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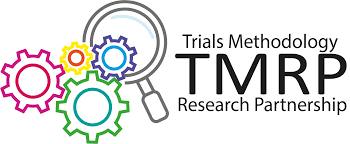
Description automatically generated

An evaluation of whether using routinely collected data, to shorten a follow-up questionnaire, increases the retention of under-served groups, compared to using a longer, participant-reported questionnaire: SHORT-Q template Study Within A Trial protocol

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 using routinely collected data, to shorten a follow-up questionnaire, increases the retention of under-served groups, compared to using a longer, participant-reported questionnaire (SHORT-Q): template Study Within A Trial protocol. Retrieved from <https://osf.io/m2bac/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 in order 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.  We assume that the host trial follow-up questionnaire can be made shorter by using routinely collected data (i.e., some questions can be omitted from the questionnaire). Hence, this SWAT compares a shorter and longer follow-up questionnaire.  Before deciding to conduct this SWAT, it is worth investigating delays in routinely collected data relevant to your SWAT and whether there are any known quality issues. This will help protect the host trial.  We recommend working with relevant PPI partners to define under-served groups as relevant to your host trial and SWATT and to ensure the shorter questionnaire retains face-validity to participants.  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 SHORT-Q SWAT](https://osf.io/m2bac/)   \*\*\*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 using routinely-collected data, to shorten a follow-up questionnaire, increases the retention of under-served groups, compared to using a longer, participant-reported questionnaire: SHORT-Q template Study Within A Trial protocol** | |
| 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 routine data collection 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**  This strategy has been identified as high priority for evaluation in PRIORITY II (Question 2 and 17). 1,3 Use of routine data has the potential to improve data collection from under-served groups, which is an area of importance and an NIHR priority. Overall, the use of routinely collected data has potential to increase efficiency of trial conduct and therefore needs to be evaluated.  **Research question**  Does using routinely collected data (e.g., ONS/HES/GP/Hospital data), to shorten the follow-up questionnaire, improve retention rates of under-served groups, compared to using solely participant-reported data at follow-up? | |
| 4b | **Comparators** | |
|  | Most trials collect participant-reported data via questionnaires at follow-up. Hence, participant-reported data can be viewed as ‘treatment as usual’ and will be the comparator. | |
| 5 | **Objectives** | |
|  | To evaluate the effect of using routinely collected data on host trial retention of under-served groups. | |
| 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** | |
|  | **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 due a follow-up questionnaire, are eligible to be randomised in this SWAT. | |
| 10a | **Interventions** | |
|  | **How to complete:**  **Intervention:** Use routinely collected data at follow-up, any data not available as routine collected data to be included in a short questionnaire sent to SWAT participants.  **Control:** Use participant-reported data at follow-up (ask for all data i.e. longer questionnaire).  The timing of this SWAT is for follow-up when collecting the primary, or other relevant outcome, in the host trial. The mode of delivery of the intervention (short questionnaire) is as per host trial protocol. The providers are whoever apply for routinely collected data and who send out follow-up questionnaires (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:  Number of participants from under-served groups returning a completed follow-up questionnaire, defined as the proportion of SWAT participants from the relevant under-served group(s) who complete the follow-up questionnaire at the chosen outcome time-point  Secondary outcomes:   1. Unit costs, defined as the costs incurred for each participant within the SWAT (for the relevant under-served groups). 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 number of participants giving feedback and a short description of the feedback in terms of whether it was positive or negative in relation to receiving a shorter questionnaire. | |
| 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. All relevant costs associated with each intervention should be aggregated to estimate the average cost per participant in each SWAT group (for the relevant under-served groups). Please see table below and [Health Economic Guidance](https://osf.io/sebnk/) for a list of direct and indirect costs associated with this SWAT. 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.  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 short questionnaire - unit cost of long questionnaire)/ (retention rate in short questionnaire group - retention rate in long questionnaire 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 | 2 hours | [=£50 x number of PPI partners] | | **Cost of routinely collected data** |  |  |  |  | |  | The cost of routinely collected data is study specific. | N/A | N/A | [cost from supplier] | | **Total** |  |  |  | [TOTAL COST] | | |
| 13 | **Resource** | |
|  | **How to complete:**  Moderate to substantial.  [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 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 SWAT protocol template]. | |
| 14 | **Data to be collected and characteristics of SWAT participants** | |
|  | Data relating to which group participants were randomised to i.e., whether they were sent a short or long follow-up questionnaire and whether 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, gender, age, ethnicity, and any other key participant characteristics imbalanced in terms of representation]. | |
| 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. | |
| 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 analysis will be of the absolute (risk difference) and relative difference (odds ratio) in retention rates (returning a completed questionnaire or not) between those sent a short questionnaire and those sent a long questionnaire. [See Statistical Analysis Plan for details of additional analysis. 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, ethnicity and any other under-served groups deemed particularly relevant to the trial should be presented descriptively as mean (standard deviation) or number (%), as appropriate.  For the 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 length of questionnaire 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 [SHORT-Q Guidance for applying for ethics approval for a SWAT](https://osf.io/vre93/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 follow-up questionnaires are part of the host trial process and participant facing. Any additional data about trial participants’ membership of under-served groups required for evaluation of the SWAT should also be detailed in the ethics application. 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. At the end of the [host trial/SWAT], participants will be fully debriefed about the SWAT at the time when the results are shared.  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 this SWAT evaluating whether offering shorter vs. longer questionnaires on retention rates impacts on retention rates, seeking individual participant consent 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 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](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 [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](mailto:swats-group@york.ac.uk)

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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. 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 SHORT-Q SWAT.

A diagram of a swot analysis

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