-up time points, or directly reported versus derived variance estimates. Sensitivity analyses will not be selected on the basis of statistical significance.

Language restriction No language restrictions will be applied.

Country(ies) involved China.

Other relevant information This registration concerns a substantially redesigned V2 review. The investigators had access to the included studies and to results from an earlier broader synthesis before development of the revised protocol. The redesign was initiated following an independent methodological audit that identified substantial variation in intervention comparability, inconsistencies in trial-level data handling, and ambiguity in the interpretation of parent-only versus parent–child treatment contrasts. The revised eligibility assessment, re-screening, data re-extraction, risk-of-bias assessment, and statistical synthesis will be conducted according to the prespecified V2 protocol. The present registration should therefore be interpreted as prospective specification of the redesigned V2 procedures before formal V2 re-screening, re-extraction, and re-analysis, rather than as evidence that the investigators were unaware of the previous evidence base or synthesis results.

Protocol amendments after registration will be documented with date, original specification, revised specification, rationale, and whether relevant outcome results were known at the time of amendment. Anticipated completion of the V2 review: January 2027. Ethics approval is not required because this systematic review and meta-analysis will use data from previously published studies and will not involve collection of individual-level participant data.

Keywords pediatric obesity; childhood obesity; parent-only treatment; parent–child treatment; family-based treatment; behavioral weight management; child attendance; randomized controlled trial; systematic review; meta-analysis.

Dissemination plans The completed systematic review and meta-analysis will be submitted to a peer-reviewed journal in pediatric obesity, obesity treatment, behavioral medicine, or public health. The protocol registration number and DOI will be cited in the final manuscript. Results may also be presented at relevant academic meetings. Where feasible, de-identified trial-level extraction data, analysis code, and supporting review materials will be deposited in an open research repository.

Contributions of each author

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