SWAT 154: Follow-up within global surgEry triAls: a qualiTative investigation to improvE trial Retention (FEATHER)

Objective of this SWAT
The FEATHER study will use qualitative methods, informed by a behavioural science approach, to explore participants' experience of trial follow-up pathways and reasons for loss to follow-up and identify potential interventions to improve trial retention for testing in future research.

The overall aim is to explore the reasons why participants are lost to follow-up in trials across low- and middle-income countries (LMICs), and to explore the potential impact of interventions to improve retention of participants in future research.

The two specific objectives are:
(1) To explore the barriers and facilitators to retaining participants within in-person and telephone-based trial follow-up pathways in LMICs.
(2) To explore how retention interventions could be applied to participants recruited to trials in LMICs in an ethical, culturally and contextually sensitive manner.

Study area: Retention, Follow-up
Sample type: Healthcare Professionals, Patients, Researchers
Estimated funding level needed: Medium

Background
Retention is a major challenge in international trials and has been recognised as a global research priority through a James Lind Alliance Priority Setting Partnership (PRIORITY-II) (1). The Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) guidelines define non-retention as instances where participants are prematurely "off-study" (i.e., consent withdrawn or lost to follow-up) preventing the collection of outcome data from them (2). Trial retention may be particularly challenging in low resource setting where patients may have to travel long distances to return to hospital or take further time out of work where they are already financially vulnerable following their index operation. Minimising burden on trial participants during trial follow-up and identifying culturally-attuned methods for encouraging ongoing participation may reduce the risk of attrition bias and the cost of randomised trials (3-5). However, there is insufficient evidence to make recommendations for global surgery studies (6, 7). FEATHER is a SWAT that will use qualitative methods embedded within several international multi-centre randomised trials. The protocol for FEATHER has been approved by an International Ethics Committee at the University of Birmingham, UK and it will be included in three host trials:
(1) A pragmatic multicentre factorial randomised controlled trial testing measures to reduce surgical site infection in low- and middle-income countries (LMICs) (FALCON, NCT03700749)
(2) Sterile Glove and Clean Instrument Change at the Time of Wound Closure to Reduce Surgical Site Infection (ChEETAh) trial (NCT03980652)
(3) Perioperative respiratory care and outcomes for patients undergoing high risk abdominal surgery (PENGUIN) trial (NCT04256798)

Interventions and comparators
Intervention 1: Stage 1: Semi-structured interview ('Diagnosis phase'), to explore challenges to trial retention across a diverse range of settings, investigating participant and investigator perspectives informed by behavioural change theory. Two specific behaviours to be examined will be (1) participant not attending a trial follow-up clinic and (2) participant not completing trial telephone follow-up. Purposive sampling will be performed across selected countries and sites within the host trial delivery networks.
Intervention 2: Stage 2: Focus groups ('Treatment phase') to identify and prioritise retention interventions for evaluation and/or adoption into future global surgery trials. Existing retention interventions identified from PRIORITY-II (1, 10), the SWAT repository (8) and the Cochrane review of retention interventions (11, 12), will be mapped to the behavioural retention themes identified from the semi-structured interviews with reference to a taxonomy for behaviour change techniques (13, 14).

Index Type: Non-randomised qualitative study informed by behavioural change theory

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: Not applicable
Secondary: Not applicable

Analysis plans
> Stage 1 analysis
Interviews and focus groups will be audio-recorded with the consent of participants and transcribed clean verbatim for analysis. Analysis will be undertaken with reference to recordings, transcriptions and field notes taken at the time of data collection. Data management will be facilitated with NVivo V12 (QSR International, Victoria, Australia). Inductive thematic analysis of content will be undertaken informed by the Framework analytical approach. Following initial familiarisation with the data, development of thematic frameworks and data coding will proceed in an iterative manner. Data collection and analysis will run concurrently so that emergent analytical themes can inform further data collection. A random sample of 5% of the data will be double-coded. Inter-rater reliability will be assessed using Cohen's kappa with >0.75 or more accepted as high agreement. Interpretation will be aided by shared within-team analysis, including patient and public partners from LMICs. Understanding of motivators and behaviours around trial non-retention will be interpreted using the AACTT framework to define behaviour (9) and the COM-B model for behaviour change (15). Data from this qualitative research will be triangulated with retention rates and attendance to in-person follow-up to assess patient and clinician experience of trial follow-up.

> Stage 2 analysis
The focus groups will explore the optimal characteristics of a retention intervention relevant to their settings and reflect on the distribution of existing interventions across the identified 'retention themes'. Prompts will be informed using the APEASE (affordability, practicability, effectiveness, acceptability, safety and equity) criteria (16). Highlighted retention interventions will be explored in detail, including ethical and culturally appropriate methods of implementation and the cultural, contextual and societal implications of each. Flexibility will be allowed to include emergent interventions proposed by focus group members. Finally, group members will be asked to prioritise retention interventions based on the discussion, attitudes and experiences, and informed by the six-item COM-B questionnaire measure (17). We will summarise this data to co-produce and prioritise retention interventions for implementation in future trials.

Possible problems in implementing this SWAT
- Using flexible models to gain ethical approval across several LMICs for patient interviews
- Travel restrictions during COVID-19 lockdowns preventing site work/patient interviews
- Qualitative training of team members in LMICs
- Challenges in reaching thematic saturation across diverse settings within the limitations of the study time window and funding

References
1. Kearney A, Daykin A, Shaw ARG, et al. Identifying research priorities for effective retention strategies in clinical trials. Trials. 2017;18(1):406.
2. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-7.
3. Skea ZC, Newlands R, Gillies K. Exploring non-retention in clinical trials: a meta-ethnographic synthesis of studies reporting participant reasons for drop out. BMJ Open. 2019;9(6):e021959.
4. Walsh M, Srinathan SK, McAuley DF, et al. The statistical significance of randomized controlled trial results is frequently fragile: a case for a Fragility Index. J Clin Epidemiol. 2014;67(6):622-8.
5. Gillies K, Bower P, Elliott J, et al. Systematic Techniques to Enhance rEtention in Randomised controlled trials: the STEER study protocol. Trials. 2018;19(1):197.
6. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 2: how to decide if a further Study Within A Trial (SWAT) is needed. Trials. 2020;21(1):33.
7. Rosala-Hallas A, Bhangu A, Blazeby J, et al. Global health trials methodological research agenda: results from a priority setting exercise. Trials. 2018;19(1):48.

8. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials. 2018;19:139.
9. Presseau J, McCleary N, Lorencatto F, et al. Action, actor, context, target, time (AACTT): a framework for specifying behaviour. Implement Sci. 2019;14(1):102.
10. Brunsdon D, Biesty L, Brocklehurst P, Brueton V, Devane D, Elliott J, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. Trials. 2019;20(1):593.
11. Gillies K, Kearney A, Keenan C, Treweek S, Hudson J, Brueton VC, et al. Strategies to improve retention in randomised trials. Cochrane Database Syst Rev. 2021;3:Mr000032.
12. Elfeky A, Gillies K, Gardner H, Fraser C, Ishaku T, Treweek S. Non-randomised evaluations of strategies to increase participant retention in randomised controlled trials: a systematic review. Syst Rev. 2020;9(1):224.
13. Michie S, Wood CE, Johnston M, Abraham C, Francis JJ, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions (a suite of five studies involving consensus methods, randomised controlled trials and analysis of qualitative data). Health Technol Assess. 2015;19(99):1-188.
14. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81-95.
15.Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42.
16. Steinmo SH, Michie S, Fuller C, et al. Bridging the gap between pragmatic intervention design and theory: using behavioural science tools to modify an existing quality improvement programme to implement "Sepsis Six". Implement Sci. 2016;11:14.
17.Keyworth C, Epton T, Goldthorpe J, Calam R, Armitage CJ. Acceptability, reliability, and validity of a brief measure of capabilities, opportunities, and motivations ("COM-B"). Br J Health Psychol. 2020;25(3):474-501.

Publications or presentations of this SWAT design

Gillies K, Bower P, Elliott J, MacLennan G, Newlands RSN, Ogden M, et al. Systematic Techniques to Enhance rEtention in Randomised controlled trials: the STEER study protocol. Trials. 2018;19(1):197.

Examples of the implementation of this SWAT

People to show as the source of this idea: James Glasbey, Aneel Bhangu, Jonathan Mathers, Peter Brocklehurst, Dion Morton, Katie Gillies; NIHR Global Health Research Unit on Global Surgery
Contact email address: j.glasbey@bham.ac.uk
Date of idea: 1/APR/2019
Revisions made by:
Date of revisions: