STUDY PROTOCOL

What aspects of outcome measurement instruments are important to parents and caregivers in child health trials: Survey protocol

[version 1; peer review: 1 approved]

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Abstract

Background

Trials of interventions to prevent illness and/or improve health outcomes in children play a crucial role in the advancement of paediatric healthcare, research, and policy. It is important for researchers and trialists involved in such trials to understand factors which are important to parents/caregivers when deciding to participate and provide data about their child. There is little evidence to date surrounding the impact of outcome measurement instruments (OMIs) on parents/caregivers' decisions about participation and provision of data in trials. The aim of this project is to examine what characteristics of OMIs are important in parents/caregivers' decisions to engage with and participate in trials of interventions to prevent childhood illness and/or improve child health outcomes.

Methods

An online cross-sectional survey is being conducted. Survey recruitment began July 2024 and will be completed in October 2024. Parents/caregivers are eligible to participate if they have at least one child up to 12 years of age; there are no restrictions based on factors such as gender or nationality. Survey participants are being recruited using convenience sampling via social media, parenting websites, and

Open Peer Review

Approval Status ✓

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1. **Hannah May Scott**, King's College London, London, UK

Any reports and responses or comments on the article can be found at the end of the article.

online forums. This survey includes questions about parents/caregivers' preferences for how, when, where, and with whom data is collected in child health research, as well as the types of OMIs parents/caregivers would be most comfortable using. Data will be analysed using descriptive statistics.

Conclusions

Findings from this study will address the current gap in knowledge related to preferences of parents/caregivers in how data are collected in trials of interventions to improve health outcomes in children. Study findings will inform trialists in the design and conduct of child health research in the future. Implementation of study findings in future trials can also improve experiences of children and their caregivers engaged in research and enhance the quality and quantity of data being collected.

Keywords
Children, Paediatric, Outcome Measurement Instruments, Trial Design, Data Collection

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Competing interests: No competing interests were disclosed.

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Introduction

Health research involving children can include exploring their experiences of illness and healthcare and/or interventions that seek to prevent ill health and/or improve health outcomes. Often interventions targeting child health outcomes are examined using trial methods, and findings from trials of interventions to improve child health outcomes and/or prevent illness can influence healthcare, research, and policy (Naka *et al.,* 2017). Such trials can include examination of pharmacologic, non-pharmacologic, behavioural and/or lifestyle interventions, to determine impacts on child health outcomes including prevention/reduction of illness and symptomatology and improvement/maintenance of good health (Naka *et al.,* 2017). The findings of these trials play a critical role in informing age-appropriate and evidence-based care in children. This is because, for instance, drugs often metabolize differently in children than adults (Joseph *et al.,* 2015; Rieder, 2018); certain diseases, such as hyaline membrane disease or neonatal respiratory distress syndrome in newborns, exist only in pediatric populations (Bavdekar, 2013; Dyer, 2019); and interventions may have varying levels of effectiveness in children (Field *et al.,* 2004; *Methods for Child Health Reviews / Cochrane Child Health*, n.d.). As such, it is vital that trials of interventions involving children up to 12 years of age, as well as their caregivers responsible for their care and illness management, are conducted to the highest standard. Caregivers often play a more active role in health-decision making for children under 12. From 12 years on children are suggested to have the capacity for more autonomy in "decision-making situations" (Grootens-Wiegers *et al.,* 2017), which may include the decision to engage with health research.

Within trials of child health interventions, the recruitment and retention of children and their parents and caregivers to health studies can pose unique challenges (Cohen *et al.,* 2010; Kim *et al.,* 2020). Perceived risks and benefits associated with a trial (Hoberman *et al.,* 2013), trust in the study team (Greenberg *et al.,* 2017), and participant burden (Hein *et al.,* 2015; Tromp & van de Vathorst, 2019) have been identified as factors impacting caregivers' decisions to consent or not consent to their child's participation in health research. Despite evidence for factors such as these (Greenberg *et al.,* 2017; Hoberman *et al.,* 2013), the impact of outcome measurement instruments (OMIs) used in trials on recruitment, retention, and engagement is largely under-researched. Characteristics of outcome measurement instruments, such as measurement properties, acceptability, feasibility, and burden, may impact involvement in trials of child health interventions. Given that trial findings are only as good as the data underlying them, and the type and quality of data collected are only as good as the tools used to collect them (Coster, 2013; Tugwell *et al.,* 2007) it is important to understand how best to select and utilize OMIs that are appropriate for children and their caregivers in trials.

This recognition of the importance of considering appropriateness and feasibility for caregivers and children can be seen in studies such as the 'PARENT' trial (Vanderloo *et al.,* 2021). This trial found that engaging with a parent panel early in trial design, specifically focusing on recruitment, engagement, and the intervention, contributed to notable improvements in the trial protocol (Vanderloo *et al.,* 2021). Though not explicitly focused on OMIs, these findings highlight the integral role of caregiver perspectives, and reinforce that the priorities and focus of caregivers may be different than that of trialists. For instance, in a survey of families of extremely preterm infants, behavioural problems, emotional health, and hyperactivity were identified as 'major' long-term outcomes of concern, despite often being considered 'mild by the medical literature' (Jaworski *et al.,* 2022). Such findings further underscore the value and need to consider perspectives of those stakeholders who engage with and potentially benefit from trials. While research is currently being undertaken to explore trialists' perspectives on what and how to choose OMIs when designing a trial (Matvienko-Sikar *et al.,* 2024), there is little to no evidence about these perspectives and preferences for caregivers in the context of trials of child health interventions and child health research more broadly. Caregivers' perspectives and preferences for OMIs may influence whether they and their children are likely to take part in, and contribute meaningfully to, trials that have the potential to make an impact on future child health research, policy, and practice.

The choice and characteristics of OMIs have the potential to influence the amount and quality of data collected in trials of child health interventions through impacting participant recruitment and engagement in data collection. Understanding if and what characteristics of OMIs influence caregiver engagement with data collection in child health research, can inform choice and use of OMIs in future trials of child health interventions and broader child health research. This can maximise the quantity and quality of data provided while ensuring that data collection approaches are appropriate, acceptable, and feasible for children and their caregivers.

Aim

The aim of this project is to examine what characteristics of OMIs are important in caregivers' decisions to engage with and participate in trials of interventions for child health outcomes.

Methods

Design

An online cross-sectional survey will be conducted. The study is currently ongoing; it began July 17, 2024, and is anticipated to be completed by October 2024.

Participants

Participants in this study are primary caregivers, who are ≥ 18 years of age, with at least one child up to 12 years of age. Primary caregivers are operationalised as biological and non-biological parents and can also include grandparents or others who provide a primary caregiving role to the child. An age range of up to 12 years is used as children and adolescents over 12 years of age can have a more active role

in decision making and participation regarding child health research, and so are not the focus of this study. There are no restrictions on caregiver and/or child gender, ethnicity, or location.

Recruitment

Participants will be recruited using convenience sampling online via social media (e.g. Instagram, TikTok, Reddit, Twitter/X, Facebook), parenting websites, and online forums. A study recruitment advertisement will be shared on social media and parenting websites and forums (please see extended data,); additional recruitment information (please see extended data,) will be shared on parenting forums as these platforms allow for provision of more information during recruitment. Recruitment approaches will be targeted and iteratively reviewed to maximise recruitment of a diverse and representative sample of caregivers internationally. As this study involves an exploratory survey and no hypotheses are being tested, sample size calculations have not been conducted. The study will instead aim to recruit as many participants as possible, aiming for a minimum sample size of 400 participants.

Data collection

Data will be collected using an online survey including 22 closed ended questions (please see extended data,) that will be hosted on Qualtrics. Participants will provide data on demographic factors (age, gender, nationality, ethnicity, relationship status, education level, employment status, and number of children), their child(ren) (ages, gender current health, health at birth, previous illness or health condition(s)). Caregivers will also indicate if they or their child(ren) has previously been involved in a research study, what it was about, and how they provided data. Caregivers will indicate the types of OMIs they would be most comfortable using in future child health research. They will also indicate on a 3-point scale the extent that different OMI characteristics would influence whether they provide information in a child health study. Finally, caregivers answer four questions indicating their preference for where, how, when, and with whom they would prefer to provide data in a child health study. A final open-ended question will ask participants if there is anything additional they wish to add.

Analysis

Descriptive statistics will be conducted. Frequencies and percentages will be calculated for categorical variables; means and standard deviations will be calculated for continuous variables. Dependent on the sample size and diversity, subgroup analyses will be conducted based on income, education level, geographic location, previous experience of child health research, and trust in child health research. Responses to the open-ended question will be analysed using content analysis.

Discussion

The aim of this study is to evaluate what characteristics of OMIs are important to caregivers of children participating in health research. To date, there is little to no research on the impact of the characteristics of OMIs, such as type, length, burden, or how, where or by whom they are collected, on recruitment and retention in child health trials. The results of this study will inform the selection of OMIs in future trials of child health interventions and can potentially improve recruitment to, and the experience of both caregivers and children engaging in research.

Ethics and consent

All research activities will be conducted following the University College Cork (UCC) Code of Research Conduct, the Declaration of Helsinki, and in accordance with General Data Protection Regulations (GDPR). Ethical approval was obtained from University College Cork's Social Research Ethics Committee on July 15th, 2024, (ID Log No. 2024–148), Participants will be provided with full study information leaflet (please see extended data). The information leaflet will include the study aims, what is involved in participating, their ethical rights, how data will be managed in the study, and contact information for the study team. It will be made clear in the participant information leaflet that participation is voluntary, and participants can withdraw from the study any time up to the point of submitting their survey responses (at which point it will not be possible to identify individual participants due to the anonymous nature of the survey). Following reading this information leaflet, participants will be taken to an electronic consent form and must provide electronic informed consent (please see extended data) via the Qualtrics platform before gaining access to the survey. Following survey completion, the study aims and approach to data management will be restated; participants will also be provided with the team's contact information upon completion. The anonymous aggregated dataset in this study will be stored in accordance with the UCC Code of Research Conduct, the UCC data protection policy and the European General Data Protection Regulations (GDPR). Any potentially identifying data provided by participants in 'free response' text boxes will be anonymised, with any potentially identifying features removed, in the final paper. Data will also be stored and managed in line with the Findability, Accessibility, Interoperability, and Reuse of digital assets (FAIR) Principles. Data will be stored for a minimum of ten years on the UCC-supplied OneDrive for Business using Microsoft Teams.

Dissemination

Findings from this study will be disseminated as a peer-review publication and as presentations at seminars/webinars and academic conferences. An infographic summary of anonymous aggregated study findings will also be shared on social media (i.e., Twitter/X) and on the EPOCH-Translate (Translating Early Prevention of Obesity in Childhood) website.

Study status

Data collection is currently underway.

Data availability

Underlying data

No underlying data are associated with this article.

Extended data

Open Science Framework: What aspects of outcome measurement instruments are important to parents and caregivers in child health trials

https://doi.org/10.17605/OSF.IO/5UPFN (Matvienko-Sikar & Duffy, 2024)

This project contains the following extended data:

- Extended Data (1) Survey Recruitment Flyer_Parent and Caregiver Survey.pdf
- Extended Data (2) Participant Information Leaflet_Parent and Caregiver Survey.pdf
- Extended Data (3) Participant Consent Form_Parent and Caregiver Survey.pdf
- Extended Data (4) Online Survey_Parent and Caregiver Survey.pdf

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Publisher Full Text

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Open Peer Review

Current Peer Review Status: ✔

Version 1

Reviewer Report 31 October 2024

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✔ **Hannah May Scott**
King's College London, London, England, UK

Thank you for the opportunity to review this study protocol. This work this protocol is aiming to conduct is to identifying aspects of outcome measurement instruments that parents and care givers of children under 12 feel are most important. This is incredibly important given the limited existing evidence in this area and the importance of using standardised, psychometrically valid and acceptable outcome measures in clinical trials in paediatrics.
This protocol has many strengths.
The introduction is very comprehensive and identified a clear gap and need for the study.
The methods are well detailed and provide ample detail to enable replication.
Ethical considerations have been well addressed, which is especially important in paediatric research.

One minor comment:
If the authors could provide a rationale for the sample size, it would strengthen the protocol.
Overall the protocol is comprehensive and well written and I recommend it is accepted for indexing.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Research with children and families, outcome measurement development and implementation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.