RHABIT | Recording HArms in Behavioural change Intervention Trials

Summarised form of: Recommendations on how to identify and record harms in Behavioural Change Intervention Trials

Executive Summary

Background

Harms can arise from Behavioural Change Interventions (BCI); however, there are difficulties in how to record harms efficiently. Harms are often defined by medical terminology which may mean important harms or consequences of an intervention are missed. There are also problems in how to efficiently collect and record harms. There can often be a high burden of recording harms not relevant to BCIs or trial procedures.

This document provides a summarised form of the recommendations on how to identify and record harms specifically within BCI trials.

Methods

The recommendations are based on evidence generated from a project called RHABIT, funded by the NIHR Efficient Studies funding stream.

The aim of this project was to collaborate across Clinical Trials Units to determine appropriate practice for the collection and recording of harms in BCI trials to develop recommendations.

The recommendations were developed in four work packages (WP).

WP1: A systematic scoping review was undertaken to identify categories and mechanisms of harms, as well as principles, methods, or approaches to recording harms in BCI trials.

WP2: A qualitative study using in depth qualitative interviews (n=15) and focus groups (n=3) was conducted with multi-disciplinary trial experts to explore views and experiences of harms recording in BCI trials.

WP3: The evidence identified in the systematic scoping review and qualitative study was used to draft recommendations on how to record harms in BCI trials.

WP4: The draft recommendations were reviewed in two online workshops attended by multi-disciplinary experts in clinical trials.

Results

A summarised and full format of the recommendations were produced.

The summarised recommendations

This is the summarised version of the recommendations which comprise this document, an overview infographic (Figure 1), and signposting to further information/resources including the full recommendations.

The full recommendations

The full recommendations are published in the BMJ Research Methods and Reporting:
Papaioannou D, Hamer-Kiwacz S, Mooney C, Sprange K, Cooper C, O'Cathain A.
Recommendations on recording harms in randomised controlled trials of behaviour change interventions. 2024;387:e077418. doi:10.1136/bmj-2023-077418

The supplementary material in the full recommendations also includes two checklists to guide 1) Identifying anticipated potential harms from behaviour change intervention; 2) Data collection of anticipated and unanticipated harms in behaviour change trials.

There are two parts to the recommendations:
Part One describes:

- The need to acknowledge harm is possible from BCIs
- Three steps to identify plausible harms from an intervention: Theorising, searching the literature and considering stakeholder views- particularly the patient/public.
- Consider if anticipated harms are captured by the Good Clinical Practice definition of harm.
- The need to identify harms which are expected with a trial population (i.e., events because of their medical condition or due to other conditions/life circumstances).
- The need for a proportionate and efficient and efficient approach to harms recording.
- The importance of transparency in harms recording.

Part Two focuses on practical tips on how to collect harms data such as:

- Using a range of data collection methods including both direct and open-ended questions, qualitative research and instruments.
- Monitoring and adapting the approach to harms recording.
- Training the research team.

- Considering the potential of reporting bias between trial arms.
- Attribution.

The systematic scoping review is reported here:

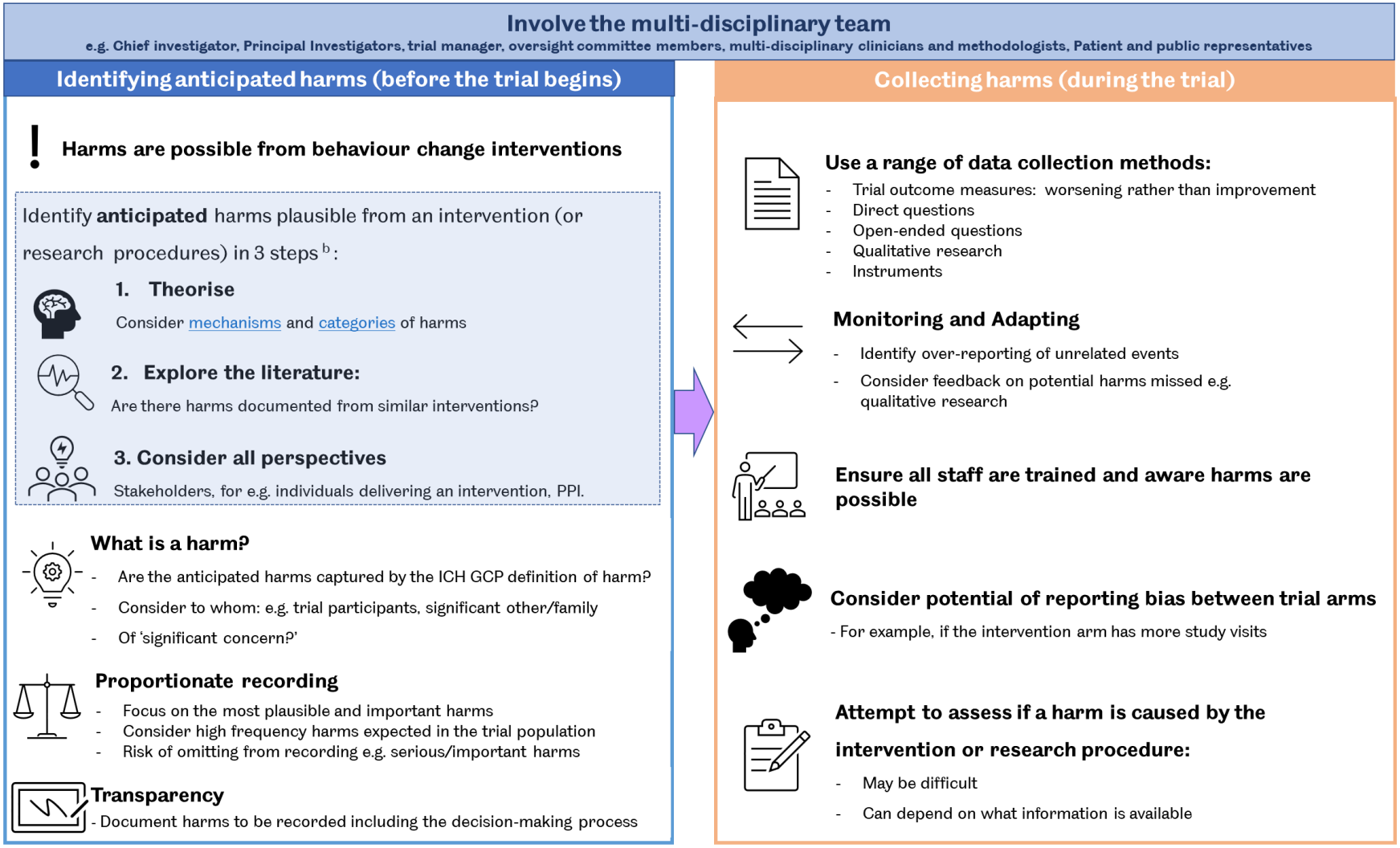
Papaioannou D, Hamer-Kiwacz S, Mooney C, Cooper C, O'Cathain A, Sprange K & Moody G (2024) Recording harms in randomised controlled trials of behaviour change interventions: a scoping review and map of the evidence. Journal of Clinical Epidemiology, 111275-111275. https://doi.org/10.1186/s13063-024-07978-1

The systematic scoping review identified mechanisms and categories of harm in behaviour change interventions. These are described within the manuscript. The systematic scoping review also provides empirical examples of harms arising from BCIs in different clinical areas/populations; select examples appear in the manuscript, with further examples within the supplementary material.

Conclusions

These recommendations on recording harms in randomised controlled trials of behaviour change interventions has been produced through evidence-based research from the findings of a systematic scoping review and qualitative study. Multi-disciplinary trial experts including clinical trials unit staff, clinical investigators and patient and public representatives welcomed these recommendations and could envisage themselves using.

Figure 1: Infographic of the recommendations



[a] Dark logic model approach: Bonell C, et al. J Epidemiol Community Health. 2015; 69: 95-98; [b] Harm defined as an event or an unintended consequence plausibly caused by the trial intervention or procedures, and which is of concern to a study participant or other relevant person e.g., a significant other (e.g., partner, family member) or other person involved in trial delivery or participant care (e.g., intervention facilitators, research personnel, General Practitioner). ICH GCP definition of harm= adverse event "untoward medical occurrence"