Promoting the use of SWATs (PROMETHEUS): recruitment and retention awards

Promoting the use of SWATs (PROMETHEUS): Pump priming awards to develop the science of recruitment and retention in trials

We are pump priming trials up to £5,000 to host innovative recruitment and retention interventions.

PROMETHEUS is a major national programme of research funded by the Medical Research Council (MRC) to facilitate the routine embedding of a methodology research study within a planned or ongoing trial. This uses Studies Within A Trial (SWAT) (1) methodology to build the evidence base on participant recruitment and retention in trials.

Background

Many aspects of trials have not been subjected to rigorous evaluation. Despite many trials experiencing challenges with recruitment and retention, interventions to address these challenges tend often to be based on 'custom and practice' rather than using approaches that have been tested using the most rigorous methodological approaches: particularly randomisation. However, there is an increasing interest in embedding methodological studies within randomised controlled trials.

Previously, members of our team were funded by the MRC to undertake the START study (2), which tested two interventions for recruitment across a number of clinical trials by performing SWATs, and found it is feasible to undertake them across a range of different trials.

Our ambition in this programme of research is to make embedding 'Studies within a Trial' or SWATs standard practice across multiple clinical trials units.

In this programme of research, we aim to **test commonly used recruitment and retention strategies** for improving trial recruitment and retention by embedding RCTs within already funded trials. The ultimate goal is to make the inclusion of SWATs routine when conducting a trial. Teams wishing to submit a SWAT as part of a new funding application should consider applying to the NIHR SWAT programme.

Scope of the awards

The SWAT should evaluate a methodological aspect of participant recruitment or retention in trials. The target of the intervention could be participants, or the people tasked with recruiting and retaining them. This award is available to trial teams based in, and undertaking recruitment or follow-up of participants in, the UK. We particularly welcome expressions of interests from teams based in or working with UKCRC registered Clinical Trials Units.

SWAT interventions

We welcome host trial teams interested in implementing a SWAT focusing on any of the key recruitment or retention questions outlined in Table 1 below. These interventions have been identified from existing systematic reviews, databases and priority lists (3–9), and will be revised on an ongoing basis as the evidence base develops.

We have prioritised these interventions because there are existing high-quality SWATs testing them, or the interventions are easy to implement in host trials, meaning they can be replicated to obtain definitive answers within the lifetime of the PROMETHEUS programme. Some interventions have been selected because they might be a little more challenging or expensive to implement as a SWAT, but have the potential to make a significant impact on recruitment or retention. Further details of each intervention are available from the PROMETHEUS team.

Table 1: List of key recruitment and retention questions

Recruitment questions

HIGH PRIORITY QUESTIONS		
Recruitment interventions	Host trials testing or planning testing	Rationale
What is the effect of adding a pen printed with the trial/university logo to the trial invitation on recruitment rates (SWAT 37)?	MSS3, OTIS	Existing data; matches Priority no. 6 from the PRioRiTy top 10
SWAT 53: including a generic doctor-patient photograph on the invitation letter for a prospective study.	CLEAR	Matches Priority no. 2 from the PRioRiTy top 10
MEDIUM PRIORITY QUESTIONS		
What is the effectiveness of a brief participant information leaflet (PIL) versus standard length PIL on participant recruitment rates?	MSS3; IBD BOOST	Existing data; matches Priority no. 2 from the PRioRiTy top 10. [*six host trials already*]
What is the effect of offering financial incentives to potential trial participants on recruitment rates? (SWAT 59)	VITA, [Gentle years yoga]	Prioritised by Cochrane recruitment review; Existing data; matches Priority no. 17 from the PRioRiTy top 20. [*Not highest priority because there are 8 studies altogether and we will probably have enough data*]
What is the effect of a personalised invitation letter on recruitment rates?	ENGAGE	No interest from trial teams to date
LOW PRIORITY QUESTIONS		

What is the impact of a training workshop for staff recruiting patients into trials on recruitment rates?	DISC; PROFHER 2; IntAct; START:REACTS	Matches Priority no. 2 from the PRioRiTy top 10. Currently in follow-up. [*We have done this SWAT, hence low priority*].
Does the format of the participant information sheet affect the recruitment rate into an interventional trial?	SARC	No interest from other trial teams to date
A variation of SWAT 3, which will explore generic versus personal wet signature on invitation letters.	CLEAR	No interest from other trial teams to date
What is the effect of a handwritten versus printed name on invitation letters on recruitment rates?	OTIS	No interest from other trial teams to date
What is the effectiveness of telephoning people who do not respond to a postal invitation on recruitment to randomised trials? (SWAT 61)	NONE	Prioritised by Cochrane recruitment review; Existing data. However, no interest from other trial teams to date
What is the impact of recruitment sites receiving an extra trial co-ordinator visit on recruitment rates? (SWAT 27)	NONE	No interest from other trial teams to date
What is the effect of mentioning scarcity of trial places in invitation letters on recruitment of trial participants? (SWAT 60)	NONE	No interest from other trial teams to date

Retention questions

Retention Interventions	Host trials testing or planning testing	Rationale
HIGH PRIORITY QUESTIONS		
Do courtesy telephone calls to trial participants following enrolment increase future retention rates?	ARTISAN; L1FE	Existing data; matches Priorities no. 4, 8 and 9 from the PRioRiTy 2 top 10
Sending Christmas cards to trial participants to improve retention. (SWAT 82)	ACTIVE; ASICA; C-GALL; CPIT III; DISC; FAME; FUTURE; GYY; L1FE; OSTRICH; PROFHER-2; PUrE RCT; ProtectT; REFLECT; SWHSI-2	Matches Priorities no. 8 and 9 from the PRioRiTy 2 top 10
What is the effectiveness of a theoretically informed cover letter on improving response rates to annual postal questionnaires? (SWAT 24)	(COMICS)	Existing data (5 SWATs being done in Edinburgh)
What is the effect of a text message notification versus no text message on questionnaire response rates? (SWAT 25/SWAT 31)	(COMICS)	Existing data; matches Priorities no. 4 and 6 from the PRioRiTy 2 top 10.
What is the effectiveness of a personalised text message versus a standard text message for promoting response to postal follow-up questionnaires? (SWAT 35)	MAGIC, KReBS, GRASP; MIQUIT, OTIS; CHAMP-1	matches Priorities no. 4 and 6 from the PRioRiTy 2 top 10; Likely to be able to answer the question within timeframe of PROMETHEUS
What is the effectiveness of sending pre-notification cards to trial participants 1-month before outcome measurement to improve retention.	ActWELL; WORKWELL; TOPAZ	Matches Priorities no. 4 from the PRioRiTy 2 top 10.
MEDIUM PRIORITY QUESTIONS		
What is the effect of adding a pen printed with the trial/university logo to the trial questionnaire on retention rates (SWAT 37)?	OTIS, KREBS, SSHEW	Existing data; matches Priority no. 6 from the PRioRiTy top 10

What is the effect of timing text message prompts to increase trial participant response to postal questionnaires? (SWAT 44)	UKFROST; MIQUIT, CHAMP-1	Matches Priorities no. 4 and 6 from the PRioRiTy 2 top 10
What is the impact of receiving a social incentive intervention cover letter compared with a standard covering letter on response to postal questionnaires? (SWAT registration submitted)	OTIS, ACL SNNAP	Matches Priorities no. 4 from the PRioRiTy 2 top 10.
SWAT 54: giving participants a thank you note or card after each study visit.	CLEAR	
Effect of birthday cards with or without nudge on retention and data completion rates in trials involving children (SWAT 79)	OSTRICH	
Responsive versus non-responsive text message reminder	ACTIVE	

We aim to test each intervention in between three and five host trials, in order to assess the effectiveness of each intervention in different trial contexts and patient populations. More than one intervention can be evaluated at a time in a SWAT using a factorial design.

Novel methodology questions not on the list are welcome; however these should be replicable in SWATs in multiple trial settings. Novel SWATs will also be required to be registered on the MRC-HTMR All-Ireland Hub website.

Number of awards

We are funding 25 SWATs up to the value of £5,000 each, to include direct project costs. This could cover staff time to apply for ethics and implement the SWAT, and attendance at a conference to disseminate findings. The MRC supports open access publishing through block grants to Higher Education Institutions; therefore the PROMETHEUS funding cannot cover publication costs.

What are the other benefits of getting involved?

In addition to the pump-prime funding, the MRC SWATs team will provide ongoing advice, support and template documents such as template protocols, wording for NHS research ethics amendments etc., to ensure ease of implementing the SWAT.

If funded, you gain access to expertise and resources to implement enhanced recruitment and/or retention strategies for your trial, based on the latest evidence and current thinking. Other benefits include:

- Raise the profile of your trial
- Contribute to the evidence base on recruitment and retention in trials
- An opportunity to get involved in an MRC funded initiative

- Access to recruitment and retention interventions
- Access to current thinking on effective recruitment and retention strategies
- Resource to develop interventions relevant to your study
- Opportunity to publish study specific recruitment and retention outcomes data
- Acknowledgement in any MRC SWAT collaboration reports, dissemination and publications

Who Should Apply?

Trial teams working on a planned or ongoing randomised trial are invited to apply. There are no eligibility restrictions for the lead applicant and early stage career researchers or trial coordinators/managers are welcome to apply, provided that the trial Chief Investigator supports the application. We particularly welcome expressions of interests from Clinical Trials Units.

Eligibility criteria

To be eligible, host trials will be:

1. Registered or eligible for registration on the UK Clinical Research Network Portfolio
2. In the planning phase, be in the process of applying for ethics permission, or recruiting or following up participants
3. Willing to apply for ethics permission or amendment to undertake at least one SWAT of a recruitment or retention intervention
4. Willing to randomise and deliver the recruitment or retention intervention according to a shared protocol and share data with the MRC SWATS team and help to write up findings for publication
5. Willing to use or register their SWAT on the MRC-HTMR All-Ireland Hub website, a free-to-use online database of ongoing SWATs if the intervention being evaluated is not already registered
6. Able to provide evidence of funding for the host trial (e.g. letter from funder)

Host trials wishing to test strategies to improve retention should be willing to share a copy of their consent form with the PROMETHEUM team.

Publication strategy for funded SWATs

Host trial teams are encouraged to publish findings from individual SWATs, in line with guidelines for reporting embedded recruitment trials (10), and taking any of the following approaches:

1. Individual host trial teams can complete the analysis and write up with minimal involvement from the PROMETHEUS team. We would expect relevant members of the PROMETHEUS team to be involved as co-authors.
2. The PROMETHEUS team is able to assist individual host trial teams with any or all of the following: data analysis, writing the manuscript, including providing text on the development of the interventions, general background and criteria for reporting standards in SWATs. We would expect relevant members of the PROMETHEUS team to be involved as co-authors.
3. Host trials can contribute their data to a 'meta-analysis' paper combining two or more of the same SWATs in a single publication. Such publications would be led by the PROMETHEUS team and relevant members of the included host trial teams will be involved as co-authors.

Regardless of the model of publication strategy selected**, host trials will be required to share a copy of the anonymised individual patient level data (IPD) with the PROMETHEUS team** to allow IPD meta-analysis of each category of SWAT to be undertaken. Where IPD is not possible, summary data would be required to be shared.

What does taking part involve?

Once you have submitted a valid 'Expression of Interest Form', we will contact you to hold initial discussions to:

- Introduce the PROMETHEUS study
- Check compatibility between the host trial and PROMETHEUS methods
- Discuss options for enhanced recruitment and/or retention interventions
- Discuss processes including ethics, data sharing arrangements and publications

After funding is agreed:

- Work begins to align the recruitment or retention intervention with the host trial processes (this can run in parallel with existing trial recruitment or retention procedures)
- The host trial submits a substantial research ethics and Health Research Authority amendment detailing the intervention (based on templates provided by the PROMETHEUS team)
- Once approved by research and governance, the host trial randomises patients to receive the SWAT interventions
- In line with data sharing arrangements, anonymised patient data are provided to the PROMETHEUS team to conduct a meta-analysis

Ethical Approval and R&D

Host trials will be required to submit NHS ethics substantial amendment in order to implement the SWAT.

I am interested, what next?

1. Discuss potential participation with your study team, to ensure support from the Principal Investigator
2. Complete the attached 'Expression of interest form' and email it to prometheus-group@york.ac.uk

Get in touch with us

- prometheus-group@york.ac.uk
- Dr Adwoa Parker (Tel: 01904 321671)
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The PROMETHEUS team

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- Professor Declan Devane, The National University of Ireland Galway
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