

An evaluation of whether electronic reminders increase questionnaire completion rates compared to usual follow-up (E-PROMPT): 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 30). An evaluation of whether electronic reminders increase questionnaire completion rates compared to usual follow-up (E-PROMPT): template Study Within A Trial protocol. Retrieved from <https://osf.io/vbnj5/files/osfstorage>





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| \*\*\*Preamble – 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.This retention SWAT is intended to start as soon as follow up, using self-report questionnaires, starts in the host trial. The self-report questionnaires can be administered using any mode, i.e. pen-and-paper, email, online etc. The electronic reminders should be short and written and delivered electronically. In this protocol we have used SMS texts or email as example reminders. This protocol should be used in conjunction with the following 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)

* [PRESS Health Economics Guidance for SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)
* [PRESS Guidance on applying for ethical approval for the E-PROMPT SWAT](https://osf.io/zn7vm/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 whether electronic reminders increase questionnaire completion rates compared to usual follow-up (E-PROMPT): 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 whether a completely new protocol or new version of the existing protocol is needed. For example, starting the SWAT after the host trial follow up 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 using participant reminders to support 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. 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**In addition to the above, this strategy has been identified as high priority for evaluation in PRIORITY II (Question 4). 1,3 Reminders are frequently used in trials to increase response rates at follow up timepoints. There is uncertainty in the evidence base for the effectiveness of reminders, hence, evaluation is needed. The cost of electronic reminders is low, so they are likely a cost-effective option for increasing retention too. **Research question**Does using [SMS text message/email] reminders increase questionnaire completion rates, compared to usual follow-up? |
| 4b | **Comparators** |
|  | Most trials send reminders if the initial follow up questionnaire isn’t returned. Hence usual follow up is the comparator, assuming usual follow up isn’t electronic i.e., email or SMS text messages.  |
| 5 | **Objectives** |
|  | To evaluate the effect of electronic reminders on host trial retention.  |
| 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:** 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 host trial participants who have not returned an initial follow up questionnaire i.e. participants who are due a follow up reminder, are eligible to be randomised in this SWAT.  |
| 10a | **Interventions** |
|  | **How to complete:****Intervention:** Sending an electronic reminder (email or SMS text message) in addition to the usual follow-up, if a participant has not returned their questionnaire. Reminders may be automated. **Control:** Sending the usual follow up reminder when due. Ideally, the timing of this SWAT is for follow up when collecting the primary outcome in the host trial. However, if this is not feasible, or is not the most useful timepoint for the host trial, other follow-up timepoints could be used. The mode of delivery of the intervention is electronic using email or SMS text messages. The providers are whoever send follow up reminders (e.g. trial office staff or site staff). [The SWAT team should list any relevant co-interventions, e.g., financial incentives].  |
| 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 or retention strategies in this SWAT, though any additional recruitment and/or retention strategies used need to be administered to both SWAT arms.  |
| 11 | **Outcomes** |
|  | Primary outcome:Retention rate, defined as the proportion of SWAT participants in each group (electronic reminder plus usual reminder vs. usual reminder only) returning a completed follow-up questionnaire. 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 recruited [please see section 12 below and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)].
2. Time to return of completed follow-up questionnaire
3. Number of reminders sent to participants before return of completed follow-up questionnaire
4. Harms or unintended effects to be collected in terms of any feedback from participants in relation to receiving or the lack of digital reminders.
 |
| 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 and [Health Economic Guidance](https://osf.io/sebnk/) for a list of direct and indirect costs associated with this SWAT. In addition, relevant costs for the comparator intervention, should also be reported. To estimate the unit costs of electronic reminder plus usual reminder vs. usual reminder alone, 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 participant retained (if the effect of the intervention is positive), calculated as: * Incremental cost per additional participant retained = (unit cost of electronic reminder - unit cost of usual reminder)/ (retention rate in electronic group - retention rate in usual reminder 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 intervention will be direct and associated with the trial teams’ budget)].  **Example costs to report:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Intervention development** |  | **Task** | **Time** | **Total** |
|  | 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 x number of PPI partners] |
| **Intervention delivery** |  | **Unit cost** |  |  |
|  | Cost of sending one SMS text message/email  | Number of SMS text messages/emails to be sent | N/A | [=cost of one unit x numbers needed] |
| **Total** |  |  |  | [TOTAL COST] |

 |
| 13 | **Resource** |
|  | **How to complete:** Modest [The SWAT team should add necessary details as per [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/). Please see Table above in section 12 for example costs to report. The development of the intervention can add to the cost depending on the level of expert (e.g. 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 SWAT protocol template]. |
| 14 | **Data to be collected and characteristics of SWAT participants** |
|  | Data relating to SWAT allocation and whether SWAT participants returned a completed follow-up questionnaire 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 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** |
|  | [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/)].Individually randomised. The allocation ratio will be 1:1. |
| 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 [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/)]. An ‘intention-to-treat’ analysis should be performed. The analysis should be undertaken in accordance with a statistical analysis plan and health economics guidance. All statistical analyses should be conducted using [name software, e.g., Stata (StataCorp)]. The primary outcome analysis should be the difference in retention rate (completion of follow-up questionnaire at the next relevant time point or not) between those sent the electronic reminders and those sent the usual reminder only. 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 - 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 made. The cost-effectiveness outcome 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. Time to collection of questionnaire outcome data: The between-groups difference in time taken to collection of outcome data should be analysed using a Cox regression model (adjusted for SWAT stratification factors).
3. The number of follow-up reminders/calls required should be compared using a Poisson regression model, or a zero-inflated Poisson regression model if there is a large quantity of zeros. The host trial allocation and any stratification variables that were used in the SWAT randomisation algorithm should be included as a covariate.
4. Harms or unintended effects: should be reported descriptively in terms of any feedback from participants in relation to the electronic reminders 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 FLEXI SWAT](https://osf.io/vedu4/). 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 electronic reminders are 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**  |
|  | 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. Participants randomised to receive electronic reminders will have the same opportunity to opt out of receiving electronic reminders as described in the trial’s protocol for standard reminders. 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 retention strategies](https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000032.pub3/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. (2024, February 8). WP1: Identifying and prioritising trial recruitment and retention strategies. <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 [osf.io/xfkgP](https://osf.io/xfkgP/)
3. Brunsdon, D., Biesty, L., Brocklehurst, P. *et al.* What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. *Trials* **20**, 593 (2019). <https://doi.org/10.1186/s13063-019-3687-7>

## Appendix 1: Flow diagram showing participants’ flow through the EPROMPT SWAT.

