

COMMENTARY

Protocols and resources for priority recruitment and retention SWATs: the PRESS project

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Accepted 18 August 2026; Published online xxxx

Abstract

Background and Objectives: Recruitment and retention difficulties remain major threats to the success, efficiency, and value of clinical trials, yet robust evidence on how to address these challenges is limited. Studies within a trial (SWATs) provide a scalable method for evaluating trial process interventions, but their implementation is often hampered by a lack of accessible, standardized resources. The Protocols and Resources for Priority Recruitment and Retention SWATs (PRESS) project aimed to develop a suite of ready-to-use, evidence-informed materials to support rapid and rigorous evaluation of prioritized recruitment and retention strategies.

Methods: PRESS followed a structured methodological development process informed by existing evidence, stakeholder input, and Patient and Public Involvement (PPI) co-production. We used outputs from previous systematic reviews, PRioRiTy I and II, and the Trial Forge SWAT Network to identify high-priority recruitment and retention questions. Multidisciplinary working groups covering trial methodology, statistics, health economics, ethics, accessibility, and PPI independently drafted resources using an iterative consensus-building approach. Drafts were refined through internal review, cross-team consultation, and linguistic/feasibility review by PPI Partners. All outputs were standardized to support reuse across diverse trial contexts.

Results: PRESS delivered a comprehensive, openly accessible SWAT resource pack including a Master SWAT Protocol template; 9 randomized recruitment and retention SWAT protocols including two co-produced PPI-focused SWAT protocols; 9 ethics templates; 2 statistical analysis plan templates; funding application guidance; health economics guidance; and accessibility recommendations. These resources collectively support efficient and consistent implementation of high-priority SWATs.

Conclusion: PRESS provides a coherent, evidence-informed infrastructure to support high-priority SWAT evaluations and reduce barriers to their implementation. By enabling trial teams to embed SWATs more easily and consistently, PRESS has the potential to accelerate methodological evidence generation, reduce research waste, and improve participant experience. Broad uptake of PRESS resources may enhance overall trial efficiency and contribute to a stronger evidence base for recruitment and retention strategies. © 2026 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: SWATs; Trials; Recruitment; Retention; Methodology; Co-production

Funding: The PRESS project (Protocol and resources development for prioritized recruitment and retention strategies) was co-funded by the MRC-NIHR-TMRP (Medical Research Council - National Institute for Health and Care Research - Trials Methodology Research Partnership), UK, and the HRB TMRN (Health Research Board Trials Methodology Research Network), Ireland. Adwoa Parker was funded by the National Institute for Health and Care Research (Advanced Fellowship, reference:

NIHR302256). The views expressed are those of the authors and not necessarily those of the funders.

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Plain Language Summary

What is this research about?

Medical researchers run clinical trials to find out whether treatments work. To get good results, trials need enough people to join and to stay involved until the end. This is harder than it sounds. Many trials struggle to recruit enough participants, and others lose people along the way. This is a big problem because it wastes time and money and can mean that patients wait longer for new treatments.

One way to address this is to run small studies inside a trial called studies within a trial (SWATs). These test different ways of getting people to join or stay in a trial. For example, a SWAT might test whether sending a video about the trial helps more people sign up than sending a letter.

What was the problem?

Even though SWATs are a good idea, many research teams find them hard to do. One reason is that there are no ready-made plans or documents to help them get started. Teams often have to create everything from scratch, which takes a lot of time and effort that could be spent running the research itself.

What did the PRESS project do?

The PRESS project created a set of free, ready-to-use documents to make it easier for research teams to run SWATs. We created 9 ready-made study plans for specific SWATs, along with all the supporting documents a team would need, including templates for ethical approval, guidance on costs, and advice on writing documents that everyone can understand. These were co-produced with researchers and public contributors. Teams can download everything for free and adapt it for their own trial.

Why does this matter?

By making these resources freely available, PRESS helps research teams spend less time on paperwork and more time running studies. The more SWATs that get done, the faster we can learn what works to help people join and stay in trials. The faster we learn what works, the sooner better treatments can reach the patients who need them.

1. Introduction

Clinical trials are important but recruiting and retaining participants is challenging [1–4]. Fewer than 50% of trials meet their recruitment target [5] and more than 80% fail to enroll on time [6]. This leads to trial failure and wastes time and resources for trial teams, participants, and funders. Poor retention also causes research waste and can delay the implementation (or removal) of health care interventions [7] and increase trial costs [7,8]. Additionally, poor retention, when participants drop out before the study ends, compromises trial outcomes. Missing primary outcome data resulting from attrition can lead to bias and also reduces the power of the study to detect clinically significant findings [9]. This is not just about slow process: poor recruitment and retention are costly [10] and can do real harm to patients and the public [11]. Using Knowlson's et al. data from the RECOVERY trial's dexamethasone arm, it is possible to show that every 50-day delay in completion due to, for example, slow recruitment, led to

450 additional deaths in the UK during the COVID-19 pandemic [11]. Process efficiency matters.

A study within a trial (SWAT) is a self-contained research study that has been embedded within a host trial with the aim of evaluating or exploring alternative ways of delivering or organizing a particular trial process [12]. While we know that SWATs are an effective means of evaluating recruitment and retention strategies, convincing trial teams to undertake this “extra” work while simultaneously getting a trial up and running can be challenging [13]. Interviews with institutions involved in the Trial Forge SWAT Network frequently noted that availability of resources to support SWATs (eg, protocols, statistical analysis plans, intervention resources, ethical applications, etc.) could help colleagues undertake SWAT research [14].

The purpose of Protocols and Resources for Priority Recruitment and Retention SWATs (PRESS) was to reduce the burden of SWAT implementation by developing ready-to-use protocols and resources for priority recruitment and retention evaluations. This targeted approach focuses

What is new?**Key findings**

- PRESS provides a comprehensive, standardized suite of protocols and supporting resources to facilitate high-priority recruitment and retention studies within a trial (SWATs).
- It includes a Master SWAT Protocol Template, 9 randomized SWAT protocols, including 2 coproduced Patient and Public Involvement-focused SWATs, 2 statistical analysis plan templates, 9 ethics submission templates, and guidance on funding, health economics, and accessibility.
- The resources were developed through a systematic, multidisciplinary, and Patient and Public Involvement-informed process to ensure methodological rigor, usability, and adaptability across diverse trial settings.

What this adds to what was known?

- Until now, no standardised, ready-to-use protocols existed for priority SWATs, forcing trial teams to build resources from scratch for each trial.

What is the implication and what should change now?

- PRESS reduces long-standing barriers to SWAT adoption by providing ready-to-use, harmonized materials, enabling faster, consistent, and scalable evaluation of recruitment and retention strategies.
- Widespread uptake of PRESS resources may accelerate the generation of methodological evidence, reduce research waste, improve participant experience, and ultimately enhance the efficiency and quality of clinical trials.

trialists on key evidence gaps, supporting faster generation of evidence to strengthen trial recruitment and retention strategies.

2. Methods*2.1. Governance and working group structure*

The full PRESS team met monthly over 17 months, from November 2023 to March 2025, providing oversight and decision-making across all project components. To ensure ongoing public involvement during the development and review of the SWAT protocols, at least one patient and public involvement (PPI) Partner attended each whole-team meeting to provide direct input and feedback. For the workstream focused on the Master SWAT protocol

and SWAT recruitment and retention protocols, the subteam met once every 2 weeks. For the workstream focused on PPI SWAT protocols and resources, 3 PPI Partners and research team members met 7 times between March 2024 and June 2024 inclusive to co-develop the protocols and resources. To progress this work between the workstream meetings and full PRESS team meetings, the subteam met internally on a weekly basis. Where queries required immediate attention to maintain progress, or where a component needed broader team input on a specific aspect of their work, these were addressed via email. Following conclusion of the full PRESS team meetings, FS and AP completed the final harmonization and standardization of all project outputs and uploaded them to the Open Science Framework.

2.2. Preparatory work for PRESS

Four workstreams, completed in advance of the current project by members of the PRESS team, informed the development of PRESS:

1. Systematic reviews. The Cochrane Systematic Review on recruitment identified only 3 strategies with high certainty evidence that improved recruitment rates to trials [5]. The Cochrane Systematic Review on retention identified 52 comparative retention strategies, none of which were supported by high-certainty evidence as determined by GRADE assessment [15]. A systematic review of economic evaluations alongside recruitment and retention SWATs found no cost effective strategies with statistical certainty [16].
2. PRioRiTy study I and II identified 20 research priority questions to improve trial recruitment [17] and retention [3] processes as part of a James Lind Alliance Priority Setting Partnership.
3. A SWAT testing a PPI strategy [18], and a systematic review assessing PPI impacts on recruitment and retention [19] both highlighted a need for more high quality evaluations.
4. The PRESS team, as part of the National Institute of Health and Care Research (NIHR) funded Implement SWATs project (<https://www.implementswats.org>) and the Trial Forge SWAT Network involving 40+ institutions and partners [20], identified and prioritized 11 trial recruitment and retention topics and 39 associated SWAT research questions to be evaluated using randomized SWATs [21]. Prioritization was done by combining frequency of strategy use in NIHR Health Technology Assessment (HTA) trials [22], evidence from the Cochrane recruitment and retention systematic reviews [5,15], the cost-effectiveness review [16], the findings of PRioRiTy I and II [3,17] the MRC-funded Systematic Techniques for Assisting

Recruitment to Trials (MRC START) [23,24] and PROMoting the use of SWAT (PROMETHEUS) [25].

2.3. Prioritization of SWAT questions and decision rules

We began with the 39 specific prioritized recruitment and retention SWAT questions (Appendix 1) [21]. Our goal was to select one SWAT research question (column 3; Appendix 1) per 11 recruitment and retention topics (column 1; Appendix 1) and develop a protocol and associated resources to enable evaluation. We invited PPI Partners ($n = 3$; 2 male, 1 female) to select the SWAT research question they deemed most appropriate for each of the 11 recruitment and retention topics. They were given a “none of the above” option if they were not satisfied with the existing SWAT research questions, and we invited them to propose alternative questions via a free-text box. Following their selections, a consensus meeting was organized and facilitated by AP, HB, and JW. The ranked data were used to guide the agenda. The purpose of the meeting was to agree on the SWAT research questions, including reaching consensus on areas of divergence or newly proposed SWAT research questions.

A clear governance structure and decision-rule framework were applied to handle any disagreement around question selection. If the ranking and subsequent discussion yielded immediate consensus, the top-ranked question was selected for protocol development. If divergence persisted and a clear consensus could not be achieved during the meeting, the PPI panel’s qualitative arguments and key concerns were systematically recorded. The final decision rule dictated that in cases of disagreement, the selection of the final question would be deferred back to the PRESS research team to consider the PPI feedback alongside feasibility and methodological criteria. The final decision rule was not invoked for PRESS.

2.4. Resource development process

All outputs were co-produced with researchers and public contributors. Each piece of work was led by a subject specialist and their subteam. HB, FS, ST, all methodologists, led the development of the Master SWAT Protocol Template and 7 of the recruitment and retention SWATs. AP and JW, together with PPI Partners MP, KS, and PB, led the development of the 2 PPI-focused SWATs. CJS, a statistician, led the development of the Statistical Analysis Plans and AG, a health economist, together with AP, led the development of the health economics guidance. AP led the ethics and funding guidance documents and JW led the guidance on creating accessible documents.

Subject specialists drafted each output with their subteam. Completed drafts were circulated to the full PRESS team for review and comment. All comments were considered for inclusion by the relevant subject specialist. Outstanding queries or those requiring broader input were

escalated to the monthly PRESS meeting and resolved by consensus. Final protocols and associated resources were reviewed by PPI members for language suitability and approved by the full PRESS team.

2.5. Coproduction methods for PPI strategies

PPI strategies for recruitment and retention are complex interventions requiring careful development co-produced with PPI members [18,19,26]. We adopted an equitable co-production approach following best-practice guidance to ensure the PPI-focused protocols reflected public and participant priorities [27,28]. Co-production involved a structured five-step collaborative process involving 3 PPI partners working alongside the PRESS research team.

2.5.1. Step 1: orientation and project grounding

The PRESS research team introduced the PRESS project background, scope, and preprioritized PPI strategy topics to the PPI partners. This established a baseline understanding of the project. To ground the work in existing methodology, we presented empirical evidence on the impact of PPI on trial recruitment and retention [19].

2.5.2. Step 2: establishing core principles and methodological guidance

The PPI-focused recruitment and retention questions prioritized were: “Does involving patients and the public to co-develop patient-facing materials increase recruitment rates, compared to usual practice?” and “Do PPI-led follow-up strategies increase retention rates of underrepresented groups, compared to usual PPI practice?” Acknowledging there are many strategies that might answer these questions, the PRESS team met with PPI partners to brainstorm potential strategies. It was agreed that inclusive trial methodology requires equitable co-design and co-delivery. On that basis PPI partners identified 4 core principles for consideration when developing the PPI strategy protocols: (1) building trust, (2) educating the public/participants on trial value, (3) embedding active PPI within the tailoring of the strategies, and (4) ethically leveraging marketing and communication strategies to enhance engagement. In addition to these core principles, the PRESS team provided practical and methodological guidance to PPI partners to ensure the PPI protocols could be embedded in host trials and replicated by a wide range of trial teams across multiple trial contexts and patient populations.

2.5.3. Step 3: strategy selection and initial drafting

PPI partners generated PPI specific recruitment and retention strategy ideas under the prioritized questions, tailored to the core principles and methodological guidance. All 3 PPI partners voted unanimously to progress 2 specific strategies for protocol development: a participant biography for the recruitment SWAT, and a participant newsletter for the retention SWAT. One PPI partner (KS)

Table. PRESS Project Protocols and Resources

Category	Resource	Citation	Hyperlink
1	Master SWAT Protocol Template	Bruhn, H., Shiely, F., Parker, A., Wilkinson, J. A., Arundel, C., Sutton, C., ... Treweek, S. (2025, March 29). PRESS SWAT Master Protocol Template.	https://osf.io/jmpyn/
2	PPI-focused Recruitment SWAT Protocol	Parker, A., Bell, P., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., ... Shiely, F. (2025). The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): template Study Within A Trial protocol.	https://osf.io/8kcdr/
	Trial Participant Biography	Wilkinson, J. A., Sterniczuk, K., Powponne, M., Bell, P., Shiely, F., Treweek, S., ... Parker, A. (2025, March 19). Guide to Creating a Trial Participant Biography for the BIOREC Study Within A Trial (SWAT).	https://osf.io/dqv9j/
	PPI-focused Retention SWAT Protocol	Wilkinson, J. A., Sterniczuk, K., Powponne, M., Bell, P., Shiely, F., Sutton, C., ... Parker, A. (2025, March 31). 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
3	Randomized Recruitment SWAT Protocols	Bruhn, H., Treweek, S., Parker, A., Sutton, C., Wilkinson, J. A., Arundel, C., ... Shiely, F. (2025, March 28). 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/
		Bruhn, H., Treweek, S., Parker, A., Wilkinson, J. A., Sutton, C., Arundel, C., ... Shiely, F. (2025, March 31). 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
		Bruhn, H., Treweek, S., Parker, A., Sutton, C., Wilkinson, J. A., Arundel, C., ... Shiely, F. (2025, March 29). An evaluation of whether video(s) providing information about a trial increases recruitment of particular underserved groups, important for the trial, compared to written information only (VISUAL): a Study Within A Trial protocol.	https://osf.io/5mx4k/
	Randomized Retention SWAT Protocols	Bruhn, H., Treweek, S., Parker, A., Wilkinson, J. A., Sutton, C., Arundel, C., ... Shiely, F. (2025, March 30). 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
		Bruhn, H., Treweek, S., Parker, A., Wilkinson, J. A., Sutton, C., Arundel, C., ... Shiely, F. (2025, March 30). An evaluation of whether monetary incentives increase trial questionnaire return rates (retention) compared to no monetary incentive (MONCENTIVES): template Study Within A Trial protocol.	https://osf.io/t2gnf/files/osfstorage
		Bruhn, H., Treweek, S., Parker, A., Sutton, C., Wilkinson, J. A., Arundel, C., ... Shiely, F. (2025, March 29). 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-randomized Study Within A Trial protocol.	https://osf.io/274jf/
		Bruhn, H., Treweek, S., Parker, A., Wilkinson, J. A., Sutton, C., Arundel, C., ... Shiely, F. (2025, March 30). An evaluation of whether using routinely collected data, to shorten a follow-up questionnaire, increases the retention of underserved groups, compared to using a longer, participant-reported questionnaire (SHORT-Q): Study Within A Trial protocol.	https://osf.io/m2bac/files/osfstorage

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Table. Continued

Category	Resource	Citation	Hyperlink
4	Ethics Application Guidance	Parker, A., Bruhn, H., Wilkinson, J. A., Sterniczuk, K., Powponne, M., Bell, P., ... Shiely, F. (2025, March 31). The effectiveness and cost-effectiveness of trial newsletters, co-produced with Patient and Public Involvement (PPI) Partners, on participant retention rates (NEWSLETTER) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/a3496/files/osfstorage
		Parker, A., Bell, P., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., ... Shiely, F. (2025, March 30). An evaluation of whether offering flexibility in in-person follow-up visit location increases trial participant retention compared to not offering flexibility (FLEXI) : guidance on ethics submission for a Study Within A Trial (SWAT).	https://osf.io/vedu4/
		Parker, A., Bell, P., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., ... Shiely, F. (2025, March 30). An evaluation of whether using routinely collected data, to shorten a follow-up questionnaire, increases the retention of underserved groups, compared to using a longer, participant-reported questionnaire (SHORT-Q) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/vre93/
		Parker, A., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., Sutton, C., ... Shiely, F. (2025, March 25). An evaluation of whether monetary incentives increase trial questionnaire return rates (retention) compared to no monetary incentive (MONCETIVES) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/9nzka/files/osfstorage
		Parker, A., Wilkinson, J. A., Treweek, S., Bruhn, H., Arundel, C., Sutton, C., ... Shiely, F. (2025, March 24). An evaluation of whether electronic reminders increase questionnaire completion rates compared to usual follow-up (E-PROMPT) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/zn7vm/files/osfstorage
		Parker, A., Sutton, C., Bruhn, H., Gkekas, A., Wilkinson, J. A., Treweek, S., ... Shiely, F. (2025, March 29). An evaluation of whether video(s) providing information about a trial increases recruitment of particular underrepresented groups, important for the trial, compared to written information only (VISUAL) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/8h2ap/
		Parker, A., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., Sutton, C., ... Shiely, F. (2025, March 25). An evaluation of a theoretically informed written trial invitation compared to a standard written invitation to improve recruitment (INVITE) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/ht6rq/
		Parker, A., Bell, P., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., ... Shiely, F. (2025, March 25). The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/c4pr2/
5	Statistical Analysis Plan – Randomized Recruitment SWAT	Parker, A., Bell, P., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., ... Shiely, F. (2025, March 24). An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers (CASH) : guidance on applying for ethical approval for a Study Within A Trial (SWAT).	https://osf.io/hfvpn/
		Sutton, C., Gkekas, A., Shiely, F., Treweek, S., Bruhn, H., Wilkinson, J. A., ... Parker, A. (2025, March 29). PRESS Randomized Recruitment SWAT Master Statistical Analysis Plan Template.	https://osf.io/vqt6g/files/osfstorage

(Continued)

Table. Continued

Category	Resource	Citation	Hyperlink
	Statistical Analysis Plan – Randomized Retention SWAT	Sutton, C., Gkekas, A., Shiely, F., Treweek, S., Bruhn, H., Wilkinson, J. A., ... Parker, A. (2025, March 29). PRESS Randomized Retention SWAT Master Statistical Analysis Plan Template.	https://osf.io/h73ke/files/osfstorage
6	Health Economics Guidance	Gkekas, A., Shiely, F., Wilkinson, J. A., Sutton, C., Treweek, S., Bruhn, H., ... Parker, A. (2025, March 18). PRESS Health Economics Guidance.	https://osf.io/sebnk
7	Funding Application Guidance	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
8	Accessible Documents Guidance	Wilkinson, J. A., Bennett, A., Shiely, F., Treweek, S., Sterniczuk, K., Powponne, M., ... Parker, A. (2025, March 20). Guidance on Making Accessible Documents.	https://osf.io/8ek76

generated initial drafts of the example participant biography and newsletter. A second PPI partner (MP) reviewed these documents and provided feedback. Once internal consensus among the PPI partners was achieved, the drafts were shared with the PRESS team.

2.5.4. Step 4: mapping, theory alignment, and protocol finalization

To ensure the strategies were methodologically robust and theory-informed, the PRESS team analyzed the biography and newsletter content drafted by the PPI partners to identify and explicitly map the content to behavior change theory [29]. JW and AP then drafted the SWAT protocols using the standardized PRESS Master Protocol Template, and these were reviewed by PPI partners and the wider PRESS team.

2.5.5. Step 5: codevelopment of resources for implementation

To complement the protocols and support consistent adoption, we co-developed practical implementation guidance. JW drafted the initial text for the “PRESS Guide to creating a trial participant biography for the BIOREC SWAT” and the “PRESS Guidance on making accessible documents”, using the examples written by the PPI partners. PPI partners reviewed and revised these draft guides before submission to the wider project team for final review and completion.

3. Results

We developed 8 categories of resources, comprising 25 individual documents. These include: a [Master SWAT Protocol Template](#); 2 PPI-focused SWAT protocols (1 recruitment; 1 retention) with additional guidance on creating a participant biography; 3 other recruitment SWAT protocols; 4 other retention SWAT protocols; 9 ethics application templates; 2 Statistical Analysis Plan templates, one

each for recruitment and retention SWATs; health economics guidance; funding application guidance; and guidance on making accessible documents. See [Table](#) for full details with links.

Results of the PRESS project are available in full and free of charge on the Open Science Framework <https://osf.io/xfkqp/> and Trial Forge website <https://www.trialforge.org/resource/protocols-and-resources-for-priority-recruitment-and-retention-swats-press/>.

4. Discussion

The PRESS project responded to a well-documented gap in the trial methodology landscape: the absence of ready-to-use, standardized resources to support the implementation of high-priority recruitment and retention SWATs. While the value of SWATs as a mechanism for generating evidence on trial processes is well established, the practical burden of developing protocols, funding applications, and ethics applications from scratch has long been a barrier to their uptake.

Our initial focus was on a Master SWAT Protocol template, to standardize SWAT implementation, promote consistency across studies, and facilitate replication. SWAT evidence relies on replication to facilitate meta-analysis and ensure sufficient power [30]. The Master SWAT Protocol template enables trial teams to adapt and embed SWATs with minimal administrative burden, while maintaining methodological rigor. It will also ensure adequate data collection to facilitate SWAT reporting and ensure the standards set by the recent SWAT reporting guidance are met [30]. Alongside this, the Statistical Analysis Plan templates for both recruitment and retention SWATs will enable rigorous analysis, enhance reproducibility, and reduce the methodological workload for trial teams.

The decision to prioritize specific SWAT topics, rather than develop resources generically, was deliberate. By

drawing on the Cochrane systematic reviews of recruitment and retention strategies, the PRioRiTy I and II priority-setting exercises, and the Trial Forge SWAT Network, PRESS was able to focus resource development where evidence gaps are greatest and where standardized evaluation is most needed. All the SWAT protocols developed in PRESS are designed for flexible deployment. They can be evaluated individually by single trial teams, or using a co-ordinated approach by being tested across multiple trials, either sequentially or simultaneously [12]. Using a coordinated SWAT model enables the research questions to be addressed across multiple host trials at, or around, the same time. Prior work from PROMETHEUS shows that it's feasible and efficient [25]. This methodology is particularly valuable for minimizing intervention heterogeneity, enabling replication across a range of patient populations and clinical contexts, and generating a robust evidence base at speed and at scale [25].

A further strength of PRESS is its attention to the practical infrastructure around SWAT implementation. Ethics application templates, funding guidance, and health economics guidance lower the administrative threshold for trial teams considering embedding a SWAT, particularly those without prior experience of SWAT research. Requirements for ethics approval for SWATs varies from institution to institution and country to country. Given that, we created adaptable ethics application templates and provided context-specific wording for both the UK and Ireland, reflecting the PRESS team's location and the current location of the majority of SWAT activity. However, these templates can be adapted for any ethics committee. These streamline the approvals process and support ethical clarity for embedded SWATs. We simultaneously developed Trial Forge Guidance 5: Ethical Considerations for SWATs, and recommend using this to support SWAT ethics applications [31]. The funding guidance includes justification text, budgeting advice, and evidence summaries to strengthen applications and align them with funder expectations. We developed the health economics guidance to assist researchers in planning economic evaluations of SWATs. This resource outlines methods for estimating cost-effectiveness, drawing on a previous systematic review which highlighted the lack of statistically supported economic evaluations of recruitment and retention strategies [16].

The PRESS team supports inclusive research practices to reduce barriers to participation and collaboration in clinical trials. This project was conducted with the same goals. Many funders in the UK and Ireland expect trial teams to include people with lived experience of the condition, ie, the focus of the trial [32–34]. Funders do this because people with lived experience bring expertise to trial design that no one else can, making co-design more likely to lead to design choices that match patient priorities and requirements [35]. A strength of PRESS is that co-design was embedded throughout the project. Rather than relying on

top-down researcher assumptions, a co-production framework fosters mutual trust and addresses systemic inequities in research participation [36].

To ensure that PRESS outputs are usable by the widest possible audience, including researchers, PPI contributors, and stakeholders with diverse accessibility needs, we developed guidance on making accessible trial documents. This includes recommendations for document formatting, plain language, and inclusive design principles. The guidance was reviewed by PPI partners.

All PRESS resources are freely available via the Open Science Framework and the Trial Forge website, supporting broad and immediate uptake. The PRESS project does not itself evaluate the effectiveness of the recruitment and retention strategies captured in its SWAT protocols; that work remains to be done. Rather, PRESS provides the infrastructure to make that evaluation faster, more consistent, and more feasible for trial teams. Its value will ultimately be realized through the SWATs it enables and the evidence those SWATs generate.

Although we initially prioritized 11 strategies, 2 SWATs addressed overlapping questions and were merged because they both involved using video to present information to potential participants to improve recruitment. One other SWAT focused on the use of qualitative methods to improve trial recruitment; it was not suitable for a randomized design. Given our focus on randomized SWATs, we did not develop a SWAT protocol for this strategy.

5. Conclusion

Recruitment and retention challenges continue to threaten the success and efficiency of clinical trials. The PRESS project directly addresses these challenges by producing a suite of ready-to-use, evidence-informed, and openly accessible resources to support the design and implementation of high-priority SWATs.

CRediT authorship contribution statement

Frances Shiely: Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Shaun Treweek:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Hanne Bruhn:** Writing – review & editing, Writing – original draft, Resources, Methodology, Formal analysis. **Chris J. Sutton:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Michele Powponne:** Writing – review & editing, Methodology, Investigation, Data curation. **Kamil Sterniczuk:** Writing – review & editing, Validation, Investigation, Formal analysis, Data curation. **Philip Bell:**

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Declaration of competing interest

There are no competing interests for any other author.

Acknowledgments

This work was part of IMPLEMENT SWATs (<https://www.implementswats.org>) and the Trial Forge initiative to improve trial efficiency (<https://www.trialforge.org/>).

Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2026.112480>.

Data availability

All materials are available open access on the Open Science Framework and Trial Forge. Links are provided within the text.

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