Title	A scoping review of outcomes commonly reported in obesity prevention interventions aiming to improve obesity-related health behaviors in children to age 5 years
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A scoping review of outcomes commonly reported in obesity prevention interventions aiming to improve obesity-related health behaviours in children to age five years

Abbreviations

COS	Core Outcome Sets
COS-EPOCH	Core Outcome Sets for Early Prevention of Obesity in Childhood
ECEC	Early childhood education and care
BMI	Body mass index
RCT	Randomised controlled trial
COMET	Core Outcome Measures in Effectiveness Trials
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR	PRISMA for scoping reviews
WHO ICTRP	World Health Organisation International Clinical Trials Registry Platform
ICMJE	International Committee of Medical Journal Editors
ANZCTR	Australian New Zealand Clinical Trials Registry
EU CTR	EU Clinical Trials Register
BCTs	Behaviour change techniques

Abstract

Objective: This scoping review was undertaken as the first stage of development of the Core Outcome Sets for Early Prevention of Obesity in CHildhood (COS-EPOCH). The aim of this review is to identify the outcomes from randomised controlled trials of obesity prevention interventions aiming to improve obesity-related health behaviours in children to age five years.

Design: Systematic scoping review

Data sources: Search of trial registries and Medline, by two reviewers. Data were extracted using a standardised form. Outcomes were assigned to domains, with similar definitions merged.

Eligibility criteria: Randomised trials aiming to prevent childhood obesity to age five years.

Results: Eighteen outcome domains were identified from 161 included studies: 'anthropometry', 'dietary intake', 'physical activity', 'sedentary behaviour', 'emotional functioning/wellbeing', 'feeding', 'cognitive/executive functioning', 'sleep', 'study-related', 'parenting practices', 'motor skill development', 'environmental', 'blood and lymphatic system', 'perceptions and preferences', 'quality of life', 'economic', 'oral health', 'other'. The most frequently reported outcome domain was anthropometry (92% of studies), followed by dietary intake (77%) and physical activity (60%). 221 unique outcomes were identified, indicating a high degree of heterogeneity. Body mass index was the only outcome reported in >50% of studies.

Conclusions: The considerable heterogeneity in outcomes supports the need for the development of COS-EPOCH.

1. Background

Childhood obesity is a significant global concern, and urgent action is required to address this issue in children worldwide.[1] It has been estimated that 38 million children under five years of age were affected by overweight or obesity in 2019.[2] Obesity in childhood can affect a child's immediate health, quality of life and human capital.[3-7] Obesity in childhood also tracks into adulthood [8], where excess body weight is a significant risk factor for chronic diseases such as stroke, type 2 diabetes and some cancers.[9]

Given the prevalence of early childhood overweight and obesity, there has been significant growth in designing, implementing and evaluating interventions for obesity prevention in children aged up to five years.[10] Early childhood obesity prevention interventions aiming to improve obesity-related health behaviours commonly target one or more lifestyle-related behaviours, including poor nutrition, inadequate levels of physical activity and sleep, and sedentariness. Such interventions have been conducted across a multitude of settings, including in the community, home, healthcare and early childhood education and care (ECEC) settings.[11] Potential outcomes from early childhood obesity preventions (for example, changes in body mass index (BMI), or fruit or vegetable consumption) are commonly collected and reported using a variety of outcome measurement instruments. Outcomes may differ across ages of the child, for instance tummy time may be considered a relevant outcome in infants whereas time spent engaging in active transport may be relevant to toddlers and pre-schoolers.

A number of systematic reviews have been published that aimed to bring together evidence on the effectiveness of preventive interventions for obesity and/or obesity-related behaviours in children up to five years of age.[11-17] However, evidence synthesis in reviews is currently limited by heterogeneity in outcome reporting, definition and measurement across interventions targeting this broad range of behaviours across multiple settings.[14, 18, 19] This heterogeneity may be reflective of the variation in foci, scope, purpose and setting of early childhood obesity prevention interventions, and the tensions

that trialists face in terms of the depth and breadth of outcome measurement and study feasibility and statistical power. This heterogeneity can however lead to reduced power and research waste, if, for example, only half of eligible trials collect an outcome of interest and can be synthesised. In addition, systematic reviews do not typically include the entirety of outcomes reported in trials.[20]

Core Outcome Sets (COS) are an agreed set of outcomes that should be measured and reported, as a minimum, in all clinical trials within a specific area of health.[21] The core set of minimum outcomes can then be supplemented with the collection and reporting of additional outcomes that may be particularly relevant to the scope and foci of specific studies. The development and application of COS for a specific clinical area reduces issues of inconsistent and biased outcome reporting and research waste. [22, 23] COS development can improve comparability across trials, thereby increasing the relevance of results for systematic reviews and meta-analyses, and reduce selective outcome reporting.[24] COS are also useful in the design of systematic reviews and meta-analyses themselves, allowing systematic reviewers to consider outcomes that are recommended within a COS that has been developed using a rigorous process when establishing the focus of their review.[25] COS development typically involves multiple steps, the first of which is a systematic or scoping review to identify outcomes currently used in randomised controlled trials (RCTs) to inform the COS development process.[22]

In 2018 a systematic review was published, summarising the outcomes reported in feeding interventions in infants aged up to 1 year.[19] This review informed the development of a COS for trials of infant-feeding interventions to prevent childhood obesity.[26] To date, no published review has systematically considered the broader range of outcomes measured and reported in early childhood obesity prevention intervention trials, or the frequency by which outcomes are measured and reported. This scoping review was undertaken as the first stage of development of a suite of COS for early childhood obesity prevention intervention RCTs [27] that will build on the published COS for trials

of early feeding interventions[26], and aims to summarise the outcomes of interest in RCTs aiming to prevent obesity in the first five years of life.

2. Methods

2.1 Protocol and registration

Systematic scoping review methodology was selected as it has been recognised as useful in identifying and mapping the available evidence and reporting on the way research has been conducted.[28] Scoping reviews are recognised by the Core Outcome Measures in Effectiveness Trials (COMET) Handbook [22] as a validated method for identifying existing knowledge about outcomes in the COS development process.

The scoping review protocol was prospectively registered on the Open Science framework (www.osf.io/snv5e), and with the COMET Initiative (registration number 1679, http://www.comet-initiative.org/Studies/Details/1679). Guidelines for conducting a scoping review were followed [29], along with guidelines for reporting scoping reviews (PRISMA-ScR)[30] (Table S1). Institutional Review Board approval was not required.

2.2 Information sources and search strategy

Given the scope and resources required to review a very large body of literature, a systematic search of publicly available clinical trial registries (clinicaltrials.gov and via the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP; populated by 18 trial registries worldwide that meet the requirements of the International Committee of Medical Journal Editors (ICMJE))) was undertaken, using a pre-defined search strategy (Table 1). These resources were selected due to their comprehensiveness, with the WHO Registry Network incorporating a number of high quality primary and partner registries (including the Australian New Zealand Clinical Trials Registry (ANZCTR) and the EU Clinical Trials Register (EU-CTR)). Searches were run in June 2020, and updated in February 2021.

Identified records were exported into Microsoft Excel and screened for inclusion by two reviewers independently (VB, MS), with disagreements handled through discussion until consensus was reached.

Table 1 – Clinical trial registry search strategy

We also cross-referenced our search of clinical trial registries with the recently published Cochrane review including obesity prevention interventions RCTs in children aged under five years.[11] Any studies identified in the Cochrane review that met our inclusion criteria but had not already been identified through our clinical trial registry search, were also included. In addition, the Cochrane review search strategy [11] was updated to November 2020 and re-run in Ovid Medline (Table S2). Identified hits were imported into Covidence and screened independently for inclusion by two reviewers (VB, MS), with disagreements handled through discussion until consensus was reached.

2.3 Inclusion and exclusion criteria

The inclusion criteria for registered studies were:

- Any type of randomised trials conducted in any country;
- Trials in any stage of research, except withdrawn (e.g. recruiting, active, complete);
- Trials that aimed to prevent childhood overweight and obesity. This could be stated as a primary or secondary aim, or specified as condition/disease: overweight or obesity; or include anthropometry as a primary or secondary outcome measure.
- Interventions starting in the first five years of childhood (i.e. from birth to age five years inclusive), or antenatally. If interventions started antenatally they must continue for at least six months postpartum;
- Implementation of an intervention that includes a component related to lifestyle (e.g. diet, parent/caregiver practices, physical activity, sedentary behaviour, sleep). Lifestyle

interventions are defined as interventions that promote change in lifestyle behaviours for the prevention of unhealthy weight gain [31];

- Any length of follow up time.

The exclusion criteria for registered studies included:

- Non-randomised trials;
- Targeted or treatment interventions for those experiencing overweight or obesity (i.e. participant inclusion criteria above healthy weight for either parent or child; identify as treatment trial type in register; targeted to participants with specific body weight or body mass index (BMI) percentile inclusion criteria that includes above healthy weight);
- Interventions in an admitted patient hospital setting or involving pre-term infants;
- Interventions in primary school or after-school settings. While there are differing terminologies worldwide for both early childhood and primary-school institutional settings, interventions in schooling institutions where children have generally reached the age of 5+ years were excluded (for example, primary school, elementary school, after school care settings at these institutions). These studies were omitted as a separate COS is currently being developed for obesity prevention interventions delivered in the school setting;
- Intervention content only at the environmental level or intervention content delivered only to individuals within organisations (e.g. healthcare professionals, childcare providers, with no parent/caregiver/child-directed content);
- Secondary prevention interventions, defined as primarily focused on conditions other than overweight/obesity or obesity-related behaviours.

2.4 Data extraction

COMET recommendations [22] were followed to develop a data extraction tool in Microsoft Excel. The tool was trialled on the first four included studies by two independent reviewers (VB, MS), and

compared. Upon finalisation of the tool, outcomes were extracted verbatim from the source by two independent reviewers (VB, MS), to maintain transparency.[22] Data extracted included trial registration number, public or scientific study title, study acronym, study start date, study completion date, recruitment status, study aim and/or hypothesis, RCT study type, recruitment country, setting, intervention summary, comparator summary, participant inclusion criteria, sample size, participant age, primary and secondary outcomes reported, outcome measurement instruments, outcome definitions, timepoints of assessment, links to publications, primary study contact and sponsor information. Where trial registration records provided links to publications, protocol and main result publications were located and further searched for more detailed data to populate the data extraction tool. Where links to relevant publications were not supplied, we searched for peer-reviewed academic publications using keyword searches related to the trial name and lead author in the GoogleScholar database. Any additional data from linked or unlinked publications were also extracted verbatim by two independent reviewers, to maintain transparency.[22]

2.5 Data analysis

Studies were categorised by the behaviour that they focused on (i.e. physical activity, nutrition/feeding, sedentary behaviour, sleep or multiple behaviours) and the number of intervention arms. To the best of our knowledge, a comprehensive and validated taxonomy of outcomes fit for our specific purpose has not been developed in the literature.[27] A deductive iterative approach involved initial categorisation and sorting to provide essential structure to the conceptualisation of outcome domains and outcomes [22], and iterative feedback. Outcomes were initially organised into outcome domains based on key literature conceptualising outcomes [33-37] by one reviewer (VB). Outcomes with similar definitions or themes within each domain were then merged by one reviewer (VB). All results were refined through a consensus process with members of the steering group, made up of academics with expertise in each outcome domain and one researcher with expertise in developing COS.[19] Steering group members were asked to review and comment on outcome domain

and outcome mergers and definitions. This process was repeated until final consensus on outcome domains and outcomes was reached from all members of the steering group, based on 100% agreement with outcome domain and outcome definitions. Given a COS for outcomes collected and reported in trials of infant-feeding interventions has already been published [26] we did not seek to further classify dietary intake and feeding-related outcomes in included studies in infants aged ≤1 year in our study as this work has been reported elsewhere.[19]

Outcome frequencies were estimated using descriptive statistics, and presented in outcome matrices stratified by age (i.e. interventions in children aged ≤1 year; and, >1 to 5 years) and behaviours targeted (i.e. physical activity, nutrition/feeding, sedentary behaviour, sleep or multiple behaviours). Outcome matrices visually display the outcomes reported in eligible studies, allowing for the visual representation of the frequency, consistency, and disparity of outcome reporting across studies.[19, 22, 38]

The quality of included studies with respect to their measurement properties was not assessed, in accordance with some of the most recently published research on COS development.[39, 40] This decision was made due to the lack of well-validated quality assessment tools designed to assess measurement properties of included studies [27], and the fact that descriptors of reporting quality are not considered integral components of the review stage for COS development.[39]

3. Results

3.1 Study characteristics

From 6,342 trial registry records, 6,203 were excluded, leaving 139 included studies from trial registry searches. Fifteen studies were identified from either linked studies or the Cochrane review by Brown et al.[11] Updating the search by Brown et al.[11] identified a further seven studies.[41-47] A total of 161 studies met the inclusion criteria and were included in our scoping review (Figure 1; Table S3).

Figure 1 – PRISMA diagram of study selection

Studies were undertaken across a wide range of countries, with the most studies being conducted in the United States of America (n=72, 45%), followed by Australia (n=19, 12%) and Canada (n=10, 6%). Studies were undertaken in high-income countries (n=152, 94.4%), middle-income countries (n=8, 5%), and both high and middle-income countries (n=1, 0.6%); there were no studies conducted in low-income countries. Studies targeted multiple behaviours (n=100, 62%), physical activity only (n=40, 25%), nutrition or feeding only (n=14, 9%) or sedentary behaviour only (n=7, 4%). No included studies targeted sleep only. Interventions were conducted in a wide range of settings, including home, community, ECEC, primary care and maternal child health care settings (Table S3). Intervention content was delivered by a wide range of people in varying roles, including educators, healthcare professionals (e.g. community health nurses, dentists, pediatricians), ECEC staff, research staff, community members (e.g. parent or carers, peer mentors) and via technology (e.g. web-based applications, telephones). Intervention durations ranged from brief (e.g., an educational program delivered on a tablet in a primary care setting [48]) to a four-phase intervention with time-sensitive goals, spanning from pre-conception to child age 5 years [49] (Table S3).

3.2 Outcome domains

Eighteen outcome domains were identified across the 161 included studies. (Table 2). Outcome domains were further categorised into 221 outcomes (Table S4).

Table 2 – Outcome domains

The most frequently reported outcome domain was anthropometry (n=148, 92%; Figure 2), although this may be expected given the study inclusion criteria of interventions aimed at preventing childhood overweight and obesity. Thirteen studies (8%) did not include an anthropometric outcome despite identifying as obesity prevention interventions; these studies instead collected data on intermediate

outcomes (e.g. diet, physical activity) or study-related measures such as acceptability or feasibility. Dietary intake was the second most frequently reported outcome (n=124, 77%), followed by physical activity (n=96, 60%) (Figure 2). All studies reported at least one outcome from within the four most frequently reported outcome domains. The least frequently reported outcome domain was oral health, with only 6 studies (4%, Figure 2) reporting outcomes from this domain. The average number of outcome domains reported in included studies was five (range 1 to 12, median= 5, IQR=3; Table S5.1). The Healthy Life Trajectory Initiative (HeLTI-Canada)[49] study reported the highest number of outcome domains (n=12, Table S5.1). Supplementary Files S5.1 to S5.3 present the frequency of outcome domain reporting in all included studies, and stratified by the behaviours the intervention focused on and participant age at intervention commencement.

Figure 2 – Frequency of outcome domains reported in included studies (n=161)

3.3 Outcomes

Frequencies of outcomes within each outcome domain are presented in Supplementary Files S6.1-S6.18. Most frequently reported outcomes included BMI (n=126, 78%; Table S6.1), physical activity (n=68, 42%; Table S6.3), screen time (n=61, 38%; Table 6.5) and parent/caregiver self-efficacy (n=46, 29%; Table S6.4). Seven per cent of included studies reported all four of these outcomes together (n=11). Fruit and vegetable intake and beverages intake were reported in 26% and 24% of all included studies respectively (Table S6.2). Body composition was reported in 20% of all included studies (Table S6.1) and sleep duration was reported in 19% of all included studies (Table 6.8).

The relatively high proportion (46%) of studies collecting emotional functioning/wellbeing outcomes was driven by over a quarter (29%) of all included studies collecting outcomes relating to parent/caregiver self-efficacy for promoting healthy behaviours (Table S6.4). Collection of outcomes relating to both parent/caregiver knowledge of and attitude towards healthy behaviours was also relatively common (18% and 10% respectively, Table S6.7). Only 14 studies (9%) reported health-

related quality of life outcomes, with only ten of these reporting outcomes related to health-related quality of life in child participants. A large proportion (83%) of the identified outcomes were reported by less than 5% of all 161 included studies (Tables S6.1-S6.18).

Discussion

Review findings suggest considerable heterogeneity in the reporting of outcomes in early childhood obesity prevention interventions. No studies reported outcomes in all 18 outcome domains, although it could be argued this would be unlikely within each individual study due to the diversity of outcome domains identified in this review. Anthropometric, dietary intake and physical activity outcome domains were reported in more than half of the studies included in our review. Only three identified outcomes (BMI, physical activity and screen time) were collected in more than one-third of included studies. This heterogeneity suggests scope for streamlining the outcomes that are collected and reported in early childhood obesity prevention interventions to better facilitate comparability across studies.

The focus on anthropometric, dietary, feeding, physical activity and sedentary behaviour outcome domains was expected given the nature and focus of early childhood obesity prevention interventions. Anthropometric outcomes were collected and reported in 92% of all included studies, with BMI the only outcome to be reported in more than 50% of included studies across all outcome domains. While other measures such as body composition may be considered as better indicators of adiposity in children [50], the collection of BMI is relatively inexpensive and so this is logical. In comparison, the published review of outcomes reported in early feeding interventions [19] found the most frequently reported outcome domain was “breastfeeding and formula feeding”, with anthropometric outcomes reported in approximately half of studies included.

The collection and reporting of outcomes related to parent/caregiver self-efficacy, knowledge of and attitudes towards healthy behaviours reflects the growing evidence base for the use of behaviour change techniques (BCTs) in early childhood obesity prevention interventions.[51] Recent work has

highlighted the importance of the incorporation of theories of behaviour change that posit that these aspects are necessary for parents/caregivers to engage in appropriate behaviours, incorporating family and system approaches.[52]

By contrast, oral health outcomes were reported in a very small number of studies (n=6, 4%). This is despite an increasing body of work examining the interconnections between oral health, nutrition and obesity[53] and suggests far greater focus could be given to oral health outcomes in early childhood obesity prevention research.[54] Our findings also suggest that a more prominent role could be given to sleep as an outcome in early childhood obesity prevention research. Proposed mechanisms for an association between sleep and obesity in infancy and childhood include the direct or indirect effect of shorter sleep duration on energy expenditure or intake, hormonal and biological responses leading to appetite dysregulation and the effect of insufficient sleep on executive functioning.[55] More evidence is required into sleep outcomes and obesity in infants and children.[56-58] In addition, the effect of sleep should not be considered in isolation from other movement behaviours that make up the 24-hour day (physical activity and sedentary time) given that increasing one behaviour means that one or more of the other behaviours must automatically reduce.[59]

Environmental outcomes (including outcomes related to ECEC, healthcare and other environments) were also less commonly reported (included in 13% of studies), and this is an area for future work given the recognition of the influence of physical, social and policy environments on child obesity.[9] This may in part reflect our study inclusion criteria and exclusion criteria (i.e. excluding studies with intervention content only at the environmental level, or with content delivered only to individuals within organisations such as childcare providers, and with no parent/caregiver/child-directed content), and the tension that trialists experience in managing a feasible scope for data collection within a trial. It should however be noted that the outcomes of food environments were more commonly reported within our study inclusions (n=13, 8%), than outcomes related to the physical activity home environment (n=5, 3%), sedentary behaviour home environment (n=3, 2%) or sleep

environment (n=1, 0.6%). Recent calls for evaluations to consider how interventions may help to alter the obesogenic system, rather than solely focusing on changes in outcomes per se [60], coupled with our findings support the need for greater consideration of these outcomes in the context of early childhood obesity prevention.

Given competing demands for scarce intervention resources, early childhood obesity prevention interventions must demonstrate cost-effectiveness in improving population health. Findings from our review suggest the need for trialists and health economists to work more closely to ensure that economic-related data collected alongside trials are accurately recorded in trial registration records. The number of studies reporting economic outcomes within trial registry records was low (n=12, 7%; Figure 2). However, several economic studies related to the 161 trial inclusions in our review currently exist or are planned. For instance, while both the trial registrations for the PRIMROSE trial (ISRCTN16991919) and the Miranos! Program (NCT03590834) mention economic evaluation in their aims, they do not explicitly list the economic-related outcomes reported within their trial registry records. In a published economic evaluation, the PRIMROSE intervention effect was not statistically significant although pointed in the "right" direction and so the intervention could not be deemed cost-effective.[61] To the best of our knowledge, the economic evaluation of the Miranos! Program is planned, but yet to be published.[62] Improved reporting of the economic-related outcomes collected alongside trials would provide better transparency around the building of the evidence base for the cost-effectiveness of early childhood obesity prevention interventions, and more information on the economic methods and data that currently exist in the field.

In addition, health-related quality of life outcomes in children were only collected in a small number of studies, and this is reflective of the significant challenges in valid measurement of health-related quality of life in very young age groups.[5, 63] Preference-based health-related quality of life plays an important role in cost-effectiveness analysis, and significant scope exists for future work to better understand the impacts of childhood obesity prevention interventions on health and wellbeing.[63]

Outcomes related to mental health and psychosocial wellbeing may be important to detect positive and/or negative effects of childhood obesity interventions [64], as children approach school age and beyond. The relative lack of evidence on adverse events for either children or their parents/caregivers presents a significant opportunity for future work in the area of childhood obesity prevention more broadly, to assess and minimise the potential for unintended negative effects on physical, mental and fiscal health.

Heterogeneity in the outcomes reported and collected in early childhood obesity prevention interventions currently poses a significant challenge in evaluation and knowledge synthesis and is likely leading to research waste.[65] This heterogeneity is reflected in the number of individual outcomes included across studies, and the low frequencies with which some outcomes are reported. While it is not conceivable that all, or even many, studies would be able to measure and report all identified outcomes, the lack of minimal consistency with which most outcomes are measured and reported impacts on our ability to compare and contrast across studies to determine intervention effectiveness. The findings from this comprehensive scoping review will inform the development of a COS, ultimately aiming to reduce the disparity in data collection and reporting and reduce barriers to data synthesis. This will ultimately allow for more comprehensive and robust analysis of the components of obesity prevention interventions that are most effective and a better understanding of which groups they are most effective for. While COS offer significant benefits in recommending a minimum set of outcomes to be collected in a specific area, it will be important that innovation in measurement (e.g. brief tools or use of technology) continues to reduce trial and respondent burden. This will ensure the benefits of COS are achieved while minimising the tradeoff that researchers face between power versus breadth of measurement within a study.

This review represents the first stage of the development of the Core Outcome Set for Early Prevention of Obesity in CHildhood (COS EPOCH). The outcomes identified in this review will form the basis of a consensus process for establishing recommended outcomes and outcome measurement instruments

for early childhood obesity intervention [27], following COMET guidelines.[22] COMET guidelines provide comprehensive guidance on the development of COS, including recommendations on best practice for consensus building through use of the Delphi technique and face-to-face consensus meeting of relevant stakeholders.[22]A Delphi study will assess the importance of different outcomes, using a priori criteria to prioritise outcomes. Representatives from relevant stakeholder groups will then participate in a face-to-face consensus meeting to discuss results of the Delphi study and agree on final COS inclusions.

This scoping review has a number of limitations. The scope of the review needed to be feasible given the available resources to conduct it, and so decisions regarding inclusion and exclusion criteria were required. These decisions will have impacted on the types of interventions captured in this review (for instance, non-randomised controlled trials were not included and so this review does not encompass the outcomes collected and reported in such studies). While the scope of our review focused on interventions that included a component related to lifestyle (e.g. diet, parent/caregiver practices, physical activity, sedentary behaviour, sleep) there is significant future scope for exploration of outcomes related to environmental interventions in this population (for example, interventions that aimed to change policy or practices in early childhood education and care settings). Inconsistent reporting of outcomes and outcome measurement instruments posed a significant challenge in identifying, classifying, synthesising and reporting the outcomes in early childhood obesity prevention intervention studies.[22, 66] A multidisciplinary team was involved in all stages of the classification and data synthesis of outcomes, minimising the risk of inappropriate classification. Outcomes were extracted verbatim following COMET guidelines [22] and narratively summarised, however no attempt at classifying or re-classifying these as process or intermediate outcomes or other variables was made. While data on outcome measurement instruments were extracted, we have not reported on the frequency of outcome measurement instrument application here. These data will be synthesised and presented in a future publication in the COS development process [27], summarising the outcome

instruments most frequently used in early childhood obesity prevention interventions and their measurement properties.

Findings from our review also highlight that a more concerted effort to update trial registry records with complete information on the outcomes collected and reported, resultant publications and trial status should be pursued. Trial registry records present an opportunity for complete information on the outcomes collected within a trial, and the methods for collecting these outcomes to be reported. This opportunity could enhance the transparency around commonly collected outcomes, and would better support the analysis of commonly collected outcomes if taken up by the majority of research trials. It is possible that trials included in our review collected additional outcomes that were not reported in trial registry records or the related publications that we were able to search within the scope of our study and the resources able to be devoted to it. Many trial registry records do not provide information of linked publications that were subsequently able to be identified using our GoogleScholar search, but at times the linking of these publications to registered trials was unclear. Given the inexact nature of relying on a GoogleScholar search to identify resultant publications, it is possible that relevant publications were not located. To the best of our knowledge, we have included all trials and outcomes within our scoping review according to the methods used, but acknowledge that due to challenges in inconsistent and incomplete reporting, some may have been inadvertently omitted.

Strengths of this review include adherence to published scoping review guidelines[29, 30] and the COMET initiative guidelines.[22] Another significant strength was our search of both clinical trial registries and the published academic literature, as the former captures outcomes which may not have been reported within an academic publication.

Conclusions

This review identified significant heterogeneity in the outcomes measured and reported in early childhood obesity prevention intervention trials. Eighteen outcome domains were identified, with a

large number of outcomes currently reported in relatively few studies. High rates of early childhood overweight and obesity worldwide require action, through effective and efficient intervention to improve the health of children. Results from this scoping review will support the development of COS EPOCH, aiming to guide early childhood obesity prevention intervention research, and to facilitate knowledge synthesis between studies to determine the most effective components of early childhood obesity prevention interventions.

Author contribution statement

VB conceived the study, with input from all co-authors on study design and methods. VB and MS undertook the systematic searches and screening, and extracted data. VB synthesised data, with input from all co-authors. VB drafted the manuscript, which was reviewed by all co-authors. All authors critically revised the manuscript and provided expert analysis. All authors have read and approved the manuscript.

Data accessibility statement

The data are available by request to the lead author.

Figures legend

Figure 1 – PRISMA diagram of study selection for inclusion into the review

Figure 2 – Frequency of outcome domains reported in included studies (n=161)

Tables legend

Table 1 – Clinical trial registry search strategy

Table 2 – Outcome domains

Table 1 – Clinical trial registry search strategy

Registry	Search strategy
World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP)	"Advanced search" Title: prevent OR prevention Condition: obesity OR overweight Recruitment status: all Limit: search for clinical trials in children Status: all
Clinicaltrials.gov	"Advanced search" Condition or disease: Obesity OR obese OR adiposity OR overweight Age: Child (Birth-17 years) Type of studies: interventional studies Other terms: prevent OR prevention

Table 2 – Outcome domains

Outcome domain	Outcome domain definition	Number of outcomes	Outcomes measured in	Example of outcomes
Anthropometry	Measures and proportions of the human body, including muscle, bone and adipose tissue	6	Child, parent/caregiver	- Body mass index - Body composition
Dietary intake	Measures of food, energy intake, calories, nutrients, and food and eating patterns	38	Child, parent/caregiver	- Fruit and vegetable intake - Meal patterns
Feeding	Measures of food provision and associated parenting practices	19	Parent/caregiver	- Feeding style - Feeding interaction
Physical activity	Measures of movements of the body and associated parenting practices	17	Child, parent/caregiver	- Active transport - Physical activity parenting practices
Sedentary behaviour	Measures of waking behaviours characterised by an energy expenditure ≤1.5 METs while in a sitting, reclining or lying posture[67]	5	Child, parent/caregiver	- Screen time - Time spent sedentary
Sleep	Measures of sleep and associated parenting practices	15	Child, parent/caregiver	- Sleep duration - Sleep quality
Cognitive/executive functioning	Measures of cognitive or executive functioning, including outcomes related to parent/caregiver knowledge, attitudes and beliefs[37]	14	Child, parent/caregiver	- Attention control - Language development
Emotional functioning/wellbeing	Measures of emotions or overall wellbeing[37]	20	Child, parent/caregiver	- Emotion regulation - Child internalising or externalising behaviours
Parent/caregiver practices	Measures of general parenting practices, not specifically related to feeding, sleep, sedentary behaviour, physical activity	10	Parent/caregiver	- Parental warmth - Sensitive scaffolding
Perceptions and preferences	Measures of perceptions of and preferences for relevant indicators	10	Child, parent/caregiver	- Food preference - Perception of weight
Motor skill development	Measures of motor skills and physical literacy	3	Child	
Environmental	Measures of the environment, including home, ECEC and other	7	Parent/caregiver	- ECEC environment - Obesogenic home environment

Blood and lymphatic system	Measures of the blood, heart, blood vessels and the lymphatic system	17	Child, parent/caregiver	- Biomarkers - Glucose
Quality of life	Measures of quality of life, including health-related quality of life	1	Child, parent/caregiver	- Health-related quality of life
Economic	Measures of resource use, cost, cost-effectiveness	5	Parent/caregiver	- Economic evaluation - Intervention cost
Oral health	Measures of oral health	3	Child	- Oral hygiene - Caries
Study-related	Study-related measures	12	Study	- Acceptability - Fidelity
Other	Other measures	19	Child, parent/caregiver	- Adverse events - Child safety

Table notes: References are provided where commonly accepted definitions of the outcome domains exist. ECEC= early childhood education and care; METs= metabolic equivalent task

Author Disclosure Statement

The authors declare that they have no competing interests. The authors declare that they have no personal financial interests.

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