Research protocol

Experiences of involving patients and the public as partners in randomised clinical trials: a qualitative evidence scoping review protocol.

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Introduction

Over the past two decades, there has been growing interest in involving patients and the public as partners in health research, rather than only as research participants (1). The practice of involving patients and the public as partners has also become more common in randomised controlled trials (herein referred to as 'trials'). Patient and public partners have roles in many aspects of trials including identification of research priorities, protocol development and co-developing recruitment and retention strategies (2–5).

There are several aspects why Patient and Public Involvement (PPI) is important to trials (6). Firstly, it is considered 'the right thing to do' as the public should 'have a say' on publicly funded research. Secondly, it aims to improve the quality of research and help research to be more person-centred. PPI could also bring in people's perspectives of their lived experience to positively influence research. Furthermore, it is increasingly expected by research funders, organisations and research ethics committees (6).

While the general experience of relevant parties engaged in PPI within health research has been evidenced in the literature; experiences specifically in a trials context is often less well evidenced. Of the studies that have investigated experiences of trials teams, patients, or the public as partners within trials, these have focused on experience in certain contexts. For example, in trials in a specific clinical field (e.g urology, oncology) or trials of specific types of interventions (e.g surgery) (7–9). The scoping review described in this protocol seeks to bring together the reporting of experiences of involving patients and the public as partners across trial contexts, regardless of the clinical fields or type of interventions, to support transferable learning. This scoping review aims to review the evidence to understand the experience of relevant parties when involving patients and the public at any stage of a trial, specifically exploring what worked well and what could be improved.

Objectives

- To review the evidence reporting the experience of trial teams of PPI at any stage of trials.
- To review the evidence reporting the experience of patients, and/or the public of PPI at any stage of trials.
- To identify research gaps within existing evidence of experiences of trial teams and patient/public partners of PPI at any stage of trials.

Methods

A scoping review will be conducted to identify available evidence on experiences of involving patients and the public as partners in trials. Scoping review methodology has been chosen to appropriately synthesis findings from our study objectives (10). According to the guidance (11), one of the uses of scoping review is to identify available evidence and identify gaps across a body of literature without an exhaustive search to gather all of the evidence. The purpose of this method is different to a systematic review, a systematic review (often with a meta-analysis) is useful for a specific defined question (for example, what is the effectiveness of intervention of X compared to Y in Z population?). Although scoping reviews have a broader remit compared to systematic reviews, they are required to be systematic and transparent in their methods(10,12).

The scoping review will use the Joanna Brigg Institute (JBI) methodology (13). Studies eligible for inclusion in the review will adopt the Population, Concept and Context (PCC) framework (13).

- Population : Trial teams, patients, and/or public partners.
- Concept : The phenomenon of interest is trial teams', patients', and/or public partners' experience (as captured using qualitative methods) of PPI at any stage of trials.
- Context : Any stages of trials (from design to dissemination) in any country.

Prior to this review, a preliminary search of protocols on the PROSPERO database was conducted to ensure no ongoing review on this topic.

Search Strategy

The scoping review will use two approaches to searching the literature for relevant studies: a database search and snowballing of references and citation.

Database searching

Search terms used for the database search is attached in Appendix 1. The database search strategy will be designed by the lead author and reviewed by an information specialist. Ovid MEDLINE will be searched from 2014 to March 2024. We will limit the database search from the previous ten years, however, the snowballing method will capture papers prior to 2014. Results from the database search will proceed to the screening process and full text assessment where relevant (see Screening process for details). The snowballing method will be applied to eligible papers identified from the database search.

The snowballing method

The snowballing method will be used to complement the search strategy. The search will commence with the identification of an initial set of studies, herein referred to as 'initial set' (see Initial set for details).

The snowballing method consists of the following steps (Figure 1):

1. Identification of an initial set of relevant papers.
2. Retrieval of abstracts from citations (forward snowballing), references (backward snowballing) for each paper in the initial set.
3. Application of inclusion/exclusion criteria to all new abstracts and full texts to assess final inclusion.
4. If new studies are included, repeat the snowball process.

5. This will be repeated for an additional two iterations (3 iterations in total; following recommendations from Hirt (14)).

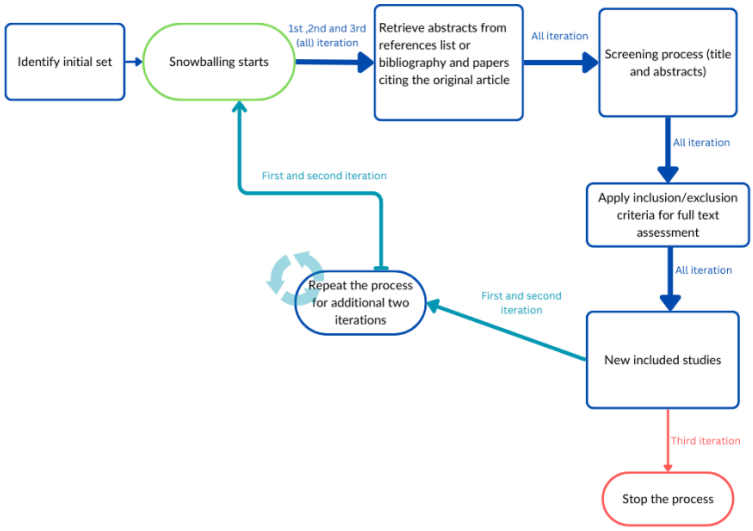

Figure 1 Snowballing process

Each step is detailed below.

Initial set

The initial set is defined as a list of papers sourced at the beginning of the review to systematically guide the snowballing process, as outlined by Wohlin et al (15). Papers in the initial set will need to satisfy the eligibility criteria for the studies to be included in the final inclusion (15,16). We will check and confirm the eligibility criteria of papers in the initial set by using an eligibility form. In this review, the initial set was identified by the study team.

Snowballing process

The snowballing method is a search strategy that uses citation network surrounding a 'source' paper to identify more papers (14). It will involve examinations of the citation network of the initial set. A citation network consists of backward and forward snowballing. Backward snowballing is performed by scanning the references or bibliography of the original paper. Forward snowballing is performed by scanning the papers that cite the original paper (14).

Forward snowballing will identify papers cited in the initial set as listed in PubMed. Backward snowballing will identify papers which the original articles cite as listed in Scopus or other databases or manually.

There will be three iterations of snowball cycles following recommendations from Hirt (14) demonstrated in Figure 1.

The snowballing method will support a broadening of the literature search without having large numbers of irrelevant studies. It is estimated this snowballing method will help to produce a more targeted and refined review (14).

Eligibility criteria

Inclusion criteria

- Participants/population of interest
    - Studies involving trial teams and/or patient and/or public partners.
- Phenomenon of interest
    - The phenomenon of interest is trial teams', patients', and/or public partners' experience (as captured using qualitative methods) of PPI within trials.
- Context
    - Any stages of trials (including design, delivery, analysis or dissemination) and any phase (I, II, III or IV) in any country.
- Study design of interest
    - Any study with qualitative data that is set within trial contexts.
    - Studies with qualitative data collection methods such as interviews, focus groups, observations, workshop, and/or document analysis.
    - Studies with qualitative data analysis such as thematic analysis, content analysis, or other qualitative analysis.
    - Qualitative evidence synthesis.
- Time frame
    - Database search: studies conducted from 2014 to March 20, 2024.
    - Snowballing method: studies conducted from inception up to March 2024.
- Language
    - All.
- Publication type/status
    - Published literature.

Exclusion criteria

- Studies reporting trial experiences of (potential) trial participants i.e. not patient/public partners in research.
- Studies reporting involvement experiences of trial teams and/or patient/public in general research, other health research or lab related research.
- Protocol, editorials, commentaries and other studies that have not adopted clear qualitative methodology.

Screening process

Screening stage (Title and abstract)

Papers will be retrieved, and duplicates will be removed prior to screening. The number of duplicates will be recorded for the PRISMA Scr flow chart (13). Pilot screening will be conducted by all reviewers for a subset of title and abstracts (up to 20 titles) to ensure consistency in application of eligibility criteria. A screening decision tool will be used to record decisions and compare screening decisions between reviewers. During pilot screening, any papers with overlapping agreement (i.e all reviewers

agree to include) will be included for the next review stage. Papers with varying decisions will be discussed between reviewers to reach consensus, and any adjustments to the eligibility/screening criteria will be revised accordingly. Screening will be conducted on the remaining titles and abstracts against the eligibility criteria by one reviewer, with a random 10% double checked by another reviewer. Any uncertain abstracts will be discussed by the review team to reach consensus. In cases where abstracts remain to be 'uncertain' after discussion, abstracts will undergo full text retrieval and assessment.

Full text assessment

Papers from abstracts that require full text assessment will be retrieved. Full texts will be carefully assessed using inclusion and exclusion criteria by one reviewer. The first reviewer will review all the papers during this stage and the second reviewer will screen a sample of papers (10%), or all if only a small number of studies are identified. Any disagreements will be resolved through discussion and a third reviewer's opinion will be asked to reach consensus. Reasons of exclusion will be recorded.

Reference and data management

A reference manager (Zotero) will be used to manage any necessary metadata from the papers or abstracts. The reference manager will also be used to record the snowballing process. Deduplication of papers will be supported using Microsoft Excel. All data from the review will be stored securely in a backed-up University shared drive.

Data extraction form

A data extraction form will be developed. The data extraction form will be piloted on 2-3 studies. A data extraction form will be created in a spreadsheet and will include the following details:

- Study identification
    - Author, title, article type, journal, country, source of papers, year of publication.
- Study details
    - Aim of study, study design, trial stage, clinical field, intervention type, stage of involvement in the trial, time points of data collection.
- Population details
    - Who is the relevant parties/person, numbers of participants, gender information, age, ethnicity, socio-demographics, other noteworthy characteristic of participants.
- Reported data on experiences and views:
    - First order construct
        - Description of experiences of trial teams and/or patient/public (participant quote verbatim).
    - Second order construct
        - Author's interpretation of experiences of trial teams and/or patient/public.
- Other noteworthy description or details

First and second order constructs conceptualized by Schütz will be used to guide data extraction(17). First order constructs use the reported experiences of trial teams and/or patients and/or public (from participants quotes) from the results section of a paper. Second order constructs use author's existing interpretations (including themes) which will be likely found in the discussion or result sections of the paper (17).

The first reviewer will extract all data from full text studies. Following this, a second and/or third reviewer will double check a subset of data (10%) to ensure consistency.

Analysis and Presentation:

A PRISMA-scr diagram (13) will be used to report the scoping review process. Descriptive statistics will be used to describe the participant and trial characteristics of the included studies. A narrative summary using thematic synthesis will be undertaken to report relevant parties' experiences of involvement in trials. We will thematically synthesise the findings following steps recommended by Thomas and Harden (18): coding, development of descriptive themes and analytical themes. Qualitative data management software (e.g NVivo, Citavi) may be used to facilitate data organisation.

Following the JBI guidance of scoping reviews, it is not a requirement to conduct a quality appraisal of the findings; findings will be summarised narratively and will be presented as textual description and tabular forms. A narrative summary will be described in relation to the review objectives.

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Appendix 1

Ovid MEDLINE(R) anOvid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to March 20, 2024>

1 exp Clinical Trials as Topic/ 389037

2 (clinical adj3 trial?).tw,kf. 531421

3 1 or 2 815345

4 *community participation/ or *patient participation/ or *Intersectoral collaboration/ or *Community-Based Participatory Research/ 30929

5 ((public or patient? or citizen? or survivor? or volunteer? or consumer? or user? or stakeholder?) adj3 (involv* or participat* or engag* or collaborat* or cooperat* or co-operat*)).ti. 14557

6 4 or 5 41591

7 exp Empirical Research/ or Interviews as Topic/ or Personal Narratives as Topic/ or Focus Groups/ or exp Narration/ or Nursing Methodology Research/ or Narrative Medicine/ 185686

8 (Interview or Personal Narrative).pt. 37164

9 interview*.tw,kf. 477377

10 qualitative.tw,kf. 348421

11 (theme* or thematic).tw,kf. 183774

12 ethnograph*.tw,kf. 14642

13 phenomenol*.tw,kf. 35946

14 mixed method?.tw,kf. 46155

15 (grounded adj (theor* or study or studies or research or analys?s)).tw,kf. 16116

16 ((purpos* adj4 sampl*) or (focus adj group*)).tw,kf. 90720

17 (open-ended or narrative* or textual or texts or semi-structured).tw,kf. 200546

18 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 969284

19 3 and 6 and 18 670

20 limit 19 to yr="2014 -Current" 416