An evaluation of a theoretically informed written trial invitation compared to a standard written invitation to improve recruitment (INVITE): template Study Within A Trial protocol

How to cite this template SWAT protocol

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. Retrieved from <https://osf.io/r735x/files/osfstorage>

 



|  |  |
| --- | --- |
| \*\*\*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) or exactly how you would implement the SWAT. 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 theory-informed intervention letter has not been developed. However, see Trial Forge Evidence pack for the retention version by downloading the resource bundle (SWAT 24 on NI SWAT repository): <https://www.trialforge.org/resource/evidence-pack-retention-theory-based-cover-letter-id-ret1/>Lastly, the SWAT intervention is suitable to test on any kind of written trial invitation (letters, emails, SMS texts, WhatsApp etc) for recruitment. In this protocol, we have used invitation letters and emails as examples. This guidance should be used in conjunction with the following documents:* [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)
* [Guidance for Researchers Applying for Funding to Conduct High-Priority SWATs of Recruitment and Retention Strategies](https://osf.io/w6zym/)
* [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/)
* [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)
* [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/files/osfstorage)

\*\*\*This document has been prepared using a table so choose ‘all borders’ in Paragraph menu before completing it.\*\*\* |
| **Administrative information** |
| 1 | **Title** |
|  | An evaluation of a theoretically informed written trial invitation compared to a standard written invitation to improve recruitment (INVITE): Study Within A Trial protocol |
| 2 | **Registration** |
|  | SWAT registration on Northern Ireland SWAT repository pending. |
| 3 | **Protocol version** |
|  | 28th March 2025 Version 1.0**Guidance:***If significant modification of the protocol is required, consider whether a completely new protocol or new version of the existing protocol is needed. For example, starting the SWAT after the host trial has started (rather than at the same time as the host trial) would require a new version of the 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 sending potential trial participants invitation letters by post to optimise recruitment rates?’ 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 recruitment strategy for evaluation1. To answer the SWAT question, this SWAT study was chosen by three patient and public partners as part of the PRESS project2. **Rationale for this intervention**This strategy has been identified as high priority for evaluation in PRIORITY I (questions 2 and 4). 1,3The theory-informed letter is created as a behavioural change intervention using behaviour change theory. The behaviour targeted is responding to the invitation to take part in the host trial. There is evidence that a theory-informed cover letter sent with host trial questionnaires probably increases retention, so it is worth evaluating in recruitment too.1,4**Research question**Does a behavioural theory-informed trial invitation [*letter/email*] increase randomisation rates, compared to a standard [letter/email]? |
| 4b | **Comparators** |
|  | When trials recruit by invitation letter or email these are sent routinely. The routinely sent standard invitation letter or email will be used as a comparator as it can be viewed as ‘treatment as usual’. |
| 5 | **Objectives** |
|  | To evaluate the effect of a theoretically-informed trial invitation [letter/email] on host trial recruitment. |
| 6 | **Design** |
|  | The SWAT design is parallel group, with allocation ratio of 1:1, using a superiority framework.  |
| **Methods: Participants, interventions, and outcomes** |
| 7 | **PPI partner involvement** |
|  | There has been PPI involvement in selection of this SWAT for evaluation. Patient and public involvement partners were asked to rank suggested SWATs for each of 11 SWAT questions, including this one1. SWATs ranked first were taken forward if PPI partners agreed on the ranking while disagreements were discussed until agreement was reached. [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 potential host trial participants will be randomised in this SWAT. The trial invitation letters will be [posted/emailed] by [insert staff member title].  |
| 10a | **Interventions** |
|  | **Intervention:** A theoretically informed trial invitation letter will be [posted/emailed] to eligible patients identified for inclusion in the host trial, inviting them to take part in the host trial.**Control:** A standard trial invitation letter will be [posted/emailed] to eligible patients identified for inclusion in the host trial, inviting them to take part in the host trial. The timing of this SWAT is at first contact for recruitment. The mode of delivery of the intervention is via postal letter or email, the SWAT team should add details as to the mode used or if mixing modes, how this is decided. The providers are the staff sending invitation letters on behalf of the host trial team. [The SWAT team should list any relevant co-interventions e.g., reminders]. |
| 10b | **Additional interventions that can be used at the same time** |
|  | **How to complete:**There are no limitations on permitted or prohibited concomitant interventions/recruitment strategies in this SWAT, though any additional recruitment strategies used need to be administered to both SWAT arms. |
| 11 | **Outcomes** |
|  | Primary outcome:-Numbers randomised in the host trial, defined as the proportion of SWAT participants who are randomised into the host trial. Secondary outcomes:-Unit costs, defined as the costs incurred for each participant within the SWAT [please see section 12 below and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)].-Numbers retained in the two groups being compared at the most feasible follow-up point in the host trial, defined as the proportion of those SWAT participants randomised in the host trial who complete the most feasible follow-up in the host trial. -Harms or unintended effects to be collected in terms of any feedback from potential participants in relation to the invitation letter they have received (i.e., number of participants who have provided feedback and a short description of the feedback as negative or positive). There is no evidence, but concerns persist that a theoretically informed letter/email might annoy potential participants and/or jeopardise the relationship with clinical or research staff. Hence the description of harms or unintended effects will help other teams judge if this is likely an issue for their INVITE SWAT.  |
| 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 - please see table below for a breakdown of potential costs. To calculate the costs, 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 of the intervention. 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 made5. To estimate the unit costs, 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 SWAT participants allocated to the respective intervention group. Where relevant, the cost-effectiveness outcome should be reported as the incremental cost per additional participant recruited (if the effect of the intervention is positive), calculated as: * Incremental cost per additional participant randomised = (unit cost of theoretically informed cover letter - unit cost of standard letter)/ (recruitment rate in theoretically informed cover letter group- recruitment rate in standard letter group).

Where an economic evaluation is undertaken, we recommend that this adopts the trial team’s perspective (i.e., the reported effects and costs of the intervention will be direct and associated with the trial team’s budget)].**Example costs to report:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intervention development staff** | **Task** | **Time** | **Total** |
| Health psychologist [pay grade]  | Plan and design written invitation intervention | 3 hours | [=hourly pay x time in hours] |
| Patient and public partners involvement Payment per NIHR guidance: https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals | Review and feedback on written invitation | 1 hour | £25 |
| **Total** |  |  | [TOTAL COST] |

 |
| 13 | **Resource** |
|  | **How to complete:** Modest. [The development of the intervention can add to the cost depending on the level of expert (e.g. Health Psychologist and/or Health Economist) and Patient and Public Involvement partners’ involvement. There is no additional staff needed to deliver this SWAT so there is no ongoing resource need. The SWAT team should add necessary details as per the SWAT protocol template].Any indirect costs will involve staff time in managing the development of the written trial invitation liaising between different contributors (e.g. Health psychologist and PPI partners) and setting up the SWAT in the trial liaising with other staff e.g. IT services, ethics committee etc.  |
| 14 | **Data to be collected and characteristics of SWAT participants** |
|  | Data relating to which group participants were randomised to i.e., which invitation [letter/email] they were sent 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/)]. [While participant characteristics might not be available pre-trial consent, 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, at a minimum in terms of sex and gender, age, and ethnicity].  |
| 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** |
|  | Individual randomisation. [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/)]. |
| 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/)]. |
| 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/)]. |
| 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 [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/). Describe who will and won’t be blinded after the assignment of participants to the intervention (e.g., recruiters, 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 see [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/) and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)].An ‘intention-to-treat’ analysis will be performed. The primary outcome will be analysed as both the absolute difference (risk difference) and relative difference (odds ratio) in the proportions of SWAT participants randomised to the host trial between those receiving the theoretically informed invitation [letter/email] and those receiving the standard invitation [letter/email].The primary outcome analysis should be of the difference in recruitment rate between those receiving the theoretically informed trial invitation (intervention group) vs. those receiving the standard written invitation (control group). 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: All relevant costs associated with each intervention should be aggregated to estimate the average cost per participant in each SWAT group. Unit costs should be calculated and reported in the currency of the relevant country of the SWAT team, adjusted to current price levels, with any necessary inflation adjustments made. The cost-effectiveness outcome should be reported as the incremental cost per additional participant recruited (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 recruitment rates between these groups.
2. Numbers retained in the two groups being compared at the most feasible follow-up point in the host trial should be analysed following the same method as the primary outcome, using suitable statistical techniques.
3. Harms or unintended effects should be reported descriptively in terms of any feedback from potential participants in relation to the recruitment intervention 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 [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/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 either together with the host trial or as an amendment to the host trial application. Ethical approval is needed as the invitation letter is part of the host trial process and participant facing. The SWAT team should add details as to which option suits their SWAT and host trial].  |
| 22 | **Consent or agreement to participate**  |
|  | As is the nature of a SWAT design, it is not necessary to ask potential participants for separate SWAT informed consent to be randomised into the SWAT. We do not consider this a major ethical issue as this is a low-risk study. When testing whether a theoretically informed trial invitation vs. a standard written invitation impacts on recruitment rates, seeking individual patient consent is not appropriate. It may confuse potential participants as to what they are consenting to and may impact on their behaviour if they are aware that different recruitment methods are being tested, confounding the evaluation. At the end of the [host trial/SWAT], participants will be fully debriefed about the SWAT at the time when the results are shared.  |
| 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/). 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]. |
| 24 | **Confidentiality and access to Data** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)]. |

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

* Hanne Bruhn, Frances Shiely, Adwoa Parker, Chris J. Sutton, Catherine Arundel, Jacqueline Wilkinson, Shaun Treweek - [PRESS project](https://osf.io/xfkgp/) team.

# Please share your SWAT findings

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

## 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.

### References

1. Parker, A., Way, R., Okanlawon, A. A., Mongelli, G., Coleman, E., Arundel, C., … Treweek, S. WP1: Identifying and prioritising trial recruitment and retention strategies. (2024, February 8). <https://doi.org/10.17605/OSF.IO/CZ829>
2. Parker, A., Bruhn, H., Wilkinson, J. A., Treweek, S., Arundel, C., Sutton, C., … Shiely, F. (2025, March 4). PRESS. Retrieved from <https://osf.io/xfkgP/>
3. Healy P, Galvin S, Williamson PR, Treweek S, Whiting C, Maeso B, Bray C, Brocklehurst P, Moloney MC, Douiri A, Gamble C, Gardner HR, Mitchell D, Stewart D, Jordan J, O'Donnell M, Clarke M, Pavitt SH, Guegan EW, Blatch-Jones A, Smith V, Reay H, Devane D. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership - the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. Trials. 2018 Mar 1;19(1):147. doi: 10.1186/s13063-018-2544-4. PMID: 29490702; PMCID: PMC5831203.
4. Trial Forge Evidence Pack – Retention: Theory-based cover letter: <https://www.trialforge.org/resource/evidence-pack-retention-theory-based-cover-letter-id-ret1/>
5. Office for National Statistics. CPIH ANNUAL RATE 00: ALL ITEMS 2015=100 [Internet]. 19 February 2025. Cited 04 March 2025. Available from: <https://www.ons.gov.uk/economy/inflationandpriceindices/timeseries/l55o/mm23>

Appendix 1: Flow diagram of SWAT participants’ movement through the INVITE SWAT.

