

Information for host trial teams

The effectiveness, cost-effectiveness and process evaluation of monetary incentives for recruiting and retaining trial participants: Studies Within A trial

We are collaborating with trial teams and awarding up to £10,000 to host a Study Within A Trial (SWAT) to test the effectiveness and cost-effectiveness of monetary incentives for recruiting and retaining trial participants.

What is Implement SWATs?

Implement SWATs: [‘Using IMPLEMENTation science and Studies Within A Trial to improve evidence-based participant recruitment and retention in randomised controlled trials’](#) is a national programme funded by the National Institute for Health and Care Research (NIHR). Implement SWATs aims to develop and promote the use of evidence for recruiting and retaining participants in randomised controlled trials, using a Studies Within A Trial (SWAT)¹ methodology.

Background: monetary incentives for recruiting and retaining participants in trials

Randomised controlled trials are crucial for testing health treatments to inform which treatments should be used in practice. However, more than half of trials struggle to find enough participants², and many participants who do join end up dropping out or providing incomplete data. This causes a lot of wasted research and delays in providing effective treatments to patients, causing potentially harmful treatments to continue being used. Increasing participant numbers can speed up the delivery of trials and the identification of effective and ineffective treatments, ultimately saving lives and improving health outcomes.

There's a lack of evidence on efficient ways for trial teams to recruit participants and keep them engaged. One solution is to use a randomised 'Study Within A Trial' (SWAT) design, where a randomised trial is embedded within another trial. This method, done within a single host trial or across several simultaneously, produces rapid, high-quality evidence. However, few SWATs have been carried out, and more are needed to guide trial teams better.

Monetary incentives, such as offering participants money in the form of cash or vouchers, could potentially boost participant recruitment and retention in trials. Our priority setting exercise identified monetary incentives as key strategies to test for their effectiveness in recruiting and retaining participants. Previous studies suggest that offering incentives between £5 and £100 might help, but the evidence isn't strong. Questions remain about the ideal amount and type of incentive—cash, vouchers, or payment cards that can be used in place of cash (e.g., [ClinCard](#))—as

well as their cost-effectiveness. We will therefore coordinate a series of randomised SWATs evaluating the effectiveness and cost-effectiveness of different variations of monetary incentives for recruiting or retaining trial participants.

Although the randomised SWATs testing monetary incentives can help us understand whether different strategies are more effective or cost-effective than others, they will not tell us why. To help understand why a particular monetary incentive did or didn't work, whom they work best for, and in what circumstances they are likely to be most effective we will carry out a process evaluation alongside the SWATs. Additionally, the process evaluation will explore potential ethical issues surrounding offering monetary incentives to trial participants. The process evaluation will involve interviewing key stakeholders such as the SWAT participants and host trial teams to understand the ethical, process and implementation issues better.

What are the research objectives?

We aim to answer the following questions focused on the use of monetary incentives for recruiting and retaining trial participants, which is outlined in Table 1.

Table 1: Research objectives

Objective	Research question
1.	How effective is £10 cash, £10 voucher, £10 payment card or £5 donation to a person's choice of charity compared to no incentive for increasing participant recruitment and retention in trials?
2.	How effective is a higher amount (e.g. £20) of cash, voucher or payment card incentive compared to a lower amount incentive (e.g., £10) of the same format (voucher or payment card incentive) or no incentive?
3.	How effective is a £10 cash incentive compared to the offer of a £5 charity donation for increasing participant recruitment and retention in trials?
4.	Some trials are already funded to offer monetary incentives. So where a trial is already planning to offer incentives, we will test the effectiveness of randomising people to different formats of the monetary incentive (e.g., cash, voucher, payment card or nothing) on recruitment and retention.
5.	For some trials already funded to use monetary incentives, we will test the effectiveness of randomising differing amounts of monetary incentives using the same format (e.g., £10 voucher vs. £20 voucher) on recruitment and retention.

6.	How effective are monetary incentives, compared to non-monetary incentives of similar or lower value?
7.	We will test the cost-effectiveness of these monetary incentive strategies for improving recruitment and retention.
8.	We will do a process evaluation to explore the ethics as well as the processes around using and implementing monetary incentives in trials

Scope of the awards

This award is available to trial teams based in, and undertaking recruitment or follow-up of participants in the UK.

SWAT strategies

We welcome host trial teams interested in implementing a monetary incentive SWAT using the recruitment or retention strategies outlined in Tables 2 and 3 below. We also welcome host trials already funded to offer monetary incentives to randomise their incentives.

These strategies will be revised on an ongoing basis as the evidence base develops, with the least effective strategies being dropped and the most effective strategies being tested further against other promising strategies until definitive evidence emerges.

Table 2: Proposed initial SWAT arms: monetary incentives for recruitment

SWAT Group: recruitment	SWAT strategy arms
Group A - Recruitment	<ol style="list-style-type: none"> 1. £10 cash 2. £10 voucher 3. £10 payment card (e.g., ClinCard) 4. £5 payment to the person's chosen charity 5. No incentive
Group B - Recruitment: Host trials already funded to use monetary incentives	<ol style="list-style-type: none"> 1. Cash – amount as already funded 2. Voucher– amount as already funded 3. Payment card – amount as already funded (e.g., ClinCard)
Group C - Recruitment: Host trials already funded to use monetary incentives	<ol style="list-style-type: none"> 1. Lower amount voucher 2. Higher amount voucher
	<ol style="list-style-type: none"> 3. Lower amount cash 4. Higher amount cash
	<ol style="list-style-type: none"> 5. Lower amount payment card (e.g., ClinCard) 6. Higher amount payment card (e.g., ClinCard)

Table 3: Proposed SWAT arms: monetary incentives for retention

SWAT Group: retention	SWAT strategy arms
Group A - Retention	6. £10 cash 7. £10 voucher 8. £10 payment card (e.g., ClinCard) 9. £5 payment to the person’s chosen charity 10. No incentive
Group B - Retention: Host trials already funded to use monetary incentives	4. Cash – amount as already funded 5. Voucher– amount as already funded 6. Payment card – amount as already funded
Group C - Retention: Host trials already funded to use monetary incentives	7. Lower amount voucher
	8. Higher amount voucher
	9. Lower amount cash
	10. Higher amount cash
	11. Lower amount payment card
	12. Higher amount payment card

We aim to test each strategy in between two and eight host trials each for recruitment and retention, in order to assess the effectiveness of each intervention in different trial contexts and patient populations. More than one strategy can be evaluated at a time - e.g., where feasible, a host trial could test the effectiveness of monetary incentives for both recruitment and retention.

‘Group A’ SWATs

Host trials interested in the Group A’ SWATs can choose a minimum of two arms (e.g., £10 voucher vs. No incentive); however, one of those arms should be the ‘no incentive’ arm, to enable the definitive assessment of the effectiveness of monetary incentives compared to no incentive.

Where feasible and sample sizes allow, host trials are encouraged to randomise participants/potential participants to more or all of the SWAT strategy arms.

£5 payment to chosen charity: We are testing this strategy because the Implement SWATs PPI group recommended including strategy 4, £5 payment to the person’s chosen charity (from a short-list of charities offered by the host trial team), and suggested that a lower amount to a chosen charity may be as acceptable and therefore as effective for recruitment/retention as a higher amount given directly to the potential participant. Host trial teams will be encouraged to choose a shortlist of relevant charities and include details of these in the trial invitation letter/email/text for potential participants.

‘Group B’ SWATs: for host trials already funded to offer monetary incentives

These are aimed at host trials already funded to offer monetary incentives for recruitment or retention. For these SWATs, host trials are encouraged to randomise potential participants to a minimum of two different formats of the same value incentive, e.g., offering £10, comparing cash vs. vouchers. Where feasible and sample sizes allow, host trials are encouraged to randomise to all three formats (cash vs. voucher vs. payment card).

‘Group C’ SWATs: for host trials already funded to offer monetary incentives

These are also initially aimed at host trials already funded to offer monetary incentives for recruitment or retention. For these SWATs, host trials are encouraged to randomise participants or potential participants to different incentive amounts, e.g., £10 voucher vs. £20 voucher. The Implement SWATs team can provide additional funds to test higher value payments should this be required.

SWAT registration

These SWATs will be registered on the [MRC-HTMR All-Ireland Hub](#) website, as part of the Implement SWATs registration.

Number and value of collaborative awards

We are providing collaborative funding for up to 22 SWATs.

For host trials with existing funding for monetary incentives, we can award up to £5000 to cover staff time to liaise with the Implement SWATs team, distribute the incentives, prepare the data and share it securely with the Implement SWATs team.

For host trials without existing funding for monetary incentives, we can award up to £10,000 to cover the costs of the incentives, staff time to liaise with the Implement SWATs team, distribute the incentives, prepare the data and share it securely with the Implement SWATs team.

What are the other benefits of getting involved?

In addition to the funding, the Implement SWATs team based at the University of York will provide coordination for the SWATs, including coordinating the ethics approval processes. You will be offered ongoing advice, support and template/example documents to ensure ease of implementing the SWAT.

Other benefits of being involved include:

- Raise the profile of your trial
- Contribute to the evidence base on recruitment and retention in trials. Evidence from these SWATs will be included in the Cochrane systematic reviews of recruitment² and retention³ strategies, and will inform the development of guidelines for effective recruitment and retention in trials.
- An opportunity to get involved in an NIHR-funded initiative
- Access to current thinking on effective recruitment and retention strategies
- Acknowledgement in Implement SWATs collaboration reports, dissemination and publications
- Authorship of SWAT publication

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.

Eligibility criteria

To be eligible, host trials will be:

1. In the planning phase, be in the process of applying for ethics permission, or recruiting or following up participants
2. Willing to apply for ethics permission or amendment to undertake at least one SWAT of a monetary incentive of a recruitment or retention intervention
3. Willing to randomise and deliver the incentive strategy according to a shared protocol and share data with the Implement SWATs team and help to write up findings for publication
4. Able to provide evidence of funding for the host trial (e.g., letter from funder)
5. Using individual randomisation only (i.e., cluster randomised host trials are not eligible)
6. Participants in the host trial must have at least one follow-up remaining for retention.

Publication strategy for funded collaborative SWATs

Host trial teams will be expected to contribute their data to a 'simultaneous SWAT' or 'meta-analysis' paper combining two or more of the same SWATs in a single publication. Such publications would be led by the Implement SWATs team and relevant members of the included host trial teams will be involved as co-authors. Examples of collaborative simultaneous SWAT and meta-analysis publications are listed in the reference list^{4,5,6,7}.

Host trial teams will be required to share a copy of the anonymised individual patient level data (IPD) with the Implement SWATs 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.

Additionally, should host trial teams wish to, they could also publish findings from individual SWATs, taking one of the following approaches:

1. Individual host trial teams can complete the analysis and write up with minimal involvement from the Implement SWATs team. We would expect relevant members of the Implement SWATs team to be involved as co-authors
2. The Implement SWATs team is able to assist individual host trial teams with any or all of the following: data analysis, providing text on the development of the interventions, general background and reporting standards for the SWATs. We would expect relevant members of the Implement SWATs team to be involved as co-authors

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 Implement SWATs study
- Check compatibility between the host trial and Implement SWATs methods
- Discuss processes including ethics, data sharing arrangements, potential project timelines and publications

Selection process:

- Following the submission of an expression of interest, and initial discussion between the host trial team and Implement SWATs team, we will request a proposed SWAT project timeline from the host trial team

- An assessment will be made by the Implement SWATs team regarding compatibility between the host trial and the planned SWAT(s)

After funding is agreed:

- Letter of award and collaboration agreement will be issued to the host trial team
- Work begins to align the recruitment or retention strategy with the host trial processes (this can run in parallel with existing trial recruitment or retention procedures)
- Following discussion between the host trial team and the Implement SWATs team, a research ethics and Health Research Authority application or substantial amendment to undertake the SWAT will be made prior to undertaking the SWAT. Depending on timing and preference by the host trial team, this will either be submitted by the host trial team with support from the Implement SWATs team (including the provision of templates by the Implement SWATs team); or the Implement SWATs team will submit the approvals application in consultation with the host trial team
- Once approved by research and governance, the host trial randomises patients to receive the SWAT interventions
- Members of the host trial team will be approached to discuss their experiences of undertaking a SWAT as part of the Implement SWATs process evaluation
- In line with data sharing arrangements, anonymised patient data are provided by the host trial team to the Implement SWATs 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 swats-group@york.ac.uk
3. The Implement SWATs team will contact you to discuss the feasibility and process of undertaking the SWAT in your trial

Get in touch with us

- Email: swats-group@york.ac.uk
- The Chief Investigator, Dr Adwoa Parker can also be contacted by email at adwoa.parker@york.ac.uk, Tel: 01904 32 1671
- website: www.implementswats.org

The Implement SWATs team

- Dr Adwoa Parker, University of York (*Chief Investigator*)
- Professor Mike Clarke, Queen's University Belfast (*Programme Mentor*)
- Miss Elizabeth Coleman, University of York (*Statistician*)
- Dr Nassos Gkekas, University of York (*Health Economist*)
- Professor Jeremy Grimshaw, Ottawa Hospital Research institute, Ontario, Canada (*Programme Mentor*)

- Miss Gloria Mongelli, University of York (*Research Trainee*)
- Mrs Camila Piccolo-Lawrance, University of York (*Trial Support Officer*)
- Professor David Torgerson, University of York (*Programme Mentor*)
- Professor Shaun Treweek, University of Aberdeen (*Programme Mentor*)
- Dr Han-I Wang, University of York (*Health Economist*)

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References

1. Treweek, S., S. Bevan, P. Bower, M. Campbell, J. Christie, M. Clarke, C. Collett, S. Cotton, D. Devane, A. El Feky, E. Flemyng, S. Galvin, H. Gardner, K. Gillies, J. Jansen, R. Littleford, A. Parker, C. Ramsay, L. Restrup, F. Sullivan, D. Torgerson, L. Tremain, M. Westmore and P. R. Williamson (2018). "Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)?" *Trials* **19**(1): 139.
2. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, Jackson C, Taskila TK, Gardner H. Strategies to improve recruitment to randomised trials. *Cochrane Database of Systematic Reviews* 2018, Issue 2. Art. No.: MR000013. DOI: 10.1002/14651858.MR000013.pub6. Accessed 13 December 2023.
3. Gillies K, Kearney A, Keenan C, Treweek S, Hudson J, Brueton VC, Conway T, Hunter A, Murphy L, Carr PJ, Rait G, Manson P, Aceves-Martins M. Strategies to improve retention in randomised trials. *Cochrane Database of Systematic Reviews* 2021, Issue 3. Art. No.: MR000032. DOI: 10.1002/14651858.MR000032.pub3. Accessed 13 December 2023.
4. Parker A, Arundel C, Mills N, et al. Staff training to improve participant recruitment into surgical randomised controlled trials: A feasibility study within a trial (SWAT) across four host trials simultaneously. *Research Methods in Medicine & Health Sciences*. 2023;4(1):2-15. doi:10.1177/26320843221106950
5. Coleman E, Arundel C, Clark L, Doherty L, Gillies K, Hewitt C et al. Bah humbug! Association between sending Christmas cards to trial participants and trial retention: randomised study within a trial conducted simultaneously across eight host trials *BMJ* 2021; 375 :e067742 doi:10.1136/bmj-2021-067742
6. Madurasinghe VW, Bower P, Eldridge S, Collier D, Graffy J, Treweek S, Knapp P, Parker A, Rick J, Salisbury C, Man MS. Can we achieve better recruitment by providing better information? Meta-analysis of 'studies within a trial'(SWATs) of optimised participant information sheets. *BMC medicine*. 2021 Dec;19(1):1-8.
7. Madurasinghe VW, Knapp P, Eldridge S, Collier D, Treweek S, Rick J, Graffy J, Parker A, Salisbury C, Torgerson D, Jolly K. Can we achieve better trial recruitment by presenting patient information through multimedia? Meta-analysis of 'studies within a trial'(SWATs). *BMC medicine*. 2023 Nov 8;21(1):425.