STUDY PROTOCOL

Factors influencing use and choice of Core Outcome Sets and outcome measurement instruments in trials of interventions to prevent childhood obesity: A survey protocol [version 1; peer review: awaiting peer review]

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Abstract

Background

Two core outcome sets for childhood obesity prevention have been developed; standardised sets of outcome measurement instruments for these core outcome sets are currently being developed. Core outcome sets and standardised measurement sets can reduce heterogeneity and improve evidence syntheses for trials of interventions to prevent childhood obesity and/or interventions to improve child health behaviours related to childhood obesity. Such benefits are only realised if core outcome sets and standardised measurement sets are used in trials. The aims of this study are 1) to examine trialists' awareness and attitudes towards the two existing

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core outcome sets and factors influencing their use; 2) to explore the characteristics of outcome measurement instruments that trialists currently use; and 3) to better understand how trialists choose outcome measurement instruments and the factors that influence those choices.

Methods

A cross-sectional online survey will be conducted with researchers involved in the design and/or conduct of trials of interventions to prevent childhood obesity and/or to improve child health behaviours related to childhood obesity, in children aged 0 to 5 years (trialists). Trialists will be recruited using purposive sampling, and will complete a 22-item survey examining trialist characteristics, awareness of the existing core outcome sets, factors influencing use of the existing core outcome sets, characteristics of measurement instruments, how trialists choose measurement instruments, and factors influencing choice of measurement instrument. Quantitative data will be analysed descriptively; responses to open-ended questions will be analysed using qualitative content analysis.

Conclusions

Findings from this study will inform approaches to maximising use of core outcome sets and standardised measurement sets for childhood obesity prevention. Use of standardised approaches to what and how outcomes are measured in this area will reduce heterogeneity and research waste and enhance evidence syntheses to better determine intervention effects.

Keywords
Childhood obesity; child health behaviours; core outcome set; outcome measurement instruments

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Introduction

Approximately 39 million children under the age of 5 are living with overweight or obesity globally[1]. The aetiology of childhood obesity is multifaceted, with childhood obesity arising from a complex interplay of individual, behavioural, interpersonal, environmental, and structural factors[2,3]. While some interventions developed to prevent childhood obesity and/or improve child health behaviours related to childhood obesity (e.g., diet, physical activity), have demonstrated benefits, findings are inconsistent overall. A potential reason for this inconsistency is the heterogeneity in outcomes being measured and reported in intervention trials[4,5], which limits our ability to compare findings and identify effective interventions[6]. For example, in a previous review of outcomes examined in the infant feeding literature, 126 studies reported 236 different outcomes[5]. Similarly, in a review of outcomes reported in early childhood obesity prevention interventions, 221 outcomes were reported in 161 studies[4]. Standardisation of what outcomes are measured, and how they are measured, can address this issue.

To address heterogeneity in outcome measurement in trials of interventions to prevent childhood obesity, two Core outcome sets (COS) have been developed[7,8] (see Extended data). Core outcome sets (COS) are agreed-upon standardised sets of outcomes representing **what** to measure and report in all trials in a specific health area[6]. The first COS in this area is a COS for infant feeding interventions conducted with children aged from birth to 1 year to prevent childhood obesity[7]. It includes 26 outcomes, such as 'responsive infant feeding', 'portion size', 'duration of exclusive breastfeeding', and 'child weight'[7]. The second COS (COS-EPOCH) is for use in trials of early interventions in children aged up to 5 years to prevent obesity in childhood[8]. It includes 22 outcomes, such as child physical activity, screen time, meal patterns, and sleep duration[8]. Dietary outcomes in COS-EPOCH[8] are related to children from 1–5 years, with infant feeding outcomes up to 1 year included in the infant feeding COS[7]. As such, outcomes from both COS can be used together or separately depending on the intervention focus and/or child age. These COS represent **what** to measure in childhood obesity prevention interventions, and work is currently ongoing to determine **how** to best measure these outcomes through the development of standardised sets of outcome measurement instruments for the COS outcomes[9,10].

These developments will only improve evidence syntheses and identification of effective interventions to prevent childhood obesity to the degree that they are actually used by researchers[11]. There is evidence of low use of COS across different health areas[12–16]. Barriers to the use of COS across general cohorts of health areas include knowledge about what COS are and how to identify and use them, measurement issues associated with COS use, and trialists' own outcome preferences[12,14,17,18]. While developing standardised measurement sets helps to address issues around the identification of measurement instruments for COS, it is important that recommendations of measurement instruments consider previously identified issues related to measurement properties (e.g., validity, reliability), feasibility, acceptability, cost, and participant and administration burden[19,20]. While research has been conducted on factors influencing the use of broad cohorts of COS[12,14,18] and choice of measures, such as patient-reported outcome measures[19,20], such work has not been conducted in the area of childhood obesity.

It is important to understand attitudes of researchers working on trials of interventions to prevent childhood obesity and/or to improve child health behaviours related to childhood obesity, about existing COS developed for this area. It is also important to identify and understand factors influencing their use of these COS. Such understanding will inform approaches to maximise future COS use. Similarly, understanding the most important factors for trialists working in childhood obesity prevention regarding choice of outcome measurement instruments ensures that recommended outcome measurement instruments are appropriate, feasible, and acceptable. Therefore, the aim of the current study is threefold: 1) to examine trialists' awareness and attitudes towards the two current COS for trials of childhood obesity prevention interventions, and factors influencing use of these COS; 2) to explore the characteristics of outcome measurement instruments that trialists currently use in obesity prevention interventions and/or interventions to improve child health behaviours related to childhood obesity; and 3) to better understand how trialists choose outcome measurement instruments in trials of childhood obesity prevention interventions, and/or interventions to improve child health behaviours related to childhood obesity, and the factors that influence those choices.

Methods

Design

A cross-sectional online survey will be conducted.

Participants

Participants in the survey will be trialists, defined as researchers involved in the design and/or conduct of trials of interventions to prevent childhood obesity and/or to improve child health behaviours related to childhood obesity, in children aged 0 to 5 years. Child health behaviours related to childhood obesity include, but are not limited to, diet, physical activity, sedentary behaviour, screen time, and sleep. Trialists in this study can include researchers at all stages and roles, including, but not limited to, principal investigators, postdoctoral researchers, doctoral students, research assistants, trial statisticians, trial coordinators, site managers, and researcher members of steering or advisory committees. Trialists of any age, gender, and geographical location can participate in the study. As this is an exploratory, descriptive study, sample size calculations were not conducted; recruitment will instead aim to recruit as many participants as possible.

A purposive sampling strategy will be used to recruit trialists involved in trials of interventions to prevent childhood obesity and/or improve child health behaviours related to childhood obesity. Potential participants will be identified from: 1) publications of childhood obesity prevention

interventions and interventions to improve child health behaviours related to childhood obesity (including protocol and outcome publications) that were identified in reviews of childhood obesity prevention outcomes and outcome measurement instruments[4,5,9]; 2) relevant trials included in the Transforming Obesity Prevention for CHILDren (TOPCHILD) Collaboration (https://www.topchildcollaboration.org/) registry[21]; and 3) via professional contacts and channels including, but not limited to, the Centre of Research Excellence in Translating Early Prevention of Obesity in Childhood (EPOCH-Translate) which includes researchers in in Australia, New Zealand and Ireland, the international TOPCHILD Collaboration, the International Society of Behavioral Nutrition and Physical Activity (ISBNPA), and the European Association for the Study of Obesity (EASO). Contact details for all potential participants will be identified from publicly available information. All identified trialists will be invited by email to take part in the online survey, with follow-up emails sent two weeks later. All invitation emails will include the study invitation, and a link to the online participant information leaflet, consent form, and online survey. Participants will also be recruited via social media (e.g., X, formerly Twitter) using a post including the study title, a brief description, and a link to the participant information leaflet, the consent form and online survey.

Data collection

Data will be collected using a 22-item survey hosted on UCC Microsoft Forms. Section 1 includes nine questions on trialist characteristics (career stage, years of trial experience, trial methods training, number of childhood obesity trials involved in to date, countries in which trials were conducted, if currently involved in a trial and current stage of trial, current or previous role in trials, how outcomes are chosen for trials). Section 2 includes five closed-ended questions examining trialists' awareness of COS (1 question), the two current COS for trials of childhood obesity prevention interventions (2 questions), and factors influencing use of these COS (2 questions). Participants will indicate yes/no responses, or will select from pre-specified outcomes in response to these questions. Section 3 includes five closed-ended questions, whereby participants select pre-specified responses, will be used to examine characteristics of outcome measurement instruments (3 questions), how trialists choose outcome measurement instruments in trials of childhood obesity prevention interventions (1 question) and the factors that influence those choices (1 question). Section 4 includes two open-ended questions at the end of the survey will allow participants to provide additional information on what influences their choice of outcomes, use of core outcome sets, and measurement instruments for trials of interventions to prevent childhood obesity. The final question asks how participants heard about the survey, to support ongoing participant recruitment strategies if needed. The survey was developed by a multidisciplinary team and was informed by findings from examinations of factors influencing the use of COS[12,14,17,18] and factors influencing the selection of outcome measurement instruments[19,20]. See see Extended Data for the full survey.

Analysis

Data will be analysed descriptively using means and standard deviations for normally distributed continuous variables, medians and interquartile ranges for non-normally distributed continuous variables, and frequencies and percentages for categorical variables. R Version 4.3.3 will be used for data analyses. Open-ended responses will be analysed using qualitative content analysis. An inductive approach will be used wherein data will be open-coded initially, followed by grouping codes together into higher order categories. NVivo 12 will be used for qualitative content analysis.

Conclusion

Examining the factors that influence trialists use of childhood obesity prevention core outcome sets, and their choice and use of outcome measurement instruments can inform approaches to maximising uptake of these resources in future trials. Use of core outcome sets and standardised outcome measurement sets in interventions to prevent childhood obesity can reduce research waste and outcome hetereogeneity and improve evidence syntheses in this area.

Ethical issues

Ethical approval will be obtained prior to study commencement from the University College Cork Social Research Ethics Committee. Due to the nature and focus of this study, there are no anticipated ethical issues, and it is not expected that participants will experience any form of distress. Members of the study team (e.g., KMS, LS, BJ, SR, HS) may have existing research collaborations with survey participants, however identifiable trialist and trial data will not be collected in the survey and raw data will only be accessed by KMS, RA, MD and EL to minimise any risk of identification based on data collected. In addition, the study will include the following ethical considerations: All participants will be provided with an online participant information leaflet prior to providing informed consent and completing the online survey. The participant information leaflet will include information about the aims and processes of the study. This includes that participation is voluntary and that individual participant data will be confidential and anonymous as no identifying information will be collected. It will also include information on participants right to withdraw from the study at any point up to survey completion as individual submissions will not be identifiable due to the anonymous nature of the survey. The information leaflet will also include data management and storage information, which will be conducted in line with the University College Cork Code of Research Conduct.

Dissemiantion: Findings from this study will be disseminated as a peer-reviewed publication and as a presentation at conferences and methodological seminars.

Data availability

No data are associated with this article.

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