

An evaluation of whether offering flexibility in in-person follow-up visit location increases trial participant retention compared to not offering flexibility (FLEXI): template cluster-randomised Study Within A Trial protocol

How to cite this template SWAT protocol

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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) or exactly how you would implement the SWAT. 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.This SWAT is intended to start at the same time as follow-up starts in the host trial. If the SWAT is started later, this protocol needs to be amended accordingly and given a new version and date. Note – exactly how the flexibility in the location will be arranged in the intervention of this SWAT has not been detailed as it depends on the host trial, what an acceptable location would be and resources available. SWAT teams are strongly advised to consult with relevant patient and public partners as to which locations should be offered to SWAT participants to choose between. This protocol 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/)

* [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 FLEXI SWAT](https://osf.io/vedu4/)

\*\*\*This document has been prepared using a table so choose ‘all borders’ in Paragraph menu before completing it.\*\*\* |

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| **Administrative information** |

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| 1 | **Title** |
|  | 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-randomised Study Within A Trial protocol |
| 2 | **Registration** |
|  | SWAT registration on Northern Ireland SWAT repository pending. |
| 3 | **Protocol version** |
|  | 29th 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 offering flexibility to support 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. 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 (Questions 4, 7 and 15).1,3 The intervention of offering flexibility in order to collect in-person follow-up data is the most frequently used strategy to collect outcome data in NIHR-funded trials. However, there is no evidence on the most effective ways to offer flexibility.1 Hence, evaluation is needed. **Research question**Does offering trial participants flexibility in in-person follow-up visit location increase retention rates, compared to not offering flexibility? |
| 4b | **Comparators** |
|  | Offering flexibility to capture in-person follow-up data is the most frequently-used strategy to collect outcome data in NIHR-funded trials. However, there is no evidence on the most effective ways to offer flexibility.1 Hence, the comparator is to not offer a choice of locations for follow-up visits.  |
| 5 | **Objectives** |
|  | To evaluate the effect of offering a choice of follow-up visit location on host trial retention.  |
| 6 | **Design** |
|  | The SWAT design is parallel group cluster-randomised, 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 visit are eligible to take part in this SWAT.  |
| 10a | **Interventions** |
|  | **How to complete:****Intervention**: Offer trial participants a choice of at least two locations for their in-person follow-up visit for host trial primary outcome collection.**Control**: Follow-up offered at one location only for host trial primary outcome collection. The timing of this SWAT is for in-person follow-up visit at primary outcome collection. Participants can be told about the alternative follow-up visit locations using whatever communication methods are being used in the host trial. The providers are the staff at the follow-up visit location. [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 or retention strategies in this SWAT, though any additional recruitment and/or retention strategies used need to be administered to all SWAT arms (i.e. no further randomised comparisons are permitted).  |
| 11 | **Outcomes** |
|  | Primary outcome:Retention rate at chosen follow-up visit in the host trial, defined as the proportion of SWAT participants who attend and complete the chosen follow-up visit 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 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. Harms or unintended effects to be collected in terms of any feedback from participants in relation to the having or not having a choice of follow-up visit location.
 |
| 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 - please see table below for a breakdown of potential costs. To calculate the costs, all relevant costs associated with each arm 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 retained (if the effect of the intervention is positive), calculated as: * Incremental cost per additional participant retained = (unit cost of participants offered a choice of at least two locations - unit cost of offered at one location only)/ (retention rate in participants offered a choice of at least two locations group- retention rate in offered at one location only).

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:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Expenditure** | **Cost** | **Time** | **Total** |
| Consultation with patient and public partners about suitable locations to offerPayment per NIHR guidance: https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals | £25 per PPI partner | 1 hour | [=£25 x number of PPI partners] |
| Rent or access to additional locations | [Hourly or monthly rent or cost] | [Number of hours or months to rent or access location] | [=Number of hours or months x cost] |
| If relevant: additional staffing | [hourly or monthly pay] | Hours needed | [=hourly pay x time in hours] |
| Materials with details of additional locations e.g. PIL, maps, letters | Cost of one PIL, map, letter | Numbers needed = number of participants in SWAT intervention | [=cost of one unit x numbers needed] |
| **Total** |  |  | [TOTAL COST] |

 |
| 13 | **Resource** |
|  | **How to complete:**High. [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. There is likely additional cost associated with offering additional in-person follow-up locations in terms of staffing and renting/getting access to additional buildings. 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 sites/participants were randomised to i.e., whether they were offered flexibility in in-person follow-up location or no flexibility and whether participants attended the follow-up visit 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](https://osf.io/jmpyn/)[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** |
|  | [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/)].The SWAT will use cluster randomisation at the level of sites [include relevant features to avoid imbalance based on site characteristics, e.g. size, location]. 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 primary outcome analysis is the difference in retention rate between those offered a choice of at least two locations and those offered only one choice of location. For the primary outcome analysis, comparison of the response rate between the two SWAT groups should use a mixed effects regression model, adjusted for the size of the site (e.g., hospital, clinic) as a random effect to account for the clustering. 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 regression model. Demographic characteristics, including age and ethnic group should be presented descriptively as mean (standard deviation) or number (%), as appropriate.The primary analysis should be of the absolute (risk difference) and relative difference (odds ratio) in retention rates (attending in-person follow-up visit or not) between those offered flexibility in follow-up visit location and those not offered flexibility in follow-up location. 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 clustering and SWAT stratification factors).
3. 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 follow-up visit 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**  |
|  | Informed consent will not be obtained, as the SWAT is conducted as part of the host trial follow-up process. As participating sites are randomised to perform follow-up using the intervention or control strategies, participants will not themselves be randomised and will be follow-up by what has become, for their site, the ‘standard’ follow-up approach. We therefore consider to be a very low-risk study. In this case of testing whether being offered a choice of locations impact on retention rates, seeking individual participant prior consent is not appropriate. It may confuse participants as to what they are consenting to and may impact on their behaviour if they are aware that different retention methods are being tested in different sites, confounding the evaluation. PPI partners have informed the decision to undertake this SWAT, as well as the study methods. 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, Shaun Treweek, Adwoa Parker, Chris J. Sutton, Catherine Arundel, Jacqueline Wilkinson, Frances Shiely - [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

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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 [osf.io/xfkgP](https://osf.io/xfkgP/)
3. Brunsdon D, Biesty L, Brocklehurst P, Brueton V, Devane D, Elliott J, Galvin S, Gamble C, Gardner H, Healy P, Hood K, Jordan J, Lanz D, Maeso B, Roberts A, Skene I, Soulsby I, Stewart D, Torgerson D, Treweek S, Whiting C, Wren S, Worrall A, Gillies K. 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. 2019 Oct 15;20(1):593. doi: 10.1186/s13063-019-3687-7. PMID: 31615577; PMCID: PMC6794792.

**Appendix 1: Flow diagram of SWAT participants’ movement through FLEXI**

