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Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis (Protocol)

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[Qualitative Protocol]

Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis

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ABSTRACT

This is a protocol for a Cochrane Review (Qualitative). The objectives are as follows:

The aim of this qualitative evidence synthesis is to explore the perceptions and experiences of potential and actual participants and trial recruiters to improve understanding of how interventions, strategies and processes of recruitment to RCTs potentially work for specific groups across different settings and contexts. The specific objectives of this review are:

1. to describe recruiters' perceptions and experiences of recruiting participants to RCTs;
2. to describe potential and actual participants' perceptions and experiences of recruitment to RCTs;
3. to describe why potential participants accept or decline participation in RCTs;
4. to explore the barriers and facilitators to participation in RCTs;
5. to explore how perceptions and experiences of trial recruitment interventions, strategies and processes influence the decision-making of potential and actual participants;
6. to explore to what extent the barriers and facilitators identified are addressed by interventions and strategies designed to improve recruitment evaluated in a previously published Cochrane review ([Treweek 2010](#)).

BACKGROUND

Randomised controlled trials (RCTs, also referred to as 'ran-

domised trials') are the best design to use when evaluating the effect of competing treatments, therapies and innovations; by design

they minimise confounding and offer an evaluation method with a reduced risk of systematic errors compared to other types of studies used in health research (Burns 2011). An estimated 75 trials evaluating healthcare interventions involving medicinal products, devices and services are published globally each day (Bastian 2010); these provide evidence to support the decision-making of policy-makers, clinicians and healthcare professionals. Each of these trials requires a specific number of participants to volunteer to take part; this process of participant recruitment is known to be a challenge (Campbell 2007; Trewweek 2010).

Description of the phenomena of interest

Estimates suggest that around half of trials fail to recruit to target (Charlson 1984; McDonald 2006; Bower 2007; Sully 2013). Reduced or delayed participant recruitment to trials can have considerable consequences. If participant recruitment does not meet the sample size specified in the design stages by the trial's own statisticians, results run an increased risk of being subject to type II error (the possibility of finding no significant difference between intervention groups where one does exist) (Thoma 2010), which undermines the performance of the trial. If trials do recruit to target but suffer delays and timeline extensions, this can result in increased costs, may delay the availability of beneficial interventions to the public, or could allow harmful or ineffective interventions to be used for longer time periods than is ethically appropriate (Watson 2006). In the very worst cases of participant recruitment, a trial can stall entirely, potentially leading to premature close-down before the research question has been addressed. A study of 125 RCTs, funded by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) program reported that five trials were "abandoned, stopped or closed down". Recruitment issues were a common theme across all five, with participant recruitment ranging between just 0.25% and 20.8% of target (Raftery 2015). A study of one US medical centre identified 260 trials closed due to poor recruitment (zero or one participant) over a five-year period at a cost of almost \$1 million (Kitterman 2011).

Description of the methods being investigated

To gain a thorough understanding of the recruitment process, it is important to explore how and why potential participants are attracted (or not) to participating in a trial, how and why interventions to facilitate recruitment work, and the factors that guide decisions made by both potential trial participants and trial recruiters. By exploring in-depth experiences and perceptions of trial recruitment processes, the barriers and facilitators can be identified and described. Understanding the determinants that have a bearing on decision-making will provide trialists with the knowledge required to implement approaches to minimise negative and boost posi-

tive influences where possible. Examples of potential determinants may include perceived subtleties such as participants having an aversion to a particular communication method, logistical problems such as lack of public transport links, or more fundamental aspects of the process such as randomisation and use of a placebo. This information could have implications for all areas of a trial; from how we communicate information to potential participants, to which sites are chosen for recruitment. Understanding both positive and negative influences on decision-making therefore has the potential to improve recruitment.

How these methods might work

It is unclear whether the factors that influence the decision-making of participants to take part in trials are underpinned by clear practical or theoretical rationales. We are interested in the actions of both potential trial participants and the healthcare professionals they come into contact with, and the way that this interaction may influence the decision-making of both parties with regards to trial participation. The existing Cochrane effects review (Trewweek 2010) sheds light on interventions that are effective, but no details are given as to how these interventions are intended to work and for whom. This review is currently being updated. This will provide a more contemporary understanding of interventions that exist to improve recruitment. One purpose of our review is to examine included research studies for the theorised mechanism of both the barriers and facilitators identified. The findings from this review can be integrated to develop a programme theory that can inform interventions to be used for particular participant groups.

Why it is important to do this review

Previous reviews have focused largely on barriers to recruitment from participants' perspective and the perspective of recruiting clinicians (Prescott 1999; Fletcher 2012). Whilst this body of work offers valuable insight into potential reasons for poor recruitment, it consists of factors that act to impede or hinder trial participation only. Knowing why clinicians or potential participants *do not* participate in trials does not provide constructive information on why they *do* participate in trials. We are aware of reviews incorporating both barriers and facilitators to recruitment but these have focused specifically on participation in trials for particular therapeutic indications (e.g. oncology; Fayter 2007), or trials within minority populations (e.g. indigenous people; Glover 2015). Carrying out an up-to-date comprehensive review that explores experiences and perceptions to uncover both barriers and facilitators for a broad range of participants (both trial recruiters and potential participants), and gaining a better understanding of their respective views and experiences of interventions to facilitate trial recruitment, across a range of healthcare settings and conditions, provides a single point of access for synthesised evidence on re-

recruitment, which can be used to inform decisions around trial methodology.

This review will build on a published Cochrane review ‘*Strategies to improve recruitment to randomised controlled trials*’ (Treweek 2010), which provides a quantitative starting point for the trial methodology community to build knowledge on recruitment practices. The qualitative evidence synthesis proposed here provides a means of presenting the complexities of human experiences in a way that is recognisable to the evidence-based community (Treweek 2010). This review allows us to shed light on how both potential and actual participants and trial recruiters perceive and experience the interventions and processes of recruitment to RCTs, and the factors that impact on these processes. The barriers and facilitators to recruitment can be identified and set in context with the recruitment strategies previously identified by (Treweek 2010). The process of exploring barriers and facilitators in line with previously evaluated recruitment interventions and strategies will allow for these reviews to work effectively together; enabling readers to better understand the barriers and increase facilitators to trial participation in previously evaluated strategies.

OBJECTIVES

The aim of this qualitative evidence synthesis is to explore the perceptions and experiences of potential and actual participants and trial recruiters to improve understanding of how interventions, strategies and processes of recruitment to RCTs potentially work for specific groups across different settings and contexts. The specific objectives of this review are:

1. to describe recruiters’ perceptions and experiences of recruiting participants to RCTs;
2. to describe potential and actual participants’ perceptions and experiences of recruitment to RCTs;
3. to describe why potential participants accept or decline participation in RCTs;
4. to explore the barriers and facilitators to participation in RCTs;
5. to explore how perceptions and experiences of trial recruitment interventions, strategies and processes influence the decision-making of potential and actual participants;
6. to explore to what extent the barriers and facilitators identified are addressed by interventions and strategies designed to improve recruitment evaluated in a previously published Cochrane review (Treweek 2010).

METHODS

Criteria for considering studies for this review

Types of studies

This review will explore qualitative primary research. We will include studies that have used and reported on both qualitative data collection and analysis methods. Data collection methods will include semi-structured interviews, focus groups and observations. As recommended (Sandelowski 2007), mixed-method studies that include qualitative methods of data collection and analysis will also be included if the qualitative component is clearly identifiable and can be extracted.

Types of data

SPICE

Setting

We will include all studies exploring recruitment in RCTs and randomised feasibility studies in health care. An RCT is defined as a study in which people are allocated at random to receive a clinical intervention, one of which is the control comprising of a standard practice, placebo or no intervention at all (Treweek 2010). Feasibility studies help to determine whether the study can be done on a larger scale (Bowen 2009). We will exclude non-healthcare RCTs and non-human, laboratory-based RCTs.

Perspective

The review will explore the perceptions and experiences of people with direct experience of trial recruitment processes. This will encompass ‘recruiters’ and ‘potential and actual participants’. “Recruiters” refer to all clinical staff (e.g. nurses, physiotherapists, physicians, radiotherapists, GPs and surgeons) and/or non-clinical staff involved in recruiting participants to RCTs. We will define ‘potential and actual participants’ as individuals, for example patients, carers, or parents with experience of accepting or declining invitations to participate in RCTs.

Phenomena of Interest

The phenomena of interest include personal beliefs; perceptions and experiences of trial recruitment interventions, strategies and processes that influence decision-making; and the factors that impact on the recruitment process. These could include issues such as trust; the quality and amount of information, the issue of equipoise, and patients’ preferences for particular treatments etc.

Comparison

It is anticipated that during screening, we will identify particular subgroups that allow for comparison and greater understanding of particular factors in recruitment. The subgroups may be derived from specific clinical fields such as surgery and oncology; may be focused on participant groups, for example a comparison between recruiters and potential participants, or look at recruitment of specific groups such as children; or we may consider making comparisons between different geographical contexts.

Evaluation

We intend to use qualitative evidence to better understand the factors that impact on recruitment processes. This in-depth understanding of barriers and facilitators to recruitment will inform the development of future recruitment strategies.

Search methods for identification of studies

Searching for qualitative research is challenging due to unfocused titles, inadequate indexing and other factors (Booth 2011). Consensus has not been reached on whether systematic searching is optimal for qualitative synthesis (Tong 2012). A “berry picking model” of information retrieval (Bates 1989), has been supported by other authors (Barroso 2003; Booth 2011; Finfgeld-Connett 2013), whereby searching for qualitative research is an iterative approach rather than a report of linear search strategies. The comprehensive approach that is necessary for a high-quality, quantitative systematic review of clinical trials is not appropriate for qualitative evidence syntheses (Booth 2016).

We conducted a scoping search to help formulate our research question and identify key search terms. The search strategies for the systematic review will be developed with input from the author team. We will not exclude studies based on language. Translation services will be used to aid us in the assessment for inclusion of non-English language papers. We will not apply date or geographic restrictions.

The search process will be documented in sufficient detail to ensure that it can be reported correctly in the review (including the sources searched, platform, search terms, number of hits etc.). The Methodological Expectations of Cochrane Intervention Reviews, PRISMA and the ENTREQ statement will be used to guide the reporting of searches (Moher 2009; Tong 2012; Higgins 2016).

We will develop a search that will be expansive rather than exhaustive. Sensitivity will be a lesser priority than the specificity of the search. Gauging this will be an iterative process. We will use purposive and theoretical sampling to identify resources as is warranted for a meta-ethnography (Booth 2016). A sample search strategy for the Cochrane Library is detailed in Appendix 1 (Shamseer 2015).

Electronic searches

We will search the following online resources.

1. Electronic databases: Cochrane Library, Ovid MEDLINE In-Process & Other Non-Indexed Citations and Ovid MEDLINE and Ovid MEDLINE Epub Ahead of Print, CINAHL, Embase, PsycINFO, Epistemonikos, LILACS.
2. Google Books (to retrieve books and book chapters).
3. Grey literature sources e.g. Reports, dissertations, theses databases and databases of conference abstracts (e.g. Scopus (for conference proceedings only), ETHOS, ProQuest) and websites of key organisations and professional bodies which may be relevant. Journal articles will be prioritised for inclusion over theses (Booth 2016).

Searching other resources

References

We will perform backward reference searching by examining reference lists of included studies and similar systematic reviews (e.g. TrewEEK 2010) to identify additional relevant resources. We will perform citation searching using Scopus, Web of Science and Google Scholar to view who has cited key and included studies since their publication.

Correspondence

We will contact authors or experts in the field when it is necessary to identify or track down resources which have not yet been published or are not accessible.

Data collection and analysis

Selection of studies

All of the results from the search strategy will be collated and possible duplicates removed. Titles and abstracts will be screened independently by two review authors (CH, LB, AH, MD, PM, HG). Where necessary, another team member will be consulted to confirm and agree decisions (Houghton 2016b). All full-text screening will be undertaken by two review authors.

Data extraction and management

We will extract data directly into QSR NVivo from the full-text resources. NVivo was recently used in another qualitative evidence synthesis and successfully managed all stages of the review from screening to synthesis (Houghton 2016a; Houghton 2016b). In

this review, NVivo will facilitate the authors to extract and synthesise the data in a comprehensive and audit-able way. It will also facilitate the running of 'queries' to determine the adequacy of the data as outlined in the section of 'Assessment of confidence in the review findings'.

We will extract information on: study design, setting, sample, methods, limitations, recommendations and conclusions. In addition, we will extract the findings or data from the studies. Review authors CH, LB, AH, MD, PM and HG will individually extract pertinent information from the full-text resources.

Assessment of methodological limitations in primary studies

Assessment of methodological limitations will be undertaken using a modified version of the Critical Appraisal Skills Programme (CASP) quality assessment tool for qualitative studies (Atkins 2008; CASP 2013). This tool has been used in other reviews and protocols of qualitative evidence synthesis published by Cochrane (Glenton 2013; Rashidian 2013; Munabi-Babigumira 2015; Ames 2017).

CASP does not include some items considered important in relation to the quality assessment of qualitative research (Tong 2012); a view also held by the authors of this review. We propose that CASP does not pay sufficient attention to identifying the scope and purpose of a study and little reference is made to the reflexivity demonstrated by the researcher. To this end, questions 1, 14 and 15 were added to our modification of the tool. We decided that a differentiation between assessment of study conduct and appraisal of study reporting was necessary and both should be included. To support this decision, questions 6 to 11 specifically consider the reporting of the research methods.

The modified tool comprises the following 15 questions.

1. Is the study context and rationale described clearly in light of the relevant literature?
2. Is the qualitative research approach appropriate for the research question?
3. Is the qualitative research approach stated clearly?
4. Is the qualitative research approach justified clearly?
5. Are ethical issues considered and is formal ethical approval granted?
6. Is the sampling method described clearly?
7. Is the sampling method appropriate for the research question?
8. Is the method of data collection described clearly?
9. Is the method of data collection appropriate for the research question?
10. Does the approach to data analysis address the research question?
11. Is the approach to data analysis described clearly?
12. Are the researcher's findings supported by sufficient evidence and by the literature?
13. Are the conclusions/value of the research clearly stated and supported in the text?
14. Is the researcher's role described clearly/discussed?
15. Is there evidence of reflexivity?

The review authors (CH, LB, MD, PM, AH, HG) will work in pairs to assess the methodological limitations of each study. One author will apply the quality appraisal tool to each study; a second author will check the data for any discrepancies. Any disagreements will be resolved in consultation with a third review author. We will conduct a pilot on three included studies. The aim of the pilot is to ensure the feasibility of the tool and the integrity of the assessment.

The appraisal of methodological limitations may not be used to exclude studies, it is recognised that studies deemed to be of a low quality may still provide new insights (Dixon-Woods 2005; Noyes 2008). As suggested by (Hannes 2011) we will include a sensitivity analysis to evaluate the impact of studies of low quality on the findings and the discussion of this synthesis.

Data synthesis

We will synthesise qualitative data to explore the views and experiences of recruitment to trials and the factors that act as barriers and facilitators to participation. We will undertake a thematic synthesis using the three stages recommended by (Thomas 2008). Although we cannot anticipate numbers at this point, thematic synthesis is useful when there are a larger number of studies to review.

As previously outlined, the full-text resources will be imported into NVivo software. The first and second stage of this process involves coding text and developing initial themes. The exact findings of the identified studies will be extracted and 'line-by-line' coding according to content and meaning will be carried out by two review authors independently. We will follow recommendations on a previous synthesis outlining how best to utilise the functions in NVivo, such as cases, nodes, attributes and query tools (Houghton 2016a). All nodes created will be defined for clarity and to enable coding consistency.

Once initial 'line by line' coding is complete, the review authors will examine the findings and 'cross code' comparing codes based on differences and similarities, condensing, and merging nodes of similar content and developing preliminary sub-themes. Each theme will be 'cross coded' against other sub-themes to test their content. This phase of synthesis will involve further distilling of sub-themes and themes by cross checking content, condensing, and merging nodes of similar content. This should result in the number of themes being reduced.

The third stage involves generating the analytical themes. This stage of the process involves interpretation where the review authors will generate new constructs and explanations. Study findings will be re-read to cross check the general context against the sub-themes and themes. The memo function of NVivo will be

used to summarise each review author's beliefs at that point of the analytical process, and allow checking to see whether their interpretation is a true representation of the combined attitudes and beliefs of study participants. Review authors will initially independently 'go beyond' the content of the original studies by considering the themes against the original review questions. Once initial interpretations are obtained, review authors will discuss interpretations as a group and in this way develop abstract or analytical themes (Thomas 2008).

Assessment of confidence in the review findings

We aim to make judgements about the confidence that can be placed in synthesised findings. The Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approach was developed by (Lewin 2015) for this purpose and will be used in this review. An earlier version of GRADE-CERQual has been used in previous Cochrane qualitative reviews (Glenton 2013; Rashidian 2013), with a more recent version outlined in a Cochrane protocol and review (Munabi-Babigumira 2015; Ames 2017). Application of CERQual involves making an assessment of the methodological limitations and relevance of studies contributing to a finding combined with the coherence of the finding and adequacy of data (Lewin 2015).

1. Methodological Limitation refers to the extent of limitations in the design or conduct of the primary studies. If there are important methodological limitations, less confidence can be placed in that review finding (Lewin 2015).

Methodological limitations can be ascertained using a tool for critical appraisal. As described in the previous section, we will use an adapted version of CASP for this review.

2. Relevance is the extent to which the evidence from the primary studies is applicable to the context specified in the review question (Lewin 2015). This may pertain to the relevancy of the population researched, the phenomenon of interest or the setting. We will consider each review finding for relevancy and categorised as having: indirect relevance, partial relevance, and uncertain relevance (Lewin 2015).

3. Coherence refers to identifying patterns in the data across the primary studies included in an evidence synthesis. Coherence explores whether the finding is well-grounded in data and provides a convincing explanation for the patterns found in these data. The review findings are developed from the synthesis and therefore this process is more of a self-reflective exercise (Lewin 2015). We will exercise reflexivity throughout this review both as individual and group endeavours.

4. Adequacy of data is an overall determination of the degree of richness and quantity of data supporting a review finding (Lewin 2015). We will conduct a sensitivity analysis within NVivo software to determine the depth of coding for a review finding (Carroll 2011; Carroll 2013; Houghton 2016a). This will help to identify findings that are not well-grounded in the

data. We will use Matrix coding within NVivo to provide a colour-coded illustration to clearly depict the depth of coding for each review finding (Houghton 2016a).

'Summary of qualitative findings' table

Once these four elements (methodological limitations, relevance, coherence, and adequacy of data) have been considered, the authors (CH, LB, AH, MD, PM, HG) will decide as to whether there are concerns that would impact on the overall assessment of confidence in the review finding. This was the approach used in another review (Ames 2017). The decisions made using CERQual will be presented in a 'Summary of qualitative findings' table. This table, as recommended by (Lewin 2015) and used by (Ames 2017), will illustrate the key findings, and our confidence in the evidence for each, with an explanation of the assessment of confidence.

Integrating the qualitative findings with the linked Cochrane intervention review

We then intend to integrate the qualitative findings with the Cochrane review: '*Strategies to recruit participants to randomised trials*' (Trewick 2010) to better understand how and why interventions and strategies work or not, and for whom in what contexts. This review is currently being updated so we envisage that the ability to integrate our findings will be synchronous.

In addition to knowing what strategies are successful in maximising recruitment, we will potentially have an understanding of what needs to be considered when developing new recruitment interventions and strategies. In an iterative approach we will develop the methods of integration when we have a depth understanding of the qualitative synthesis findings. Gaps in evidence will also be articulated for future research.

Subgroup analysis and investigation of heterogeneity

Depending on the results of our search and screening, subgroups may be identified and synthesis conducted on RCTs in specific clinical areas (e.g. oncology, surgery), participant groups (e.g. recruiters and potential participants; populations (e.g. children, minority groups); or geographical contexts. If applicable, these subgroups will also be applied to the integration of the two reviews. During the subsequent integration with the Cochrane intervention review - there may be opportunities to explore trial heterogeneity with the synthesised qualitative findings.

Sensitivity analysis

We will conduct a sensitivity analysis as outlined in relation to assessment of confidence in the review findings. We may also consider the impact on findings of adding or removing studies with concerns about methodological limitations.

Reflexivity

Reflexivity enhances the audit trail by providing records of personal responses and contributions and can be used by each review team member (Jasper 2005; Thorne 2004; Walsh 2005). Ensuring reflexivity is a priority across this review from protocol to data synthesis. The review team (CH, LB, AH, MD, PM, HG) comprises experienced qualitative researchers with a mix of quantitative/trials experience and clinical backgrounds. ST is author on the original effect review and both authors ST and HG are currently updating that review. As a group, moderation meetings will be held to discuss review findings and negotiate decisions and reflexivity will become part of the written audit trail (Sandelowski 2007). If there are disagreements regarding decisions made throughout the selection and review process, these will be negotiated and an ac-

ceptable resolution reached. This process will be documented, in the form of a reflexive journal and will become part of the written audit trail as proposed by (Sandelowski 2007). In addition, the review team will establish two stakeholder groups; one made up of three to five patient/public members, the other of professional stakeholders (research nurse, ethics committee member, clinical research staff, industry representative). Both of these groups will be established to add value across the review process and will be consulted at stages across the review to ensure integrity of our processes.

Reporting the review

We will implement ENTREQ (Tong 2012) reporting guidelines to report the review.

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* Indicates the major publication for the study

APPENDICES

Appendix I. Cochrane Library Search Strategy

Platform: Wiley Online Library

Years of coverage: database coverage ranges from 1992 to the present

Date of most recent search: 03/11/2016

ID	Search String	No. of Hits
#1	experience* or perceive* or perception or attitude* or opinion or agree* or accept* or refuse* or refusal or decline* or decision or decide* or judge* or prefer* or consent* or autonomy or equipoise or barrier* or facilitat* or opportunit* or challenge*: ti,ab,kw	194948
#2	MeSH descriptor: [Perception] this term only	1162
#3	qualitative or "mixed methods" or feasibility:ti,ab,kw	22078
#4	MeSH descriptor: [Feasibility Studies] this term only	4375
#5	MeSH descriptor: [Qualitative Research] this term only	681
#6	MeSH descriptor: [Patient Selection] this term only	3350
#7	recruit* near/6 trial	6336
#8	#1 or #2	194948
#9	#3 or #4 or #5	22078
#10	#6 or #7	9349
#11	#8 and #9 and #10	833

Limits: title, abstract and keyword field limiters for one search string and proximity operators where appropriate.

Total no. of hits: 833

CONTRIBUTIONS OF AUTHORS

CH, LB, AH, MD, PM, ST, KS and DD devised the review. CH, LB, AH, MD, PM, HG, AC and JRN prepared the protocol. AC developed the search strategy and will conduct the search. CH, LB, AH, MD, PM, HG will actively participate in all stages of the review (conduct searches, obtain data, extract data, synthesise data, prepare review, keep the review up to date). DD, ST, JN and KS will participate in reviewing the studies, data synthesis and will contribute to writing up the review.

DECLARATIONS OF INTEREST

JN: Convenor of the QIMG and Co-Chair of the Methods Executive

DD: Editor with the Cochrane Pregnancy and Childbirth Group