has been highlighted as a key limitation across health and related disciplines. To address this limitation, the strategy was replicated in the INTERVAL Dental Recalls trial to investigate if the intervention would improve participant questionnaire response rates in a similar patient population (primary dental care), with a similar level of non-response.

Method

1867 INTERVAL participants were sent annual questionnaires at year 2 and 3 of follow-up and randomly allocated to receive either the standard covering letter (control group) or theory-based cover letter (intervention cohort). The response rates between the groups to both the iquad and INTERVAL replicated SWAT were estimated with 95% confidence intervals. A fixed effect meta-analysis was calculated using the Mantel-Haenszel method.

Results

The participants in both the iquad and INTERVAL trials had similar baseline characteristics; the mean age of INTERVAL participants was 48.4 (14.9) years, 60% female and iquad participants 47.8 (15.7) years, 64% female. The response rate in INTERVAL was 67% for the intervention cohort and 66% in the control group. There was a +1% difference (95% CI −3 to 5%) between groups favouring the intervention. In iquad the response rate was 72% in the intervention cohort and 65% in the control group. There was a +7% difference (95% CI +2 to +12%) between groups favouring the intervention. On meta-analysis of results there is a risk difference of 3% (95% CI 0 to +7%) in favour of the intervention.

Conclusions

To our knowledge, this is the first true replication of a behaviour change intervention for improving response rates in a similar population. These results indicate that inclusion of a theory-based cover letter with postal questionnaires provides a cheap and effective method for improving participant response rates by 3% compared with a standard letter in a dental primary care population. We believe this study provides strong evidence of the effectiveness of the intervention in this population. However, the study has raised interesting methodological challenges around when should replication stop and the role of context (settings and population). As such further replication of this strategy is planned in different trial settings and populations through the Trial Forge initiative (http://trialforge.org) and through the Medical Research Council (MRC) Hubs for Trial Methodology Research (https://www.qub.ac.uk/sites/thenorthernirelandnetworkfortrialsmethodologyresearch/swatswarinformation/) to add to the evidence base.

Reference

1. Duncan A, Bonetti D, Clarkson J, Ramsay C. Improving trial questionnaire response rates using behaviour change theory. Trials 2015, 16(Suppl 2):P92

P429

Recruitment in GP practices: research assistant or research nurse?

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Background

It's important when designing clinical trials to select an appropriate method of recruitment. Traditionally research nurses recruit participants from GP practices. They are often familiar to the patients which could mean those patients are more likely to enter and complete clinical trials. A randomised controlled trial to test the effectiveness of a brief intervention for weight management in primary care compared practices using research nurses (N = 17) with practices using research assistants (RA) (N = 44) to opportunistically recruit participants.

Aims

Compare two different methods of recruitment, specifically the effect on participant enrolment and follow up.

Methods

Data was analysed as proportions. We reported the number of those enrolled and those being followed up in each group, divided by the total number eligible and the total number enrolled in each group respectively i.e. the risk ratio with 95% confidence intervals.

Results

93.8% in the RA group and 96.6% in the nurse group (RR 0.97 95% CI 0.94, 0.99) were enrolled of those that were eligible. 58.1% in the nurse group and 81.1% in the RA group (RR 0.71 95% CI 0.65, 0.79) were followed up at 3 months.

Conclusions

Research nurses were slightly more effective at successfully enrolling eligible participants into the trial than research assistants however the difference between the groups is barely significant. Once enrolled, participants were more likely to return for follow up in the RA group. This significant result suggests that using research assistants for recruitment is more likely to result in better follow up rates.

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Development of the CORKA trial screening tool for identifying patients at increased risk of poor outcome following knee replacement

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Background

Community based Rehabilitation after Knee Arthroplasty (CORKA) is a multicentre two-arm individually randomised controlled trial with blinded outcome assessment at 12 months. It aims to determine if a multi-component rehabilitation programme, provided to patients who had knee replacement (KR) and are deemed at risk of poor outcome, as measured by the Late Life Function and Disability Instrument (LLFDI) score, is better than usual care.

Objective

To describe the development of the trial's screening tool to recruit KR patients at greater risk of poor outcome and who therefore might benefit more from the intervention.

Methods

The screening tool was developed based on the principles of prognostic model development, using data from the KAT randomized clinical trial [1] which contains pre-operative and 12 months outcome data on more than 2,192 KR patients. As a proxy for poor outcome, since the KAT trial did not include the LLFDI score, poor outcome was defined as a score 26 in the Oxford Knee Score (OKS). Pre-operative characteristics considered as candidate predictors in the development of the screening tool included age, sex, height, body mass index (BMI), mobility, ASA grade, SF-12 (questions 6 and 11) and OKS (question 1) components. Multivariate imputation by chained equations (MICE) was used to handle missing data in the KAT dataset. Ten complete datasets were produced by MICE. One of these datasets was selected at random and multivariable logistic regression models were fitted to identify the statistically significant predictors of poor outcome after KR. Predictors were selected by using backwards elimination (stepwise) procedure. The final model was aimed to be simple and easy to implement in the clinical setting, considering both the clinical and statistical relevance of the predictors. Model simplification was done by rounding up the logistic regression coefficients (odds ratio) of the predictors in the final model to the nearest integer. Model performance was evaluated in terms of discrimination and calibration. Discrimination was quantified by the c-index (area under the receiver operating characteristics curve). Calibration was assessed by grouping individuals into tenths of predicted risk and graphically comparing the agreement between the mean predicted risk and the observed events in each tenth. The cut-offs to classify individuals at increased risk of poor outcome was determined with the aim of achieving a balance between model's specificity and recruitment feasibility.

Results

Subjects in the KAT dataset were aged 71(SD = 7.1) years on average, with a mean ASA grade of 2(SD = 0.6). From a total set of nine candidate predictors, four were selected for the screening tool: BMI, ASA grade, OKS question 1 and SF-12 question 6. Model discrimination, as measured by the c-index was 0.67. The screening tool score range is 0–10 and patients scoring 5 or more (29% of the KAT sample) are considered at increased risk of poor outcome following KR.

Conclusions
We developed a simple and objective screening tool to identify patients at increased risk of poor outcome for inclusion in to the CORKA randomized clinical trial, with a moderate discriminatory ability.

Reference
[1] J Bone Joint Surg Am. 2009;91:134–41.

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Informed consent and proxy decision making for research involving adults lacking capacity: a systematic review (framework synthesis)

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Introduction
Decisions about the participation of adults lacking mental capacity in medical research are complex, and raise considerable legal and ethical issues. There are differences between decisions relating to the medical treatment of adults lacking capacity, and those concerning their participation in medical research. Carers and relatives of adults lacking capacity are regularly called upon to make such decisions on their behalf, however little is known about the ethical basis on which these proxy decisions are made and there is a dearth of information or support available. The coming decades are expected to see a significant rise in health challenges resulting from ageing populations, with a proportionate rise in conditions characterised by cognitive disorders. Ambitious UK research agendas have been set out in order to address these challenges, however these will require considerable numbers of research participants.
Background
There are specific legal provisions in England and Wales governing proxy decision making by another individual, such as a family member of friend, for those unable to provide consent for themselves to participate in research. Data regarding the ethical and regulatory factors influencing these decisions, and interventions to inform and support those involved, are urgently required in order to maximise the participation of adults lacking capacity in research. Research participants, their families and carers, clinicians and researchers require a clear, evidence-based ethical framework for research enrolment of adults lacking capacity. This systematic review forms part of an NIHR Doctoral Research Fellowship to investigate informed consent and proxy decision making in research involving adults lacking capacity, and the development of an intervention to support informed proxy decision making, set within ethical and legal frameworks.
Methods
A mixed methods systematic review will be conducted to determine the ethical and legal issues encountered in proxy decision-making for research participation by adults lacking capacity, using a framework synthesis approach. The aim is to synthesise empirical evidence from qualitative, quantitative or observational studies which examine the relevant ethical issues. The review will be registered with PROSPERO database of systematic reviews.
Results
The findings from the systematic review will be presented, which will include an examination of the ethical issues encountered, what factors are involved when proxy decisions are made, and factors that affect the quality of informed consent and proxy decision making in practice. The review will provide an overarching synthesis of proxy decision-making for research participation, and the development of a conceptual framework.
Conclusions
This systematic review will examine a range of factors encountered in research involving adults lacking capacity, and what influence these and other factors have on informed consent and proxy decision making in practice. The findings will be used to develop a conceptual framework of proxy decision making which will form the basis of a subsequent qualitative study to explore how proxy decisions are made, and whether legal and ethical obligations are being met. The review and the qualitative study will then be used to determine the factors that must be included in a decision support intervention for research participation by proxy decision makers for adults lacking capacity.

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New methods for categorising recruitment research: a case study

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Background
Research into optimising recruitment to RCTs is commonly undertaken, however there is no agreed method for organising and reporting studies. Adequately describing and classifying recruitment study types may enable researchers to evaluate and compare studies more reliably.
Aim
This study developed and applied a categorisation system for different recruitment studies, encountered during a systematic review of recruitment to RCTs in unplanned hospital care (UHC), to inform future recruitment research.
Methods
Search strategy
The ORRCA (Online Resource for Recruitment Research in Clinical Trials; www.orrca.org.uk) database was utilised in this systematic review. ORRCA includes studies of all designs, systematically extracted from the literature, reporting on recruitment into RCTs and non-randomised clinical studies. In this review, ORRCA was searched for primary research reports of studies that reported on recruitment to RCTs in adult patients receiving UHC.
Development of study categories Reading the articles led to initial categorisation of the recruitment studies into those with a randomised or non-randomised recruitment designs. Iterative refinement of the study structured categories through discussion between study authors (CR, JMB, LR, JR).
It was noted that papers reporting surveys in the community (community consultations) had been undertaken to establish the likelihood of recruitment success or acceptability of a trial. In recognition of this, a clear differentiation was made between studies that focused on recruitment to an actual clinical RCT (a 'host RCT') versus potential recruitment to a RCT that did not yet exist (a 'hypothetical RCT').
Latterly a further categorisation was introduced to classify whether the recruitment study evaluated an intervention to modify recruitment, or simply reported on recruitment experiences. The final classification for papers was formulated based on whether i) randomised or non-randomised study design was employed during the recruitment study ii) an intervention to optimise recruitment was evaluated, and iii) a host or hypothetical RCT was used.
Category A - Randomised controlled trials of interventions to optimise recruitment within one or more host RCTs Category B - Non-randomised studies of interventions to optimise recruitment within one or more host RCTs Category C - Non-randomised studies without interventions evaluating recruitment to one or more host RCTs Category D - Randomised studies to consider recruitment within proposed hypothetical RCTs (community consultations) Category E - Non-randomised studies to consider recruitment within proposed hypothetical RCTs (community consultations).
Results
3114 papers were available in ORRCA and 39 met the inclusion criteria. The new categorisation was able to be applied to all papers with 1, 11, 16, 0 and 11 within categories A to E respectively.
Conclusions
This case study illustrates new methods for categorising recruitment studies. It has potential utility to researchers by encompassing the