replication, we have demonstrated the potential of simple, theory-based adaptations to enhance participant engagement.

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Development of participant-centred interventions to enhance retention in randomised controlled trials: a theory-informed study

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Introduction: Participant drop-out affects the credibility of findings from randomised controlled trial (RCT) and reduces their potential to influence clinical practice. Several aspects of trial retention can be thought of as a behaviour e.g. returning a questionnaire or attending a clinic. Most existing retention interventions have no theoretical basis, do not explicitly target behaviour change, and have little evidence to support acceptance by participants. Our research develops theoretically informed, participant-centred, behaviour change interventions to improve retention in RCTs. This presentation will introduce the potential benefits of using insights from behavioural science (specifically the Theoretical Domains Framework (TDF) and behaviour change techniques (BCTs)) to consider how to improve retention in RCTs.
Methods: Sixteen telephone interviews were conducted using a TDF-based topic guide with participants who had either failed to return a follow-up questionnaire and/or attend a follow up clinic. Participants were invited from a range of RCTs with poor retention identified from clinical trial unit portfolios, UK. Theory based content analysis was conducted. Domains were prioritised based on frequency and content and then mapped onto BCTs. Crucially, retention specific interventions were co-designed with trial participants using these BCTs.
Timing of Potential Results and Potential Relevance and Impact: We will know the form (i.e. content, mode, timing) of our interventions in September 2019. This is one of the first studies to apply a theoretical lens to the development of participant-centred interventions to improve trial retention. These findings provide a new methodology to develop interventions in clinical research trials to target participant retention using a behaviourally focussed approach that can be applied across trials in different contexts and ultimately lead to more reproducible, participant centred, interventions.

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Abstract withdrawn

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Moving to direct electronic capture of patient-reported data: lessons from the UKSTAR trial

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Introduction: Aims: It is sometimes assumed that collecting data electronically is less staff resource-intensive than collection on paper, and that follow-up will be more complete. Evidence to support this is lacking. Our aims were to assess the impact of switching from data collection via postal paper questionnaires (paper-data) to electronic data collection (e-data) on follow-up rates.
Objectives: To report on the effectiveness of e-data compared to paper-data.
Setting: In the UKSTAR trial, we switched data collection from paper-data to e-data during follow-up. UKSTAR is an RCT comparing treatments for patients with Achilles tendon rupture.
Methods: 540 adult participants were invited to complete questionnaires 3, 6 and 9 months post-randomisation. Questionnaires were sent by post, during the first 15 months of follow-up. Data collection then switched to e-data for a further 13 months, with invitations sent via email and/or text. Relevant data collected for this sub-study included: patient demographics and follow-up rates.
Results: 1577 invitations were sent (732 postal, 845 electronic). Response rate after the initial invite was lower at all time-points with e-data than postal invitations (combined over time 59% vs 81% respectively). Both sexes had higher response rates to paper-data than to e-data (men 79% vs 56%; women 89% vs 70% respectively). Participants aged 55 and over responded better to a first invite by post than by edata (82% vs 60% respectively), as did younger participants (78% vs 59% respectively).
Discussion: In this study we showed that e-data collection has lower response rates than paper-data collection in an adult population that includes people of working age. Results of this study could have been limited by the study design; randomisation of patients to the data collection method could have provided more robust data.

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Trial questionnaire response rates - Is bigger better?

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Retention in randomised controlled trials (RCT) can often seem like the poor cousin in comparison to the time and effort that is put into recruitment. Trial managers and data coordinators/administrators often spend inordinate amounts of time and effort collecting participant reported outcome (PRO) data using different strategies (e.g. postal questionnaires, reminders etc.). This can be a large burden upon both the trial budget and time for the trial team.
Within the NIHR HTA-funded SIMS Trial (a pragmatic multi-centred surgical RCT in female stress urinary incontinence) we evaluated whether sending A4 or A5 sized questionnaires with identical content, layout and pagination to participants affected questionnaire retention/response rates.
Objectives: The aim of the study was to determine if the physical size of the questionnaires affected response rates. We will also consider economic aspects (cost of questionnaires, postage etc.).
Methods: Participants were randomised to receive either A4 or A5 sized postal questionnaire at 15 months post randomisation.
Results: There was no statistically significant difference in response rates between the A4 and A5 sized questionnaires. 58.70% of participants receiving an A4 questionnaire responded compared to 52.10% of those receiving an A5 questionnaire. N = 562, P-value = 0.116
In addition to discussing this result, economic aspects, by questionnaire size, will be presented at the Conference.

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Managing follow-up among parents of very pre-term infants: methods to improve questionnaire response rate

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Introduction: In randomised controlled trials it is important to maximise outcome ascertainment to minimise bias. SIFT (ISRCTN76463425)

was a multicentre randomised controlled trial run in neonatal units in the UK and Ireland, investigating two speeds of increasing milk feeding in 2804 infants with gestational age at birth <32 weeks and/or birth weight <1500g. Primary outcome was the proportion of infants surviving without moderate or severe neurodevelopmental disability at 24 months of age, assessed via parent-completed questionnaire.
Methods: Questionnaires were posted 17 days before participants reached 24 months of age corrected for prematurity. Lack of parental response triggered two postal reminders and one by phone, with two weeks between each.
Measures introduced to improve response included contacting parents prior to the questionnaire being posted; offering online questionnaire completion; a second reminder being accompanied by a phone call and text message; promotion by Bliss (third sector stakeholder); sending posters to sites for display in outpatient clinics; and ultimately an incentive voucher (described elsewhere). Outcome data were also sourced from routine clinical follow-up appointments at sites for infants whose parents did not complete the questionnaire.
Results: Response rate prior to all interventions was 51.0%; at data lock in April 2018 it was 76.5% (p<0.01). The largest increases (6%) following a single intervention were seen after introducing pre-questionnaire phone calls (p=0.07) and online completion (p=0.04).
Recruiting sites supplied additional data from 351 routine clinical follow-up appointments. Primary outcome could be determined for 88.5% of the cohort.
Discussion: Multiple methods of contact, especially phone contact prior to dispatch of questionnaire and availability of the questionnaire online, may improve response rate to postal questionnaires among parents of very preterm infants. Over time, promotion by sites and on social media may also play a role. Missing data can be supplemented by information from routine sources.

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Conditional versus Non-Conditional Incentives to Maximise Return of Postal Questionnaires in Clinical Trials: A Randomised Study Within a Trial

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Background: High levels of retention in clinical trials is essential to gain robust evidence to guide care. Many approaches have been used to improve participant retention, but few have been evaluated. The addition of a monetary incentive has been shown to increase retention, but it is not known whether the point at which an incentive is given matters. We aimed to determine whether there was a difference in follow-up trial questionnaires returned when a monetary incentive given to trial participants at recruitment (non-conditional), and when patients were informed at recruitment that the incentive would be given only once a questionnaire had been returned (conditional).
Method: This was a sub-study within the Antivirals for influenza-Like Illness, An rCt of Clinical and Cost effectiveness in primary CarE Trial. Sites were matched according to previous recruitment or practice list size. Practice pairs were randomised to giving either a non-conditional or conditional incentive. Analyses were conducted according to randomised group irrespective of compliance. Statistical significance was assessed at the two-sided 5% level. The primary analysis was regression adjusted for practice pair with various sensitivity analyses.
Results: Only 28 out of the 42 sites recruited at least one participant (range 1 to 56) with 10 practice pairs recruiting one or more participants at both constituent sites. There was no evidence of a difference in the proportion of questionnaires returned, time taken to return questionnaires, nor proportion of pages completed, by intervention group (all p>0.05). Findings of the sensitivity analyses yielded similar findings. The conditional incentive cost approximately £23 less per diary returned.
Discussion: There was no evidence of a difference in questionnaire returns, nor the time to questionnaire return or completeness. There was low precision, given the small number of sites which recruited, and variability between sites in recruitment performance. The conditional approach cost less.

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Pen and Social Incentive Letter Retention Study within a Trial (SWAT) - An embedded, factorial design randomised controlled trial to investigate whether the inclusion of a pen and/or social incentive text cover letter included with the 12-month postal questionnaire improved response rates

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Introduction: Poor return of questionnaires in randomised controlled trials (RCTs) affects retention rates. This can introduce bias and thus affect generalisability and validity, with an associated reduction in statistical power. The objective of this study within a trial (SWAT) was to assess whether a pen and/or social incentive text cover letter sent with the 12-month questionnaire increased postal questionnaire response rates for participants in an RCT. We aimed to compare the inclusion of a pen in questionnaires with no pen; and the use of a social incentive text cover letter compared with no cover letter.
Methods: A 2x2 factorial SWAT within the 'Occupational therapist home assessment and modification for prevention of falls trial (OTIS)' host trial. Participants due their 12-month follow-up questionnaire were randomised to be sent a pen; a social incentive text cover letter; both; or neither. Primary outcome was the proportion of participants in each group who completed and returned the questionnaire. Secondary outcomes were time to return and completeness of the questionnaire, number of reminder letters sent and the cost effectiveness. To date 624 participants have been randomised.
Timing of Potential Results: By the time of the conference we will present findings on questionnaire response rates, time to return and completeness of the questionnaire, number of reminders and cost effectiveness. Odds ratios will be calculated and reported, along with confidence intervals and p values. Adjusted hazard ratio results will be presented for time to return the questionnaire, and the need for a reminder.
Potential Relevance and Impact: Our SWAT will add to evidence for improving retention rates in RCTs. Findings of the pen SWAT will be combined with results of other SWATs in a meta-analysis to detect small but cost-effective differences. Evidence for the social incentive cover letter will need to be replicated in further SWATs.

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Factors that affect attrition in RCTs for the treatment of depression

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Introduction: Attrition is a common feature in clinical trials; higher attrition rate can affect the statistical power of an RCT and can undermine the external validity of the study. Therefore, it is important to evaluate and understand the factors that could affect attrition so that informed decisions can be made when planning a trial. We undertook a systematic review and meta-analysis of randomised studies treating depression to determine attrition, and predictors of attrition in these RCTs.
Methods:A comprehensive search was undertaken to identify RCTs of interventions to treat depression. Firstly, Cochrane reviews with "depression" in the title, abstract or keywords were identified and were eligible if were published in or after 2005; their scope matched our review's eligibility criteria; and their inclusion criteria did not