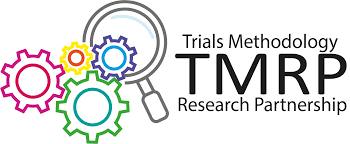


The effectiveness and cost-effectiveness of trial newsletters, co-produced with Patient and Public Involvement (PPI) partners, on participant retention rates (NEWSLETTER): template Study Within A Trial protocol

How to cite this template 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. Retrieved from <https://osf.io/cv9ag/files/osfstorage>

A white and orange rectangle

AI-generated content may be incorrect.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \*\*\*Pre-amble – to be deleted by SWAT team\*\*\* | | **Introduction to this SWAT protocol**  This protocol has been designed as part of the [PRESS project](https://osf.io/xfkgp/) for replication. As this protocol can be used by any SWAT team, in any number of host trials, we are not able to provide a fully completed protocol as we do not know your host trial(s). Hence, you will need to add some details to this protocol to tailor it for your host trial and complete the protocol. We’ve highlighted the need to add details in relevant sections entitled ‘**how to complete’**. Text in square brackets can be amended or deleted.  **Note**: The host trial patient and public involvement (PPI) and trial team co-produced newsletters have not been developed as this will differ for each host trial. However, for guidance on creating theory-informed trial participant newsletters that are accessible, please see [PRESS Guide to creating a trial participant newsletter for a Study Within A Trial (SWAT)](https://osf.io/r289b/files/osfstorage) and  [Guidance on making accessible documents](https://osf.io/8ek76/).  This protocol should be used in conjunction with the following additional documents:   * [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) * [PRESS Guidance for Researchers Applying for Funding to Conduct High-Priority SWATs of Recruitment and Retention Strategies](https://osf.io/w6zym/)  * [PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template](https://osf.io/h73ke/files/osfstorage) * [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/) * [PRESS guidance on applying for ethical approval for the NEWSLETTER SWAT](https://osf.io/a3496/files/osfstorage)   \*\*\*This document has been prepared using a table so choose ‘all borders’ in Paragraph menu before completing it.\*\*\* | | |
| **Administrative information** | | | | |
|  |  | |  | | |
| 1 | **Title** | | | |
|  |  | | **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** | | |
| 2 | **Registration** | | | |
|  |  | | SWAT registration on Northern Ireland SWAT repository pending. | | |
| 3 | **Protocol version** | | | |
|  |  | | 30th March 2025, Version 1.0  **Guidance:**  *If significant modification of the protocol is required, consider which scenario suits your study best; a completely new protocol; or a new version of the existing protocol. Any changes to the intervention would require a new protocol to be developed* | | |
| 4a | **Background and why the SWAT is required**  The SWAT question ‘What is the most effective way of involving patients and the public in trials to improve participant retention?’ was selected by the [Trial Forge SWAT Network](https://www.trialforge.org/2021/06/swat_network/) and the NIHR-funded Implement SWATs programme working group as a priority retention strategy for evaluation1. There are many potential SWATs that could answer this question, however, three patient and public partners involved in the PRESS project2, together with the research team, agreed that the effectiveness of a PPI co-produced newsletter would be one optimum way of involving PPI to improve retention. Thus this is the focus of the current protocol for replication.  **Rationale for this intervention**  In addition to the above, this strategy was also identified as high priority for evaluation in PRIORITY II (Questions 4 and 5)3. The PRESS project was jointly co-funded by the Health Research Board-Trial Methodology Research Network (HRB-TMRN), Ireland, and the Medical Research Council-National Institutes for Health and Care Research- Trial Methodology Partnership (MRC-NIHR-TMRP), UK, to develop protocols and associated documents to support teams to undertake SWATs evaluating recruitment and retention strategies2. To select a specific intervention for a PPI-focused SWAT aimed at improving trial recruitment, the PRESS PPI Partners proposed the use of a newsletter to engage with and foster trust with existing trial participants. Newsletters sent to trial participants are widely used and require both human and financial resources to create and distribute them. However, there is very low certainty evidence as to whether they are effective in aiding participant retention4. Trial newsletters that are co-produced by PPI partners and the trial team may provide information of relevance to trial participants. Co-production in a research project is a collaborative approach where researchers and patient and public partners work together, sharing power and responsibility throughout the entire process5. Hence, PPI co-produced trial newsletters, that include the most pertinent content for participants, may give a strong basis to enable the effectiveness of newsletters to be determined.  Behaviour theory informs the newsletter’s development, ensuring it built trust, provided some education about clinical trials and effectively leveraged social influence and personal storytelling. To ensure accessibility and acceptability of the intervention, this protocol is supported by the [PRESS Guide to creating a trial participant newsletter for a Study Within A Trial (SWAT)](https://osf.io/r289b/files/osfstorage) and [Guidance on making accessible documents](https://osf.io/8ek76/), both of which were co-produced with PRESS PPI Partners.  **Research questions**   1. What is the effectiveness of trial newsletters, co-produced with Patient and Public Involvement partners, on participant retention rates? 2. What is the cost-effectiveness of trial newsletters versus no trial newsletter? | | | |
|  |  | |  | | |
| 4b | **Comparators**  Many trial teams send newsletters to participants. However, the certainty of the evidence is very low. Therefore, the comparator is that participants will not receive a trial newsletter. | | | |
|  |  | |  | | |
| 5 | **Objectives** | | | |
|  |  | | 1. To evaluate the effectiveness of a trial newsletter versus usual practice (i.e., no trial newsletter) for increasing participant retention rates 2. To evaluate the cost-effectiveness of the trial newsletter versus usual practice. | | |
| 6 | **Design** | | | |
|  |  | | The SWAT design is a parallel group, with allocation ratio of 1:1, using a superiority framework. | | |
| **Methods: Participants, interventions, and outcomes** | | | | |
| 7 | **PPI partner involvement** | | | |
|  |  | | **How to complete:**  PPI partners were involved in selecting this SWAT for evaluation. PPI partners were asked to rank multiple suggested SWATs which could be used to answer each of the 11 SWAT questions1. SWATs ranked first were taken forward. This SWAT ranked first.  PRESS PPI partners and researchers worked together to co-produce this newsletter SWAT. This included PPI partners and the research team discussing the existing evidence, agreeing on ‘core principles’ for co-producing the newsletter and identifying potential SWAT questions and outcomes. PPI partners also developed a prototype newsletter, and contributed to developing the [PRESS Guide to creating a trial participant newsletter for a Study Within A Trial (SWAT)](https://osf.io/r289b/files/osfstorage) and [Guidance on making accessible documents](https://osf.io/8ek76/)].  [Add further details as per your SWAT patient and public involvement]. | | |
| 8 | **Study setting** | | | |
|  |  | | **How to complete:**  Describe the setting(s) relevant to your SWAT. | | |
| 9 | **Who can take part**  All host trial participants due a follow-up visit are eligible to take part in this SWAT. | | | |
|  |  | |  | | |
| 10a | **Interventions**  **How to complete:**  **SWAT Intervention participants:** will receive a trial newsletter and ‘usual practice’ at follow-up.  ***Guidance****: Depending on the host trial context, SWAT teams may wish to send one newsletter, or multiple newsletters at different time-points.*  **SWAT Comparator participants (control group):** will receive ‘usual practice’, i.e., no trial newsletter.  The timing of this SWAT is sending the newsletter in advance of participants’ next relevant follow-up timepoint (approximately 1-2 weeks prior to the follow-up, depending on host trial time-points). The mode of delivery of the intervention is electronic or postal. The providers are whoever sends communication to trial participants (e.g. trial office staff or site staff). | | | |
|  |  | |  | | |
| 10b | **Additional interventions that can be used at the same time** | | | |
|  |  | | There are no limitations on permitted or prohibited concomitant interventions/recruitment or retention strategies in this SWAT, though any additional recruitment and/or retention strategies used need to be administered to both SWAT arms. The SWAT team should list any relevant co-interventions, e.g., reminders, financial incentives. | | |
| 11 | **Outcomes** | | | |
|  |  | | Primary outcome:  Retention rate, defined as the proportion of participants in each group who complete the relevant measurement time point in the *[host]* trial.  Secondary outcomes:   1. Unit costs, defined as the costs incurred for each participant within the SWAT. If the effect of the intervention is positive the cost-effectiveness outcome will be reported as the incremental cost per additional participant retained [please see section 12 below and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)]. 2. Harms or unintended effects to be collected in terms of any feedback from participants in relation to receiving or not receiving, newsletters. | | |
| 12 | **Economic evaluation details** | | | |
|  |  | | **How to complete:**  [[The SWAT team should complete this section if appropriate as per [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/). We encourage SWAT teams to report the costs of the SWAT, even if a full economic evaluation is not undertaken. Please report both direct and indirect costs associated with the intervention. Direct costs may consist of training costs, postage and printing costs of newsletters and other trial materials, as well as financial reimbursement of members of the public for their involvement in the trial. Indirect costs may consist of time spent creating the newsletters and staff time for administering the intervention and managing SWAT data collection. Please see table below and [Health Economic Guidance](https://osf.io/sebnk/) for a breakdown of potential costs to include for intervention development and delivery for this SWAT. In addition, relevant costs for the comparator intervention, including printing and postage costs of trial materials and staff time for administering the comparator strategy and managing SWAT data collection, should also be reported. To estimate the unit costs of newsletter and no newsletter, SWAT teams should estimate the total costs for each cost component, then aggregate all relevant components for each intervention and divide them by the number of participants allocated to each intervention group. Where relevant, the cost-effectiveness outcome should be reported as the incremental cost per additional potential participant retained (if the effect of the intervention is positive), calculated as:   * Incremental cost per additional potential participant retained = (unit cost of newsletter - unit cost of no newsletter)/ (retention rate in newsletter group - retention rate in no newsletter group).   Where a full economic evaluation is undertaken, we recommend that this adopts the trial team’s perspective (i.e., the reported effects and costs of the newsletter intervention will be direct and associated with the trial teams’ budget, therefore costs from the point of view of the host trial participant will not be considered)].  ***Guidance****:*  *Example costs to report:*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Intervention development** | **Applicable to** | **Description** | **Task** | **Time** | **Total** | |  | Newsletter group | Patient and public partners involvement  Payment per NIHR guidance:  <https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals> | Time to create first newsletter; review newsletter drafts and agree format, finalise newsletter drafts; training, including use of unfamiliar software (as required). | 2 days | £150 (per day) x 2 days X number of PPI partners | |  | Newsletter group – subsequent newsletter(s) | Patient and public partners involvement  Payment per NIHR guidance:  <https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals> | Where relevant, time to create subsequent newsletter(s); review and finalise newsletter drafts. | 1 day per newsletter | £150 (per day) x 1 day X number of PPI partners x number of subsequent newsletters | |  | Newsletter group;  No newsletter group | Staff time [include number of staff involved with developing and administering the strategy, time taken, pay grades – use midpoint of salary and report time in terms of hours] | Liaison with and managing PPI input on newsletter; staff training on co-production methods; production of distributable newsletter; seeking ethical approval for newsletter; distributing newsletters;  SWAT data collection, analysis and reporting | X hours | [=hourly pay x time in hours per staff member] | | **Intervention delivery** | **Applicable to** | **Description** | **Unit cost** |  |  | |  | Newsletter group;    No newsletter group | Cost of printing | Number of newsletters printed;  Number of trial materials printed | N/A | [=cost of one printed newsletter x numbers needed] | |  | Trial participant newsletter group;  No newsletter group | Postage costs | Stationery costs; number of newsletters posted;  Number of trial materials posted | N/A | [=cost of one posted newsletter x numbers needed] | | **Total** |  |  |  |  | [TOTAL COST] | | | |
| 13 | **Resource** | | | |
|  |  | | Modest.  **How to complete:**  The development of the intervention can add to the cost depending on PPI time to co-produce the newsletter(s), and staff time to facilitate the co-production process and obtain ethical approval for use of the newsletter(s). The SWAT team may also require staff training costs in co-production methods and PPI training costs to use unfamiliar software. Staff time will be required to set up and undertake the randomisation of participants and to distribute the newsletter to participants in the intervention arm. If the newsletter is to be produced on paper, there will be printing, stationery and postal costs. Staff time will be needed to analyse and write up the results of the SWAT for publication.  The SWAT team should add necessary details as per the [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Please see Table above in section 12 for example costs to report. | | |
| 14 | **Data to be collected and characteristics of SWAT participants**  Data relating to SWAT allocation and whether the final follow-up was completed will be collected for the SWAT. [All other data are collected as part of the host trial]. The following data will be collected in addition: [insert relevant data as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). As a minimum, the SWAT team should be able to describe who is taking part in the SWAT and in the host trial in relation to how representative they are of the population the trial is relevant for)]. | | | |
|  |  | |  | | |
| 15 | **Participant timeline**  Please see the flow diagram in appendix 1, showing participants’ movement through the SWAT. | | | |
|  |  | |  | | |
| **Methods: Assignment of interventions (for controlled trials)** | | | | |
| 16a | **Sequence generation**  Individually randomised.  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template](https://osf.io/8pmya/)]. | | | |
|  |  | |  | | |
| 16b | **Allocation concealment mechanism** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template](https://osf.io/8pmya/). [Describe the mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned.] | | |
| 16c | **Implementation** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Provide details of who will generate the allocation sequence, who will enrol participants and who will assign participants to interventions.] | | |
| 17 | **Blinding (masking)** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template](https://osf.io/8pmya/). Describe who will and won’t be blinded after the assignment of participants to the intervention (e.g., researchers, data analysts), and, if blinded, how this will be achieved]. | | |
| **Methods: Data collection, management, and analysis** | | | | |
| 18 | **Data management** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Describe plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values)].  ***Guidance:*** *It is sufficient to provide ‘light touch’ details.* | | |
| 19 | **Statistical methods**  [Please refer to [Retention SWAT Master Statistical Analysis Plan Template](https://osf.io/8pmya/) and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)].  The primary outcome analysis is the difference in retention rate (completing follow-up or not at the next relevant outcome timepoint) between those sent the newsletter and those not sent the newsletter.  [An ‘intention-to-treat’ analysis should be performed. All statistical analyses should be conducted using appropriate software. For the primary outcome analysis, comparison of the response rate between the two SWAT groups should use logistic regression. The between-groups difference should be presented as number (%) and as both adjusted absolute (i.e., risk difference) and relative (i.e., odds ratio or relative risk) effect estimates, with 95% confidence intervals from the logistic regression model. Demographic characteristics, including age and ethnic group should be presented descriptively as mean (standard deviation) or number (%), as appropriate.  For secondary outcomes:   1. Costs: [[Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)]. All relevant costs associated with each intervention should be aggregated to estimate the average cost per participant in each SWAT group. Unit costs - both direct and indirect - should be presented, including costs to develop the intervention (e.g. PPI and staff time) and to deliver it (e.g. materials and postage). These unit costs should be reported in the currency of the relevant country of the SWAT team and adjusted to current price levels, with any necessary inflation adjustments made (e.g., in the UK, using the Consumer Price Index6). The cost-effectiveness outcome, where analysed, should be reported as the incremental cost per additional participant retained (if the effect of the intervention is positive). This should be calculated by dividing the difference in unit costs between the intervention and comparator groups by the percentage point difference in retention rates between these groups). 2. Harms or unintended effects should be reported descriptively in terms of any feedback from participants in relation to the newsletter they have received, such as number of participants who have provided feedback and a short description of the feedback, as negative or positive.] | | | |
|  |  | |  | | |
| **Methods: Monitoring** | | | | |
| 20 | **Interim analysis and stopping rules** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Describe any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the SWAT]. | | |
| 21 | **Ethical approval** | | | |
|  |  | | **How to complete:**  [Please refer to: [PRESS guidance on applying for ethical approval for the NEWSLETTER SWAT](https://osf.io/a3496/files/osfstorage). Describe the requirements for ethical approval in your jurisdiction. In the UK there are two options for submitting this SWAT for ethics review. The SWAT can be submitted together with the host trial, or as an amendment to the host trial application. Ethical approval is needed for the trial participant newsletter. The SWAT team should add details on which option suits their SWAT and host trial]. | | |
| 22 | **Consent or agreement to participate** | | | |
|  |  | | Due to the nature of the SWAT, informed consent will not be obtained, as the SWAT is conducted as part of the host trial follow up process and knowledge of the SWAT might change how potential participants interact with the SWAT intervention. However, we do not consider this to be a major ethical issue as this is a low-risk study. In this case of evaluating whether a trial participant newsletter impacts on retention rates, seeking individual patient consent prior to sending the newsletter is not appropriate as it may confuse participants as to what they are consenting to. It might also impact on their behaviour if they are aware that different retention strategies are being tested, which may adversely affect the integrity of the SWAT evaluation7. | | |
| 23 | **How findings will be shared** | | | |
|  |  | | **How to complete:**  [The SWAT team should complete this section as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). It is sufficient to provide ‘light touch’ details (e.g., simply state that SWAT results will be sent to participants together with the host trial results).  We encourage SWAT teams to publish the findings of their SWAT using [Trial Forge Guidance 4: a guideline for reporting the results of randomised Studies Within A Trial (SWATs)](https://doi.org/10.1186/s13063-024-08004-0)].  If you undertake this SWAT, please share your findings so your results can be included in future updates of the [Cochrane systematic review of recruitment strategies](https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000013.pub6/full). Please email Dr Adwoa Parker at: [swats-group@york.ac.uk](mailto:swats-group@york.ac.uk)]. | | |
| 24 | **Confidentiality and access to Data** | | | |
|  |  | | | **How to complete:**  [The SWAT team should complete this section as appropriate as per SWAT protocol template [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)].  ***Guidance:*** *We suggest that SWAT authors make the data used to generate their results available as a supplementary file, or through data-sharing data sharing platforms such as Open Science Framework (*[*https://osf.io*](https://osf.io)*).*] | |

## People to show as the source of this SWAT idea

* Kamil Sterniczuk, Michele Powponne, Philip Bell – Patient and Public Involvement partners on the [PRESS project](https://osf.io/xfkgp/) team.
* Jacqueline Wilkinson, Frances Shiely, Hanne Bruhn, Shaun Treweek, Catherine Arundel, Chris J. Sutton, Athanasios Gkekas, Rosalind Way, Andrew Willis and Adwoa Parker - researchers on the [PRESS project](https://osf.io/xfkgp/) team.

## Funding statement

This protocol was developed as part of the PRESS project is funded by the Medical Research Council - National Institute for Health - Research Trial Methodology Research Partnership (MRC-NIHR TMRP) and the Health Research Board Trials Methodology Research Network (HRB-TMRN)] in a joint (HRB-TMRN/MRC-NIHR-TMRP) Working Group Project Seed Co-Funding Award 2023. Adwoa Parker is 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 NIHR, HRB or the Department of Health and Social Care.

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## Appendix 1: Flow diagram of SWAT participants movement through the SWAT

Newsletter SWAT participant flow diagram

