

Reducing barriers to SWAT adoption: practical recruitment and retention resources from PRESS

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www.trialforge.org



HRB-TMRN / MRC-NIHR-TMRP Working Group Project Seed Funding Award 2023



Irish Lead: Dr Frances Shiely
University College Cork

Project Title: Protocol and resources development for prioritised recruitment and retention strategies (PRESS)

UK Lead: Dr Adwoa Parker
University of York



Working Group: Trial Conduct

Co-Applicants: Prof Shaun Treweek, University of Aberdeen; Ms Catherine Arundel, University of York; Dr Hanne Bruhn, University of Aberdeen and University College Cork; Dr Chris Sutton, University of Manchester

Study Team

- **Researchers**

- Frances Shiely (University College Cork, Ireland) – Lead
- Adwoa Parker (University of York, UK) – Lead
- Shaun Treweek, University of Aberdeen
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- Chris Sutton, University of University of Central Lancashire
- Athanasios Gkekas, University of York
- Rosie Way, Imperial College NHS Trust
- Andy Willis, University College Cork, Ireland

- **PPI Partners**

- Philip Bell, Michele Powponne, Kamil Sterniczuk



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Randomised controlled trials

The bedrock of evidence-based healthcare

Fairest tests

People are randomly assigned to different groups, minimising bias.

Reliable results

Comparing groups, we can confidently say whether an intervention causes an effect, rather than the outcome happening by chance.

Better decisions

Provide strong evidence that helps doctors, policymakers, and researchers choose the best interventions.



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Failure to recruit and retain participants are the biggest problems facing trials

>80%

Recruitment Delays

Fail to enrol on time, needing extensions and/or addition of new sites.

31-55%

Discontinuation Rate

Globally, 31-55% of all trials are discontinued due to poor recruitment.

>89%

Retention and missing data

- 89% of RCTs report some missing data
- 18% have >20% participants with partly missing data

Refs: Speich et al. (2025), PMID: PMC12409572; Desai (202), PMID:PMC7342339; Huang (2018); Desai (2020) Jacques (2022); Vellinga (2021); Wood(2004); Peterson (2012)



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Impacts of poor recruitment and retention

HUMAN COST

3,000+

lives lost in COVID-19 RECOVERY trial due to slow recruitment

FINANCIAL IMPACT

£14M+

potential net benefit lost per trial delay




Impacts of poor performance

- **Scientific:** Reduced power and increased risk of Type II errors
- **Ethical:** Exposing participants to risk without social value
- **Research waste:** Significant research waste (time - participants, funders, trial teams) and resources
- **Increased costs:** Funding withdrawal
- **Clinical:** Delays in adopting effective life-saving treatments; continues harmful treatments

Refs: Knowlson & Torgerson, 2020; Gkekas, 2025



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WHAT IS A **SWAT**?

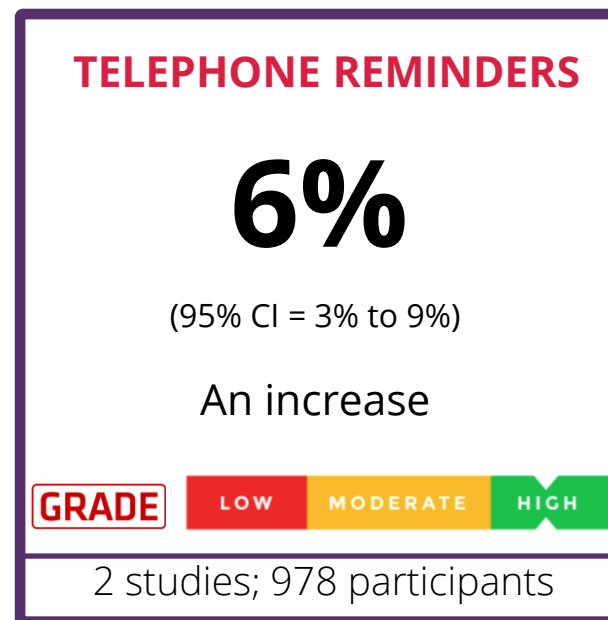
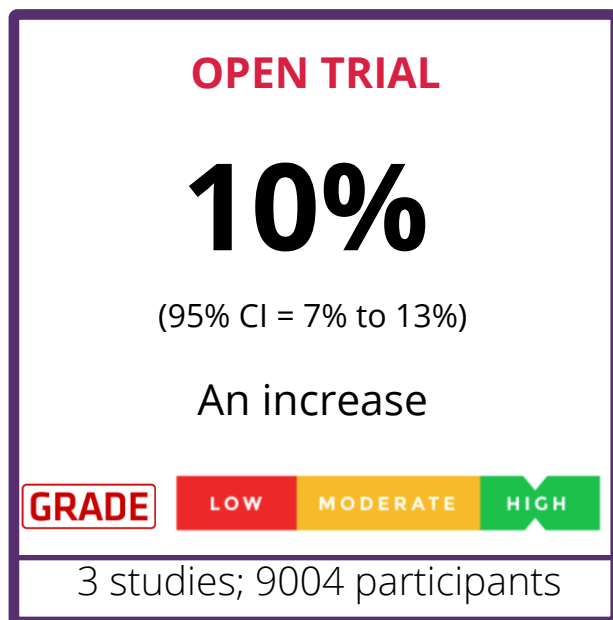
Existing Evidence: systematic reviews on recruitment and retention

- 68 papers testing strategies to improve recruitment (2018).
 - Quality of evidence: just **three** are supported by high-certainty evidence according to GRADE.
- 70 papers testing strategies to improve retention (2021).
 - Quality of evidence: **NONE** were supported by high-certainty evidence.

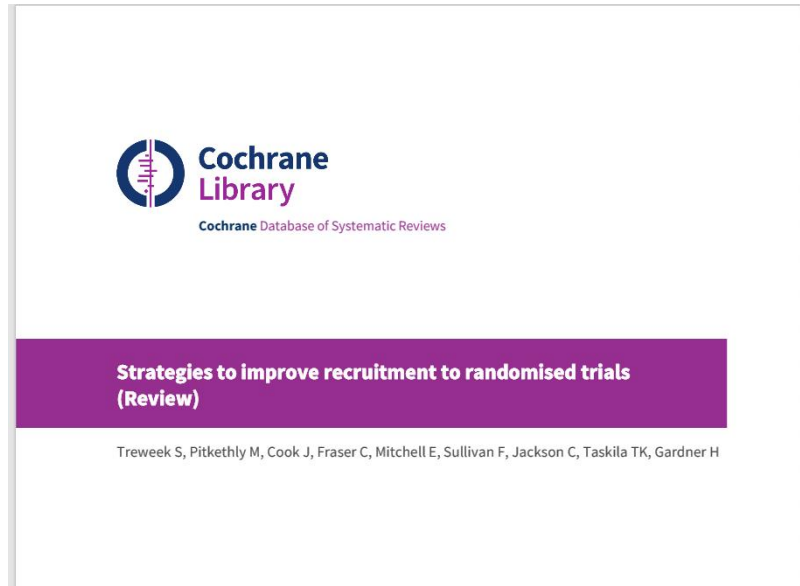


Updating the evidence in 2026: what improves recruitment?

91 papers identified (40 new)



Recruitment review conclusions



2018: “The literature on interventions to improve recruitment to trials has plenty of variety but little depth”

*2025: 70% of comparisons came from single studies - **need less innovation, more replication!***



SWAT Prioritisation: Background & Methods

Background & Rationale

- Urgent need for more SWAT replications to build high-quality evidence
- PRioRiTy & PRioRiTy II: identified recruitment and retention priorities for future evaluation
- Need to identify specific recruitment and retention strategies that can be tested in a **randomised** way.
- Implement SWATs and the Trial Forge SWAT Network initiated this work to identify high-priority evaluation targets.

Methodological Approach

- **Systematic Extraction:** Reviewed the NIHR HTA Library (2020-2022) to identify potential strategies.
- Mapped strategies to the Cochrane reviews, Economic evaluation review (Gkekas 2022), PRIORITY I & II (Healy 2018; Brunsdon 2019), MRC-START (Madurasinghe 2022, 2023) and PROMETHEUS (Doherty 2023; Parker 2024)
- **Iterative Ranking:** Conducted by the Prioritisation Working Group to narrow the field.
- **Stakeholder Input:** Collaboration with Patient and Public Involvement (PPI) partners to ensure relevance.



SWAT Prioritisation: 11 Key Strategies Identified

Recruitment Strategies (Top 6)

- Patient and Public Involvement (PPI)
- Informational Video(s)
- Postal Invitations & Reminders
- Embedded Qualitative Research
- Targeting Under-served Groups
- Financial/Monetary Incentives

Retention Strategies (Top 5)

- PPI in Follow-up Methods
- Flexibility in Data Collection
- Participant Reminders (Multi-mode)
- Financial/Monetary Incentives
- Use of Routine Data Collection

These are the broad priority questions: there are multiple sub-questions under each



A LIST OF 11 PRIORITY RECRUITMENT AND RETENTION SWATS

By Shaun Treweek Posted February 9, 2024 In News



Studies Within A Trial (SWATs) are a good way of generating evidence to support trial process decision-making. SWATs are designed to be replicated, which means it's important to have some focus otherwise we end up with lots of single evaluations that don't really provide much certainty as to what is and is not effective.

The **York Trial Forge SWAT Centre** working together with the SWAT Network has produced a list of 11 priority recruitment and retention SWATs. These SWATs were prioritised by looking at recruitment and retention interventions that are used a lot in the UK (with ones used often ranked higher), Cochrane systematic reviews of **recruitment** and **retention** strategies and the **PRIoRiTY 1 and 2 process** that identified important unanswered questions in trial recruitment and retention, respectively. Evaluations of these SWATs, including of cost-effectiveness, would be very welcome.



Example SWAT priority questions for recruitment include 'What is the most effective way of involving patients and the public in trials to improve participant recruitment?', 'What is the most effective way to use video(s) to support trial recruitment?' and 'What are the most effective strategies to recruit underserved groups?'

Priority SWAT questions for retention include 'What is the most effective way of offering flexibility to support participant retention?', 'What is the most effective way of using participant reminders to support retention?' and 'What is the most effective way to use financial incentives to support retention?'

A document describing the 11 priority SWATs, including some example SWAT questions in the priority areas and SWAT on the **SWAT repository** that fall in the priority areas can be **downloaded here**.

How to cite the priority list:

Reddy A, Wey B, Ghoshwara A, A. Mordali C, Coleman E, Arundel C, Treweek S (2024 February 9) WP1:



<https://www.trialforge.org/2024/02/a-list-of-11-priority-recruitment-and-retention-swats/>



PRESS Objectives

Make it easier for trial teams to adopt and replicate priority SWATs

1. To develop SWAT protocols and resources for prioritised trial recruitment and retention strategies
2. Develop accompanying practical resources for all 11 top prioritised recruitment and retention strategies, to support trial teams to ensure easy facilitation of SWAT implementation, e.g., ethics applications...



PRESS Methods

- Decided on the needs, approach and timeline.
- PPI-focused protocols co-designed with PPI partners.
- Selected subject specialists to lead each part.
- All members of the team contributed to each output.
- The final outputs were reviewed by the SWAT Trial Forge Network members and PPI partners and checked for language suitability.



Results

- The PRESS Protocols and Resources are available online:
- [Trial Forge PRESS Webpage](#)
- [PRESS project page on Open Science Framework \(OSF\)](#)
- Journal article submitted to *Journal of Clinical Epidemiology*



1. Master SWAT Protocol Template

- Standardise SWAT implementation
- Promote consistency
- Facilitate replication
- Facilitate coordinated approach across multiple trials either sequentially or simultaneously



PRESS SWAT Master Protocol Template

How to cite this template SWAT protocol

Bruhn, H., Shiely, F., Parker, A., Wilkinson, J. A., Arundel, C., Sutton, C., ... Treweek, S. (2025, March 29). PRESS SWAT Master Protocol Template. Retrieved from <https://osf.io/jmpvn/>



Methods: Participants, interventions, and outcomes			
7	PPI partner involvement	<p>Are patients and/or public partners involved in any aspects of the SWAT?</p> <p>Guidance: For SWAT replications – we recommend consulting PPI partners relevant to your SWAT population and setting if very different from those in the original SWAT. The GRIPP2 long or short form checklist might be helpful to describe PPI partner involvement.</p>	Cochrane Retention TFG5
8	Study setting	Provide a description of SWAT setting(s) (e.g., community clinic, academic hospital).	9 SPIRIT
9	Who can take part	<p>Provide details of who can/will take part in the SWAT and reasons why certain groups may not be included. If applicable, eligibility criteria for study centres and individuals who will perform the SWAT interventions (e.g., recruiting staff, Trial Management staff, data Management staff, Trial Monitors etc.).</p> <p>Guidance: Please note that from the above description it should be clear whether the SWAT started at the same time as or at a later date than the host trial. It should also be made clear what will be the source of the SWAT sample (e.g., all host trial participants; all host trial participants lost to follow-up; all host trial participants in its control arm; all host trial participants lost to follow-up in the control arm; all host trial participants in the intervention arm; all host trial participants lost to follow-up in the intervention arm).</p>	10 SPIRIT (Cochrane Retention)
10a	Interventions	<p>Describe the interventions for each SWAT group with sufficient detail to allow replication, including how and when they will be administered.</p> <p>Guidance: The description of each SWAT intervention should include</p> <ul style="list-style-type: none"> -Timing -Mode of Delivery -Providers -Co-interventions (existing recruitment/retention/other interventions) <p>The TIDieR guidance might also be helpful in describing the intervention in sufficient detail.</p>	11a SPIRIT Cochrane Retention

2. Recruitment SWATs (n = 4)

SWAT overarching priority Question	SWAT Protocol question chosen by PPI partners for replication	Link to protocol and resource pack online
What is the most effective way of involving patients and the public in trials to improve participant recruitment?	The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): Study Within A Trial Protocol	https://osf.io/8kcdr/files/osfstorage
What is the most effective way of sending potential trial participants invitation letters by post to optimise recruitment rates?	An evaluation of a theoretically informed written trial invitation compared to a standard written invitation to improve recruitment (INVITE): Study Within A Trial protocol	https://osf.io/r735x/files/osfstorage
What is the most effective way to use financial incentives to support recruitment?	An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers (CASH): Study Within A Trial protocol	https://osf.io/6e2fz/files/osfstorage
What are the most effective strategies to recruit underserved groups?	An evaluation of whether video(s) providing information about a trial increases recruitment of particular under-served groups, important for the trial, compared to written information only (VISUAL): template Study Within A Trial protocol	https://osf.io/5mx4k/files/osfstorage

2. Retention SWATs

SWAT overarching Question	SWAT Protocol question chosen by PPI partners for replication	Link to protocol and resource pack online
What is the most effective way of offering flexibility to support participant retention?	An evaluation of whether offering flexibility in in-person follow-up visit location increases trial participant retention compared to not offering flexibility (FLEXI): A cluster-randomised Study Within A Trial protocol	https://osf.io/274jf/files/osfstorage
What is the most effective way of involving patients and the public in trials to improve participant retention?	The effectiveness and cost-effectiveness of trial newsletters, co-produced with Patient and Public Involvement (PPI) partners, on participant retention rates (NEWSLETTER): template Study Within A Trial protocol	https://osf.io/cv9ag/files/osfstorage
What is the most effective way of using participant reminders to support retention?	An evaluation of whether electronic reminders increase questionnaire completion rates compared to usual follow-up (E-PROMPT): template Study Within A Trial protocol	https://osf.io/vbnj5/files/osfstorage
What is the most effective way to use financial incentives to support retention?	Do monetary incentives increase retention compared to no monetary incentive? (MONCENTIVES): Study Within A Trial Protocol	https://osf.io/t2gnf/files/osfstorage
What is the most effective way of using routine data collection to support retention?	An evaluation of whether using routinely collected data, to shorten a follow-up questionnaire, increases the retention of under-served groups, compared to using a longer, participant-reported questionnaire (SHORT-Q): template Study Within A Trial protocol	https://osf.io/m2bac/files/osfstorage

PRESS Methods: PPI SWATs (n = 2)

- PPI partners determined that SWAT strategies should be:
 - Co-designed & co-developed with researchers
- And their purpose was to:
 - Increase **trust** between communities & researchers
 - Educate on the value of clinical trials & benefits of participation
 - Have PPI involvement in tailoring follow up strategies
- That the team should explore how marketing strategies could help



Methods: Co-producing PPI recruitment & retention SWAT protocols

Researcher Partners

- Shared current evidence on PPI SWATs
- Provided guidance on some criteria for choosing SWAT protocols
- Facilitated meetings & between meeting tasks

PPI Partners

- Generated ideas on the purposes of the PPI SWATs
- Generated ideas for potential strategies for SWATs
- Chose which PPI SWAT questions we should develop into protocols
- Created examples of possible intervention materials & provided feedback



3. PRESS Agreed PPI SWATs

- Recruitment SWAT – use of a participant biography
- Retention SWAT – use of a PPI co-developed participant newsletter
- We mapped PPI suggestions to other priority questions for SWATs
- We used identified behaviour change theory elements that related to PPI proposed contents of the bio & newsletter
- Developed a guide to Creating a Trial Participant Biography for the BIOREC Study Within A Trial (SWAT)

Behaviour change theory taken from Jones et al. (2019) RESPONSE: A behavioural insights checklist for designing effective communications; Practitioners' Play book. Available from: <https://www.cominit.com/global/content/response-behavioural-insights-checklist-designing-effective-communications>.



4. Ethics applications templates

- Requirements for ethics approval for SWATs vary from institution to institution and country to country.
- We created adaptable ethics application templates with context-specific wording for both the UK and Ireland (n = 9).
- These can be adapted for ethics committees in any country.
- These streamline the approvals process and support ethical clarity for embedded SWATs.



Trial Forge Guidance 5

We simultaneously developed Trial Forge Guidance 5: Ethical considerations for studies within a trial.

Bruhn et al. *Trials* (2025) 26:267
<https://doi.org/10.1186/s13063-025-08958-9>

Trials

METHODOLOGY

Open Access



Trial Forge Guidance 5: ethical considerations in randomised Studies Within A Trial (SWATs)

Hanne Bruhn^{1,2,3}, Shaun Treweek³, Charles Weijer⁴, Matthias Briel^{5,6}, Mike Clarke⁷, Rachel Crowley⁸, Katie Gillies³, Heidi Green⁹, Ellen Murphy^{1,2}, Adwoa Parker¹⁰, Geneviève Shiely Hayes¹, Peter Hart¹¹ and Frances Shiely^{1,2,11*} 



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5. Statistical Analysis Plans

- We produced Statistical Analysis Plan (SAP) templates for both recruitment and retention SWATs. These standardised SAPs support rigorous analysis, enhance reproducibility, and reduce the methodological workload for trial teams.
- Sutton, C., Gkekas, A., Shiely, F., Treweek, S., Bruhn, H., Wilkinson, J. A., ... Parker, A. (2025, March 29). PRESS Randomised Recruitment SWAT Master Statistical Analysis Plan Template. <https://osf.io/vqt6g/files/osfstorage>
- Sutton, C., Gkekas, A., Shiely, F., Treweek, S., Bruhn, H., Wilkinson, J. A., ... Parker, A. (2025, March 29). PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template. Retrieved from <https://osf.io/h73ke/files/osfstorage>



6. Funding Guidance

- We developed a guidance document to support researchers applying for funding to conduct SWATs. It includes justification text, budgeting advice, and evidence summaries, to strengthen applications and align them with funder expectations.
- Parker, A., Wilkinson, J. A., Treweek, S., Gkekas, A., Bruhn, H., Arundel, C., ... Shiely, F. (2025, March 19). Guidance for Researchers Applying for Funding to Conduct High-Priority SWATs of Recruitment and Retention Strategies. <https://osf.io/w6zym/files/osfstorage>



7. Health Economics Guidance

- Guidance to assist researchers in planning economic evaluations of SWATs - methods for estimating cost-effectiveness.
- Gkekas, A., Shiely, F., Wilkinson, J. A., Sutton, C., Treweek, S., Bruhn, H., ... Parker, A. (2025, March 18). PRESS Health Economics Guidance. Retrieved from <https://osf.io/sebnk>



8. Guidance on making accessible documents

- PRESS aims to support inclusive research practices and reduce barriers to participation and collaboration.
- We make recommendations for document formatting, language simplification etc. The guidance was reviewed by PPI partners.
- Wilkinson, J. A., Bennett, A., Shiely, F., Treweek, S., Sterniczuk, K., Powponne, M., ... Parker, A. (2025, March 20). Guidance on Making Accessible Documents. Retrieved from <https://osf.io/8ek76>



LETTER

Open Access

Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)?



Dawson et al. *Trials* (2022) 23:672
https://doi.org/10.1186/s13063-022-06553-w

METHODOLOGY

Trial Forge and how from ethical guidance

Shoba Dawson¹, Kati Gosala Gopalakrishnan¹, Victoria Shepherd¹², Miles D. Witham²⁰ et al.

Bruhn et al. *Trials* (2025) 26:267
https://doi.org/10.1186/s13063-025-08958-9

METHODOLOGY

Trial Forge Guidance 5: ethical considerations in randomised Studies Within A Trial (SWATs)

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UPDATE

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Update to Trial Forge Guidance 2: addition of the Value of Information criterion



thanasios Gkekas^{1*} , Adwoa Parker¹, Shaun Treweek², Elizabeth Coleman¹, Catherine Arundel¹ and Frances Shiely^{3,4,5}

Open Access



Line randomised Studies

, D. Devane^{4,5,6}, S. Eldridge⁷, S. Galvin⁴, et al. on behalf of the PROMETHEUS GROUP



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