STUDY PROTOCOL

# Which outcome measurement instruments are used to measure core infant feeding outcomes in children up to 1 year of age? A scoping review protocol [version 1; peer review: awaiting peer review]

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## Abstract

### Background

How, what, and when infants are fed plays a role in the aetiology of childhood obesity. Heterogeneity in how infant feeding outcomes are measured in trials of interventions to prevent childhood obesity limits evidence syntheses and understanding of intervention effectiveness. An infant feeding core outcome set (COS) was previously developed to standardised outcome measurement and reporting. The COS represents ***what*** to measure; determining **how** best to measure these

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outcomes is the next essential step to improve intervention evaluations. The aim of this scoping review is therefore to identify what outcome measurement instruments have been used in trials, and how they have been used, to measure the core infant feeding outcomes.

**Methods**

A scoping review will be conducted. MEDLINE, EMBASE, CINAHL, PsychINFO, the Cochrane Central Register of Controlled Trials, OpenGrey and GreyNet will be searched from inception. Papers are eligible for inclusion if they report trials involving primary data collection that measure and report at least one core infant feeding outcome in infants ≤one year of age. Following searching and screening, eligible studies will be categorised into the following four overarching categories for data extraction, synthesis and write-up: caregiver-related outcomes; diet-related outcomes; feeding environment outcomes; child weight outcomes. Data will be narratively described and presented in tabular format, with findings presented in four separate review papers delineated by the four overarching categories.

**Discussion**

This scoping review forms part of the Standardised measurement for Childhood Obesity Prevention (SCOPE) study (www.eiascope.com). Evidence from this scoping review on what measurement instruments are used, and how they are used, represents an essential first step in developing recommendations and guidance about how best to measure core infant feeding outcomes for childhood obesity prevention. This can improve evidence syntheses and understanding of what infant feeding interventions are most effective for childhood obesity prevention.

**Keywords**
Infant feeding, childhood obesity, measurement, evidence synthesis, scoping review, core outcome set

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## Introduction

An estimated thirty-nine million children under the age of five years are living with childhood overweight or obesity worldwide[1]. Childhood obesity is associated with obesity in adulthood and a range of other adverse outcomes including diabetes, cardiovascular disease, asthma[2], and mental health issues such as anxiety and depression[3,4]. While the aetiology of childhood obesity is complex, evidence suggests that infant feeding plays a role[5–8].

Infant feeding relates to what, when, and how infants are fed during infancy (birth to one year of age). It includes behaviours such as breastfeeding, responding in a timely and developmentally appropriate manner to infant hunger and satiety cues, and the timing of solid food introduction. Complex obesity prevention interventions have been developed and evaluated that target infant feeding but the evidence base is inconsistent[9–12]. Some of this inconsistency might be due to heterogeneity in what, and how, infant feeding outcomes are measured and reported across studies[13,14]. This outcome heterogeneity impedes evidence synthesis, making it difficult to determine what interventions work, and for whom and in what circumstances[15–17]. A review of infant feeding outcomes identified 236 reported outcomes across 126 studies[13]. To address this heterogeneity, a core outcome set (COS) of infant feeding outcomes was developed for use in trials of early childhood obesity prevention interventions[14,18].

Core outcome sets are standardised sets of outcomes for measurement and reporting in trials in specific health areas[19]. By reducing or eliminating outcome heterogeneity across studies, COS can prevent research waste and enhance evidence syntheses[19]. The infant feeding COS was developed following a systematic process involving evidence syntheses and a stakeholder consensus process involving caregivers, healthcare professionals, researchers and childcare professionals[14,18]. The final COS includes 26 outcomes considered by stakeholders to be most important for inclusion in trials of early childhood obesity prevention interventions[18]. It includes outcomes related to breastfeeding and commercial milk formula feeding, age of introduction of solids, dietary intake, the feeding environment, child weight and growth, and parents' knowledge, beliefs, perceptions and feeding practices[18].

While the COS[18] helps us understand *what* is most important to measure, the critical next step is identifying *how* to best measure core outcomes[19,20]. Existing heterogeneity in measurement approaches can impede trialists decision-making about how best to measure outcomes, and choosing and including poor-quality measurement instruments that may not be fit-for-purpose can introduce bias in trial findings[21]. Further, evidence on factors influencing COS use by trialists has highlighted that lack of knowledge on how best to measure COS outcomes is a barrier to trialists using COS[22–24]. Thus, not knowing how best to measure core outcomes can lead to reduced use of COS, which can contribute to outcome heterogeneity and research waste. Currently, there are multiple measurement approaches for measuring outcomes in infant feeding interventions, including surveys, psychometric questionnaires, clinical assessment tools, diary methods, and observation[25]. In addition, measurements can be conducted in a variety of different ways across settings (*e.g.,* research, practice, community settings) by different people (*e.g.,* caregivers, healthcare professionals, researchers, childcare professionals).

Providing clear recommendations and guidance on how best to measure the core infant feeding outcomes for early childhood obesity prevention is essential to improve evaluation of intervention effectiveness. Recommendations and guidance should be appropriate for all contexts in which data for early childhood obesity prevention interventions are collected. The aim of the Standardised measurement for Childhood Obesity Prevention (SCOPE) project, of which the review outlined herein forms part, is to develop these recommendations and guidance (www.eiascope.com). To do so, the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and COMET Initiatives guidance via identifying, evaluating, and selecting outcome measurement instruments for COS[21,26–28] will be used. The first step involves identifying what measurement instruments are currently used[26].

Some previous reviews have looked at measurement of infant feeding outcomes in the context of childhood obesity prevention, including those outcomes identified as core in the infant feeding COS[18]. The reviews that have been conducted[25,29] tend to focus on assessment in children spanning a broader age range than the infant feeding COS of up to one year old[18]. For instance, one review of outcome measurement instruments used to evaluate childhood obesity treatments examined measurements used with children up to 18 years old[25]. While measurement instruments were identified for some core infant feeding outcomes, these were considered in a grouping of children aged up to 36 months[25]. Similarly, a review of dietary assessment methods in children specified an age range of 0–18 years, with only two included studies examining outcomes in children under one year of age[29]. Thus, there remains a gap in knowledge of what measurement instruments are used to measure core infant feeding outcomes for early childhood obesity prevention in children up to one year of age.

Given the range of potential measurement instruments available to measure core infant feeding outcomes, knowing what measurement instruments are used in trials, and how they are used (*e.g.,* when and in what contexts), is the essential first step before evaluations of these measurement instruments and recommendations for use can be made. The aim of this scoping review is therefore to identify what outcome measurement instruments have been used in trials, and how they have been used, to measure the 26 outcomes included in the infant feeding COS[18] for childhood obesity prevention interventions in children up to one year of age.

## Methods

A scoping review will be conducted to identify what measurement instruments have been used in trials, and how they have been used, to measure core infant feeding outcomes. A scoping

review is appropriate given the broad range of potential measurement instruments, and our aim to conduct a comprehensive examination of these instruments[30]. This scoping review will be conducted following guidance from the Johanna Briggs Institute on scoping reviews[31]. The protocol is reported in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR)[32].

## Study eligibility

As this review will identify outcome measurement instruments, study eligibility will be informed by the population, constructs of interest, and type of measurement instrument (see Table 1). The population eligibility criteria are informed by an overview of core infant feeding outcome measurement aspects developed as part of the SCOPE study (see extended data). The construct eligibility criteria are derived from the infant feeding core outcomes set[18]. The types of measurement instruments were informed by a non-systematic review of measurement approaches identified in a previous review conducted during development of the infant feeding COS[13], as well as studies included in a scoping review that informed development of a COS for childhood obesity prevention interventions in children aged up to five years[33]. Types of measurement instruments include the what (*e.g.,* questionnaire), the who (*e.g.,* self-reported by parent), the how (*e.g.*, online), and the where (*e.g.*, at home). The SCOPE team see, who include experts in childhood obesity, infant feeding, measurement and dietary assessment, initially reviewed and discussed these types of measurement instruments. This was followed by a subsequent stakeholder meeting with healthcare professionals, researchers and caregivers, conducted to finalise the measurement aspects used to inform this review. Stakeholders (n=6) involved in the stakeholder meeting were based in Ireland (n=3), England (n=1), Israel (n=1), and Canada (n=1).

***Inclusion criteria:*** Studies must measure and report at least one core infant feeding outcome in infants ≤ one year of age who were born at full-term and not less than 37 weeks (see Table 1). All measurement approaches are eligible for inclusion due to the range of different approaches potentially used to measure different feeding outcomes. In addition, infant feeding outcomes in eligible studies can be measured and/or reported by caregivers of infants, researchers, healthcare professionals, and/or childcare professionals. They can also be measured in any setting and at any timepoint(s) in the first year. Studies reporting on trials of any design (e.g., pilot trials, randomised controlled trials, factorial trials) are eligible for inclusion.

***Exclusion criteria:*** Studies are not eligible for inclusion if they examine outcomes in infants over one year of age; do not report at least one infant feeding outcome from the core outcome set; do not have childhood obesity prevention as either a primary or secondary focus; or do not report on measurement of a core infant feeding outcome. Non-trial designs, systematic reviews, meta-analyses and non-systematic reviews are not eligible for inclusion.

## Search strategy

The following databases will be searched from inception: MEDLINE, EMBASE, CINAHL, PsychINFO, and the International Clinical Trials Registry Platform. Reference lists of eligible studies will be searched for additional relevant articles. Where relevant reviews (e.g., 25,29) are identified in searches, these will not be included in the review but reference lists will also be searched for additional relevant articles. A grey literature search will also be conducted using sources such as OpenGrey and GreyNet. There are no restrictions on date, language or location of publication. The search strategy in Table 2 will be used, with the search re-run prior to final analysis.

In addition, two existing reviews will be used to supplement database searches to ensure that all relevant articles are identified: (1) the systematic review conducted as part of the infant feeding COS development[13], (2) the scoping review conducted as part of development of the Centre of Research Excellence Early Prevention of Childhood Obesity (CRE-EPOCH) COS[33]. The TOPCHILD[11] collaboration registry of early obesity prevention interventions will also be used as a resource to ensure that all relevant articles are identified.

## Study screening and selection

Rayyan software will be used for study screening. Zotero software is also freely available and can perform equivalent functions for screening. Following deduplication of identified studies, the titles and abstracts of all studies will be independently screened in duplicate against eligibility criteria by two reviewers. Full text articles of remaining studies will then be screened independently in duplicate by two reviewers. Discrepancies in screening at title and abstract and/or full text screening stages will be resolved by discussion or recourse to a third reviewer as needed. Studies eligible for inclusion will then be categorised into the following four overarching categories for data extraction, synthesis and write-up:

1. Caregiver-related outcomes (knowing what foods should be offered; knowing how to offer solid foods; pressuring the child to eat; caregiver modelling of eating behaviours, responsive infant feeding; caregiver perceptions of food preferences; caregiver perceptions of infant satiety-responsiveness; child self and/or assisted feeding)

2. Diet-related outcomes (duration of breastfeeding from mother; duration of exclusive breastfeeding; feeding method; amount/volume of commercial milk formula fed to infant; type of commercial milk formula fed to infant; breastfeeding self-efficacy; age of introduction of solids; types of food consumed; portion size; offering age-appropriate foods and beverages; infant eating home-made food; infant eating ready-made foods; types of 'other' drinks consumed)

3. Feeding environment outcomes (feeding environment; offering healthy foods)

**Table 1. Population, construct, and instrument eligibility criteria.**

| | |
|---|---|
| **Population** | Infants ≤one year of age born full term and not less than 37 weeks |
| **Construct** (Core infant feeding outcomes presented by outcome domain*) | Breastfeeding and formula feeding outcomes:<br>1. Duration of breastfeeding from mother<br>2. Duration of exclusive breastfeeding<br>3. Feeding method (breastfeeding directly, breastmilk feeding using a bottle, commercial milk formula, solids, combination)<br>4. Amount/volume of commercial milk formula fed to infant<br>5. Type of commercial milk formula fed to infant<br>6. Breastfeeding self-efficacy<br>Introduction of solid foods outcome:<br>7. Age of introduction of solids<br>Parents knowledge and beliefs outcomes:<br>8. Knowing what foods should be offered<br>9. Knowing how to offer solid foods<br>Feeding practices and styles outcomes:<br>10. Pressuring the child to eat<br>11. Caregiver modelling of eating behaviours<br>12. Responsive infant feeding<br>Practical feeding outcome:<br>13. Child self and/or assisted feeding<br>Food environment outcomes:<br>14. Feeding environment<br>15. Offering healthy foods<br>Dietary intake outcomes:<br>16. Types of food consumed<br>17. Portion size<br>18. Offering age-appropriate foods and beverages<br>19. Infant eating home-made food<br>20. Infant eating ready-made foods<br>21. Types of 'other' drinks consumed<br>Parent perceptions of infant behaviour and preferences outcomes:<br>22. Caregiver perceptions of food preferences<br>23. Caregiver perceptions of infant satiety-responsiveness<br>Weight related outcomes:<br>24. Child weight<br>25. Weight gain over time<br>26. Body composition |
| **Measurement instruments** | All measurement instruments/approaches, including but not limited to: questionnaires, individual survey items, diary approaches, healthcare records, dietary recall, direct observational methods, anthropometric measures (*e.g.,* scales, growth charts, bioelectrical impedance analysis; dual energy x-ray absorptiometry) |
| **Study designs** | All trial designs |

*Outcome names are presented as labelled in the infant feeding COS[18] and by COS domains

4. Child weight outcomes (child weight (include weight relative to length); weight gain over time; body composition)

## Data extraction

The following data will be extracted for all studies independently and in duplicate by two reviewers: article details (author, title, year of publication, country of origin), study details (study design, setting), population characteristics (target population), construct details (infant feeding outcomes measured), outcome measurement instrument details (name of instrument/approach, type of measurement, mode of administration, response format, number of items where appropriate), and details of outcome measurement instrument use (timing of measurement, recall period where appropriate, where measurement took place, who conducted and/or completed the measurement, child's age at measurement(s), frequency of measurement, any additional contextual measurement details). Pilot data extraction will be conducted with a subset of randomly selected papers prior to full data extraction to ensure the data extraction

**Table 2. Search terms.**

| | Terms |
|---|---|
| **Population**<br>Infants up to one year of age | Infant OR infancy OR child OR children OR paediatri* OR pediatri* OR newborn* OR newborn* OR baby OR babies<br><br>**AND** |
| **Construct (infant feeding)**<br>Duration of breastfeeding from mother (directly or indirectly)<br>Duration of exclusive breastfeeding<br>Feeding method<br>Amount/volume of formula fed to infant<br>Breastfeeding self-efficacy | Breastfeed* OR "breast feed*" OR breastfed OR breastmilk OR "breast milk" OR "human milk" "expressed milk" OR "formula milk" OR "formula feed*" OR 'Infant formula' OR 'baby formula' OR "formula fed" OR "bottle fed" OR "bottle feed*" OR bottle-fed OR bottle-feeding feeding OR "Infant feeding" OR "baby feeding" OR "mixed feeding"<br>"commercial milk formula" OR CFM |
| Age of introduction of solids | "introduction of solid*" OR "introduction to solid*" OR "weaning" OR "complementary food" OR "complementary feed*" OR "first food" OR "first solid" OR "supplementary feed*" OR "transition* to solid*" |
| Knowing what foods should be offered<br>Knowing how to offer solid foods | "parent* knowledge" OR "caregiver knowledge" OR "parent* belief*" OR "caregiver belief*" OR "parent* understanding" OR "caregiver understanding" OR "parent* information" OR "caregiver information" |
| Pressuring the child to eat<br>Caregiver modelling of eating behaviours | |
| Responsive infant feeding | "feeding practice*" OR "feeding style*" OR "feeding pattern*" OR "feeding behaviour" OR "feeding behavior" OR "feeding strategy" OR "feeding approach" OR "feeding habit*" OR "feeding dynamics" OR "eating behaviour" OR "eating behavior" OR "parent* model*" OR "caregiver model*" OR role model*" OR responsiv* OR pressure* OR |
| Child self and/or assisted feeding | "self-feed*" OR "baby led weaning" OR "baby-led weaning" OR "baby led feeding" OR "baby-led feeding" OR "self wean*" OR self-wean*" OR "spoon fed" OR "spoon feed*" OR "finger food*" |
| Feeding environment<br>Offering healthy foods | "food environment" OR "feeding environment" OR "eating environment" OR "meal environment" OR "nutrition environment" OR "food context" OR "foodscape" OR "social environment" OR "food availability" OR food choice* OR "food options" OR "food variety" OR "food culture" OR "feeding culture" OR "food norm*" OR "feeding norm*" OR "food proximity" |
| Types of food consumed<br>Portion size<br>Offering age-appropriate foods and beverages<br>Infant eating home-made food<br>Infant eating ready-made foods (*e.g.,* commercial baby/infant weaning foods)<br>Types of 'other' drinks consumed | diet* OR food OR eating OR fruit* OR vegetable* OR fat OR salt OR "fast food*" OR "discretionary food" OR confectionary "junk food" OR meal* OR snack* OR "diet* pattern" OR portion" OR "serving size" OR beverage* OR drink* OR juice OR "fizzy drink" OR "soft drink" OR home-made OR "homemade" or "home made" OR "home-prepared" OR "home prepared" OR "ready-made" or "ready made" OR |
| Caregiver perceptions of food preferences<br>Caregiver perceptions of infant satiety-responsiveness | "parent* perception*" Or "caregiver* perception*" OR "food preference*" OR "taste preference*" OR "diet* preference*" OR "diet* preference*" OR "eating preference*" OR "hunger cue*" OR "satiety cue*" OR "fullness cue*" OR feeding cue* OR "eating cue*" |
| Child weight<br>Weight gain over time<br>Body composition | Weight OR "infant size" OR "body size" OR growth OR "body mass index" OR bmi OR skinfold OR "skin fold" OR "waist circumference" OR "waist-hip ratio" OR "waist hip ratio" OR adipos* OR overweight OR obes* OR OR anthropometric OR "body composition" OR "body fat*" OR "fat mass" OR "lean mass" OR adipos* OR "growth pattern*" OR "growth trajectory" OR "body proportion*" OR<br><br>**AND** |
| **Measurement instruments** | None (to maximise identification of all approaches) |
| **Study designs** | RCT OR "Randomised control* trial" OR "Randomized control* trial" OR trial |

form is fit for purpose, and any modifications to the extraction process will be recorded and reported.

### Quality assessment
Quality assessment will not be conducted as the aim of this study is to identify what measurement instruments are used, and how they are used, rather than to synthesise and interpret findings of studies[30]. As such, quality assessment is not related to the aim of this research study.

### Data summary
Findings will be narratively described and presented in tabular format for each core outcome. The tables will include details of the measurement instruments used, as well as details of the frequency of use of different measurement approaches for each outcome in the identified studies. Where there is variability in details extracted across studies (*e.g.,* one study reporting use of a 12-question survey and another reporting that 'survey questions' were asked), these will be categorised by the project team for presentation in the narrative descriptions and/or tables. Where approaches are used to measure more than one feeding outcome (*e.g.,* a single questionnaire measuring multiple parental feeding practices) this will also be presented. Findings will be presented in four separate review papers delineated by the four overarching categories: (1) caregiver-related outcomes, (2) diet-related outcomes, (3) feeding environment outcomes, and (4) child weight outcomes.

## Discussion
This protocol outlines the first step in developing recommendations and guidelines for how to measure core infant feeding outcomes for childhood obesity prevention as part of the SCOPE study. Developing these recommendations and guidelines is essential to reducing heterogeneity in outcome measurement, increasing use of the infant feeding core outcome set[18], and improving evaluation of childhood obesity prevention interventions.

## Ethical considerations
As this is a scoping review, there are no potential ethical issues and ethical approval is not required.

## Dissemination
Findings from this study will be disseminated as four review publications based on the four overarching feeding categories: caregiver-related outcomes, diet-related outcomes, feeding environment outcomes, and child weight outcomes. Findings will also be disseminated as presentations at academic conferences.

## Data availability statement
### Extended data
OSF: Which outcome measurement instruments are used to measure core infant feeding outcomes in children up to one year of age? A scoping review protocol https://doi.org/10.17605/OSF.IO/PWA46.



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