Strategies to increase participant recruitment to research studies by healthcare professionals (Protocol)

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[Methodology Protocol]

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

Our primary objective is to identify and assess the effect of strategies designed to improve the recruitment of participants to research studies by healthcare professionals.

BACKGROUND

Many research studies fail to recruit sufficient participants to answer the questions posed (Pocock 2008). When a study fails to generate robust results because recruitment targets are not achieved, and the intended benefits of the research are not realised, this has economic, temporal, ethical and clinical consequences (Barnes 2005; Ewing 2004; McDonald 2006; White 2008).

Recruitment is usually a three-step process which involves (1) initially identifying potential participants against inclusion and exclusion criteria, (2) then approaching or mailing them about the study in question prior to (3) consenting. This may be guided by researchers but the first two steps (and sometimes all three) usually fall to the local clinical team who have access to patients and their medical notes. However, healthcare professionals can intentionally or unintentionally act as 'gatekeepers', potentially introducing bias to patient selection, or affecting the rate of patient identification and therefore recruitment. This review aims to evaluate strategies to increase participant recruitment to research studies by healthcare professionals.

Description of the problem or issue

The reasons why healthcare providers do not identify and approach patients for studies, despite having a responsibility to do so, are complex. They include protection of vulnerable patients, the impact on their relationship with patients, perceived lack of skill in introducing a request for research participation, concerns about treatment equipoise and the prioritisation of work-

load (Department of Health 2009; Ives 2009; Mason 2007; White 2008).

The EU data protection directive was adopted across Europe in 1994 and has resulted in much tighter controls of private data (Slemmons 1998). In the US, the privacy and data protection policies are less stringent but this has been tightened up. There has been considerable debate about the implementation of the EU directive and its effect on research access and interpretation (Lawlor 2001; Redsell 1998; Strobl 2000). In the UK in particular, the Data Protection Act 1998 places intervening stages between researchers and the target population with Multicentre (MREC) and Local Research Ethics Committees (LRECs) having responsibility for ensuring an ethical approach to patient identification and recruitment is taken in adherence with the Act and research governance directives. While ethical safeguards are needed they may have a detrimental effect on patient identification and recruitment and ultimately on the rigour and completion of studies.

Further, many research studies are multicentre or run across hospital departments. This then involves a number of clinical staff identifying and approaching potential participants on the researchers' behalf; researchers or the clinical staff may then recruit these people to the study following informed consent, depending on the study design. This has resulted in healthcare professionals acting as gatekeepers for recruitment to research studies. It is therefore critical that we find ways to facilitate the identification of patients for research studies by healthcare professionals, so that patients can exercise autonomous choice.

Current systematic reviews do not specifically focus on ways of supporting healthcare professionals in the identification of research participants. For example Treweek 2010 focus on a broader recruitment question (the effects of all strategies on participant recruitment, not just those focusing on interventions aimed at healthcare professionals) and for a single type of research design: recruitment to randomised controlled trials (RCTs). The Rendell 2007 review examined a narrower question on incentives, but again just with trials: the evidence for the effect of disincentives and incentives on the extent to which clinicians invite eligible patients to participate in RCTs of healthcare interventions. Bryant 2005 also examined the impact of paying healthcare professionals to recruit patients, but once again to trials only. There is no review which investigates strategies specifically designed to facilitate healthcare professionals to identify patients for study designs other than RCTs. If the study design requires it, healthcare professionals may have to give potential participants a verbal explanation of the study: this may be more difficult in the case of randomisation, whereas explaining an observational or interview study may be more straightforward.

Description of the methods being investigated

Non-clinical members of a research team or clinical members working in a different department or institution may have no direct contact with potential participants. Typically, when working with healthcare professionals to recruit eligible patients, researchers inform healthcare professionals of the study criteria and give them responsibility for identifying and approaching participants.

We will investigate any proposed strategy that has the potential to encourage healthcare professionals to identify, approach and ultimately recruit possible research participants. This may include inducements or incentives, methods to streamline patient identification, or methods to reduce the time or administrative burden on healthcare professionals. The final step of study entry (obtaining informed consent) may be conducted either by the healthcare professional or more likely by the research team, and is usually the primary measure of recruitment outcome.

How these methods might work

It is unclear whether methods are underpinned by clear practical or theoretical rationales for their effectiveness. Our primary interest is behaviour change: change in the actions of healthcare professionals towards rather than against identifying potential participants. It may be that theories of behaviour change will help explain successful methods. One purpose of our review will be to examine included research studies for the theorised mechanism of successful methods identified.

Why it is important to do this review

This review will provide an evidence base to enhance the recruitment of patients by healthcare professionals for research studies. This has potential to reduce bias in patient selection, increase the rate of patient identification and, ultimately, recruitment; so enabling timely and economic completion of studies with greater validity. Given the backdrop of limited access to participants for research studies, it is important that any strategies that can facilitate this are identified.

OBJECTIVES

Our primary objective is to identify and assess the effect of strategies designed to improve the recruitment of participants to research studies by healthcare professionals.

METHODS

Criteria for considering studies for this review

Types of studies

We will include designs such as quasi-randomised/randomised controlled trials, interrupted time series and controlled before and after studies. The included studies will be designed to improve recruitment by healthcare professionals to research studies of any design.

Studies will include participants from primary, secondary and tertiary care. Participants can be inpatients or outpatients. Healthcare professionals will include any registered practitioners and wider members of the clinical team who have responsibility for recruiting patients to a study and have access to their medical notes (e.g. nurses, allied healthcare professionals, doctors and clinical trials managers).

Types of data

We will include data from any eligible study which assesses the effects of different identification and recruitment strategies, which have been used to improve recruitment by healthcare professionals. This may be a trial where the primary aim is to evaluate the recruitment strategy or it may be nested within a study of a clinical question.

We are only including studies from 1985 onwards as we think that research that is useful to this review will come after this date, arising from the increase in research governance across the European Union, in particular, but also in the United States.

Types of methods

Strategies and interventions to increase the recruitment of patients to research studies by healthcare professionals.

Types of outcome measures

Primary outcomes

The proportion of the target population recruited to the study. We will use proportion recruited as a proxy for the effect of the strategy for both the identification and recruitment of participants.

Secondary outcomes

Where available we will assess the following secondary outcome measures:

- Recruitment rate (over time)
- Acceptability of recruitment strategy to healthcare professionals
- Cost-effectiveness of the strategy

Search methods for identification of studies

We plan a three-stage approach to searching for suitable studies:

1. Electronic search
2. Comprehensive search of reference lists of all review articles and included studies (Horsley 2011)
3. Citation tracking of all relevant reviews and included papers

There will be no language restrictions.

Electronic searches

We will search the following databases from 1985 onwards:

- Cochrane Methodology Register
- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE (via Ovid)
- EMBASE via Ovid
- CINAHL via Ovid
- British Nursing Index
- PsycINFO
- Applied Social Sciences Index and Abstracts (ASSIA)
- Web of Science
    - Science Citation Index Expanded (SCI-EXPANDED)
    - Social Sciences Citation Index (SSCI)

Searching other resources

We will search Web of Science conference proceedings. We will check through all reference lists of review articles and included studies. We will also citation track any included studies. We will seek ongoing studies or recently completed studies from the following research registers:

- International Register of Controlled Trials (ISRCTN Register)
- National Institute of Health clinical trials database (Clinical trials.gov)
- World Health Organization International Clinical Trials Registry Platform (ICTRP)
- United Kingdom Clinical Research Network (UKCRN)

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts of citations retrieved from the electronic searches. Where disagreements cannot be resolved through discussion, we will seek a third person to act as an arbitrator. We will seek full-text articles for potentially eligible studies. Two review authors will assess all potentially eligible studies independently to determine whether

they meet the eligibility criteria. Any disagreements between review authors will be settled through discussion or involvement of a third review author.

Data extraction and management

We will develop and pilot data extraction forms and alter them as appropriate. Two review authors will then extract data independently. Any disagreements that cannot be resolved through discussion will be discussed with a third review author. We will seek additional information from the original researchers where necessary. We will extract data regarding the methodology, the intervention (strategy), the participants and reported outcomes. We will assess:

- the risk of bias in included studies (where appropriate);
- the adequacy of allocation concealment (adequate, unclear and inadequate); and
- the completeness of reporting on the flow of participants through the trial, e.g. from a CONSORT diagram (where appropriate).

Assessment of risk of bias in included studies

We will assess the risk of bias of each study using the six domains of the Cochrane 'Risk of bias' assessment tool (Higgins 2008). We will discuss the characteristics of the studies, as related to risk of bias. We will also discuss any studies identified with serious risk of bias.

Measures of the effect of the methods

We will analyse data according to the type of intervention (e.g. designated member of staff, additional information, additional visits etc.). We will group interventions as appropriate and combine continuous data using mean differences or standardised mean differences and calculate 95% confidence intervals to summarise the data for each group of interventions.

Unit of analysis issues

We anticipate that most studies will be analysed using the individual patient as the unit of analysis. Should we identify any cluster-randomised controlled trials, the unit of analysis would be the cluster.

Dealing with missing data

We will analyse participants' data on an intention-to-treat basis. We will request missing data from authors of included studies where necessary (Young 2011).

Assessment of heterogeneity

We will seek statistical evidence of heterogeneity of results of trials using the Chi^2 test for heterogeneity. We will quantify the degree of heterogeneity in the results using the I^2 statistic (Higgins 2008). Where substantial heterogeneity is detected we will investigate possible explanations and assess the data using random-effects analysis if appropriate.

Assessment of reporting biases

We will make an assessment of publication bias if more than 10 studies of the same intervention are identified.

Data synthesis

We will perform meta-analysis to describe the overall results, if appropriate. We will synthesise studies which are not suitable for meta-analysis by means of a narrative synthesis. We will view convergence between the meta-analysis results and the narrative review as an indication of strong evidence of the effect.

Subgroup analysis and investigation of heterogeneity

We will group studies according to the type of intervention employed, such as the use of a dedicated member of staff, additional training or information, or use of technology. We will perform subgroup analysis if we think that there is a plausible explanation for heterogeneity and this will include:

- study quality;
- study site (e.g. primary versus secondary care);
- studies recruiting to RCTs rather than to observational studies, which include a theorised mechanism of success.

Sensitivity analysis

We will perform sensitivity analysis according to the methodological quality and robustness of the results, where available.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. patient selection.mp. or exp Patient Selection/
2. patient participation.mp. or Patient Participation/
3. incentives.mp. or Motivation/
4. "Health Services Needs and Demand"/ or "Salaries and Fringe Benefits"/ or Gift Giving/ or inducement.mp. or "Fees and Charges"/
5. Financing, Personal/ or Reimbursement, Incentive/ or pay$.mp. or Cost-Benefit Analysis/
6. compensation.mp. or "Compensation and Redress"/
7. gatekeeping.mp. or Gatekeeping/
8. 1 or 2
9. 3 or 4 or 5 or 6 or 7
10. 8 and 9

Appendix 2. PsycINFO search strategy

1. (recruit* OR patient AND selection OR patient AND participation OR particip*).ti,ab
2. (incentiv* OR induc* OR gatekeep* OR reward* OR altruist* OR coerci*).ti,ab
3. 1 AND 2
4. 2 AND 4
5. (recruit* OR patient AND selection OR patient AND participat* OR subjects).ti,ab
6. 2 AND 5
7. (recruit* OR patient AND selection OR patient AND participat* OR subjects).ti,ab
8. (incentiv* OR induc* OR gatekeep* OR reward* OR altruist* OR coerci*).ti,ab
9. 7 AND 8

(Limited to: Publication Year 1980-Current and Human and English Language and (Population Groups Human))

Appendix 3. ASSIA search strategy

((recruit* or (patient selection) or (patient participat*)) or subjects) and ((incentiv* or induc* or gatekeep*) or (reward* or altruist* or coerci*))

HISTORY

Protocol first published: Issue 9, 2012

CONTRIBUTIONS OF AUTHORS

The protocol was predominantly written by NP and CW but with significant input from the team (MF, GE, CS, CT, JH, LC, SB, CBW).

DECLARATIONS OF INTEREST

There are no declarations of interest.

SOURCES OF SUPPORT

Internal sources

- Lancaster University, UK.

Salary support of researcher NP

- University of Manchester, UK.

Salary support for CW, CT, SB, CBW, LC

- Loughborough University, UK.

Salary support for CS

- University of Southampton, UK.

Salary support for JH

External sources

- Cancer Experiences Collaborative (CECo), UK.

Provided funding for running the review as well as meeting costs.

- Macmillan Cancer Support, UK.

Funded the salary for two researchers SB and MF who worked part time on the review through a Macmillan Cancer Support Post Doctoral Fellowship