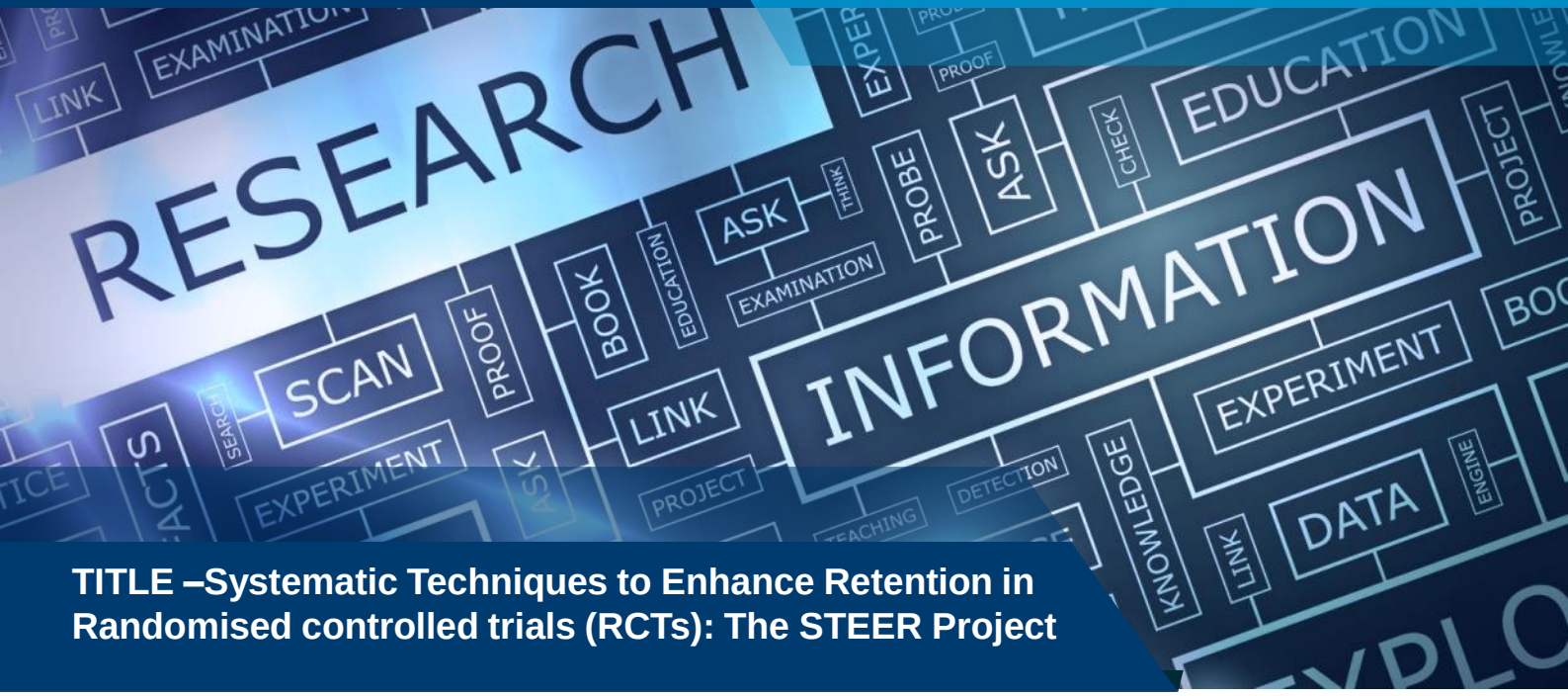
CHIEF SCIENTIST OFFICE

CODE: HIPS/16/46

RESEARCH PROJECT BRIEFING



TITLE –Systematic Techniques to Enhance Retention in Randomised controlled trials (RCTs): The STEER Project

AIMS

Randomised trials are the cornerstone of evidence-based healthcare. It is common for many trial participants (sometimes more than 20%) to drop out before the trial finishes. This seriously reduces the credibility of trial results and significantly affects the potential of a trial to influence clinical practice. Recent research has shown that the results of some clinical trials could have been overturned if the outcomes from those who dropped out were known. In other words, healthcare systems may not be basing care decisions on the best possible evidence.

Many of the causes of non-retention in trials involve people performing, or not performing a behaviour such as not returning a questionnaire. However, most research looking to improve trial retention is atheoretical (i.e. not based on a theory and as such may lack a logical investigation of a system of beliefs and problems) and has not involved trial participants in its design.

This research aimed to develop theoretically informed, participant-centred, evidence-based interventions to improve retention of participants in trials using insights from behaviour-change theory.

KEY FINDINGS

This study has provided insights into retention issues and led to the development of participant-centred behaviour change interventions to test in future trials. Specifically it has:

- identified a range of barriers (e.g. issues related to research team such as lack of communication with participants, no support to help complete a questionnaire, inflexible clinic appointments; and issues related to participants such as lack of time, other commitments, lack of knowledge regarding what activities (e.g. how many clinic visits) are involved and the importance of completing an activity) and enablers (e.g. incentives or rewards for completing an activity, options available to return a questionnaire such as online or postal, an easy questionnaire to follow, complete and return, flexible clinic appointments, knowledge about the importance of contributing to a research) to retention in trials by exploring participants' experiences of trials;
- identified relevant behaviour change techniques (BCTs, e.g. material incentives or reward, goal setting, action planning, social support, self-monitoring of behaviour, social reward) to overcome the modifiable barriers and enhance the enablers of trial retention;
- developed behaviour change interventions with trial participants to improve retention
- evaluated the feasibility and acceptability of the interventions from the perspectives of stakeholders.

WHAT DID THE STUDY INVOLVE?

This study had four interlinked phases.
Phase 1 and 2 (Identifying and accessing the problem)
We interviewed stakeholders to understand their reasons for trial non-retention and explored their perceived barriers and enablers to trial retention. Seven trials (e.g. those with more than15% missing primary outcome data) were selected purposively from the portfolios of the trials unit involved in this project. We invited participants who dropped out and staff (e.g. research nurses, trial managers and data coordinators) from these trials for interview. A total of 16 trial non-retainers and ten staff were interviewed.

The interview topic guides were informed by Patient and Public Involvement (PPI) members and a widely used theoretical framework, the Theoretical Domains Framework (TDF, which is a framework that brings together psychological theories to understand problems relevant to behaviour such as why people drop out of trials and hence, develop interventions aimed at behaviour change). Content analysis was performed to identify relevant TDF domains. 'Relevance' was measured by the frequency (e.g. most frequently mentioned by participants) with which the TDF domain was related to participants and the target behaviour (e.g. did/did not attend a clinic). These 'relevant' domains were then mapped onto BCTs to identify techniques for inclusion along with what to deliver and how it would be delivered. The Table below shows some example quotes of the top three relevant domains along with the targeted BCTs.

Top 3 relevant TDF domains (frequency, %)	Quotes	BCTs
Reinforcement (100%)	*"Yes, incentives are always good aren't they? Like shopping vouchers or cash, or …" (Male, 71y)* *"When I returned the questionnaire it would have been nice to receive a small note saying 'Thank you Mr X we have received it and its going to be included as part of the study'…" (Male, 75y)*	Material incentive or reward Social reward
Beliefs about capabilities (100%)	*"To be honest I am not good with paperwork. … I am not one for paperwork, so its not something I look forward to" (Male, 53y)* *"I meant other than rearrange the appointment and being a bit more flexible, then that's it really … I would have continued. " (Female, 34y)*	Goal setting, Social reward or support
Beliefs about consequences (100%)	*"I suppose it is a benefit if I'm able to help in the study, if my contribution helps in any way then that's a benefit to me as well, I suppose." (Female 34y)* *"I only filled in the first one, so I probably made no difference to the X study. " (Male, 75y)*	Information about health or social and environmental consequences

A total of four potential interventions were developed to explore in the next phase of the study:
1) Incentives or rewards to improve clinic attendance
2) Goal setting to improve questionnaire return rate
3) Self-monitoring to improve questionnaire return and/or clinic attendance and
4) Motivational information to improve questionnaire return and/or clinic attendance.

Phase 3 (Forming possible interventions)
Trial participants, who had dropped out of a trial were invited to take part in a co-design workshop. A total of eight participants attended the workshop. The following four interventions were agreed during the meeting-

Intervention 1: All participants, who consented to take part, would have the opportunity to receive the incentive (e.g. monetary, charitable donation) but only those who completed the behaviour would get the reward. Send 'Thank you' note after attending each clinic and mention that they are making a difference.
Intervention 2: Set goals with all participants during consenting process that all questionnaires need to be returned. Show an example of the questionnaire and provide an opportunity to work through. Provide the contact details (and photo) of a person to contact for any queries.
Intervention 3: Provide a portable sized loyalty card or a planner after randomisation indicating dates when questionnaires are to be returned or clinic attendance. On the other side of the card/planner, mention the purpose of the trial and details/photo of a person to contact.
Intervention 4: Motivational information framed as positive reinforcement (e.g. end purpose of this research, benefits of being involved, and how others are doing in the trial) should be delivered throughout the trial to stay in touch with all participants and keep them motivated

Based on the priority ratings of the participants, intervention 2 (Goal setting) and 4 (Motivational information) were selected to explore in the next stage.

Phase 4 (Evaluation of the selected interventions)
An assessment of acceptability and feasibility of the two interventions (Goal setting and Motivational information) was made at a meeting in Birmingham on the 2nd of September 2019. Attendees were 4 trial participants, 2 trial staff [e.g. Clinical Trial Unit's director, 3 trial managers, 4 research nurses, a data coordinator and4 Research Ethics Committee (REC) members from two different committees.
Participants believed that both interventions would have impacts on retention of participants and that these could be combined together, where possible, depending on the trial design and contexts. While some attendees believed that some parts of the these interventions were already being used in trials, they were not delivered consistently as a package nor had impact on retention been assessed.
In relation to intervention 2 (Goal setting), it was suggested that recruiters should have a checklist/toolkit so they were consistent with messaging and made clear to participants what was involved in taking part. Attendees raised no ethical concerns.
Regarding intervention 4 (Motivational information), attendees raised no ethical concerns and it was believed that this intervention would need less effort to deliver and implement compared to intervention 2 (Goal setting). They suggested that it could be delivered via regular trial newsletters, or perhaps an online forum depending on the trial design, context and trial population.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

This is the first study to develop behaviour change interventions that are embedded in trial participants' accounts of the barriers and enablers to completing a trial till the end. These interventions have the potential to improve data collection for trials and ultimately improve the reliability and credibility of trial results that impact on clinical practice. Key outputs from the project have been:

- Four candidate interventions were co-designed with trial participants;
- Two of these candidate interventions were taken forward for further development to explore acceptability and feasibility potential
- Summary protocols outlining the interventions and how to evaluate them have been developed to embed into future trials as Studies Within A Trial (SWATs) and test any impacts of these interventions on retention of trial participants.

WHAT IMPACT COULD THE FINDINGS HAVE?

- Patients: We believe these interventions have the potential to make it easier for trial participants to understand what a trial entails and improve motivation to stay involved.
- Policy: We believe this resource will help trial staff to make decisions about whether to implement a given retention intervention in their own trials. Reduced drop-out will lead to better evidence to improve patient care.
- Practice: We are unsure of the impact of this intervention on trial staff workload. Future evaluations of these interventions using embedded SWATs should assess staff and other resource implications.

HOW WILL THE OUTCOMES BE DISSEMINATED?

- Presentation at the International Clinical Trials Methodology Conference October, 2019
- The study protocol published in an open access journal: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2572-0
- Findings as academic paper in an Open Access Journal
- Three SWAT protocols at the SWAT Repository http://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/
- Social media tweets
- Future research will focus on expanding the SWAT protocol further (e.g. how any changes in behaviour (i.e. retention) can be assessed, and also large-scale testing of these interventions to explore their implementation.

CONCLUSION

This is the first study to apply a theoretical lens to the development of participant-centred interventions to improve trial retention. These interventions will serve as a guide for initial efforts in clinical trial retention planning.
Future testing and implementing the interventions in future trials will support retaining participants in trials until they are fully completed.

Glossary of Abbreviations

BCTs	Behaviour change techniques
PPI	Patient and Public Involvement
REC	Research Ethics Committee
SWATs	Studies Within A Trial
TDF	Theoretical Domains Framework

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Additional Information

Dates: The project ran from August 2017 – September 2019
Funding: This project was awarded £199,858