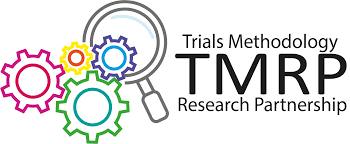


The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): template Study Within A Trial protocol

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 a trial participant biography on participant recruitment rates (BIOREC): template Study Within A Trial protocol. Retrieved from <https://osf.io/8kcdr/files/osfstorage>

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|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| \*\*\*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 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 protocol should be used in conjunction with the following documents:   * [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) * [Guide to creating a trial participant biography for the BIOREC Study Within A Trial (SWAT)](https://osf.io/dqv9j/) * [Guidance on making accessible documents](https://osf.io/8ek76/) * [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/) * [The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): guidance on applying for ethical approval for a Study Within A Trial (SWAT)](https://osf.io/c4pr2/)   \*\*\*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 a trial participant biography on participant recruitment rates (BIOREC): 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 involving patients and the public in trials to improve participant recruitment?’ was selected by the Trial Forge SWAT Network and the NIHR-funded Implement SWATs programme working group as a priority recruitment strategy for evaluation1. There are many potential SWATs that could answer this question, however, this SWAT study was chosen and co-produced by three patient and public partners as part of the PRESS project2.  **Rationale for this intervention**   * Approximately half of publicly funded randomised controlled trials (RCTs) fail to achieve their original participant recruitment targets. Among those that do meet their targets, a third require extended recruitment periods3. This recruitment strategy has been identified as a high priority for evaluation by PRIORITY I (question 3)4, the [Trial Forge SWAT Network](https://www.trialforge.org/2021/06/swat_network/), and the NIHR-funded Implement SWATs programme working group1. Previously reported patient and public involvement (PPI) interventions appear to increase the odds of participant enrolment, albeit modestly5. Determining how PPI involvement in planning trials affects participant recruitment was identified as a top 10 priority question using a James Lind Alliance priority setting partnership4. 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 featuring a biography of a current trial participant. They selected this intervention to foster trust with potential participants being recruited into the same trial. Behaviour theory guided the biography’s development, ensuring it built trust and effectively leveraged social influence and personal storytelling. The intervention’s mechanism of action aims to build trust, provide relatable experiences, and support informed decision-making. To ensure accessibility and acceptability of the intervention, this protocol is supported by a [Guide to Creating a Trial Participant Biography for the BIOREC Study Within A Trial (SWAT)](https://osf.io/dqv9j/) and [Guidance on making accessible documents](https://osf.io/8ek76/), both of which were co-produced with PRESS PPI Partners.   This biography would be distributed to potential participants along with the recruitment materials for the host trial. Given the design of this SWAT, host trials implementing this SWAT will have already begun enrolling participants, as an existing participant will be the subject of the biography. The results of this SWAT will inform trialists whether this strategy effectively aids participant recruitment and will also provide information on the cost-effectiveness of the strategy. | | | | |
|  |  | | | **Research question**     1. What is the effectiveness of participant biography versus usual practice (i.e., no participant biography) for increasing participant recruitment rates? 2. What is the cost-effectiveness of participant biography versus no biography? | | |
| 4b | **Comparators** | | | | |
|  |  | | | Trial enrolment materials, including participant information leaflets, are routinely provided to potential trial participants.  **SWAT Intervention participants** will receive standard trial enrolment materials plus host trial participant biography.  ***Guidance****: One biography can be used per host trial. If trial teams wish to target different study populations, they may include two or more biographies (for instance, focusing on multiple under-represented groups).*  **SWAT Comparator participants (control group)** will receive ‘usual practice’ and be provided with the standard trial enrolment materials (without a participant biography). | | |
| 5 | **Objectives** | | | | |
|  |  | | | 1. To evaluate the effectiveness of participant biography versus usual practice (i.e., no participant biography) on increasing participant recruitment rates 2. To evaluate the cost-effectiveness of participant biography versus usual practice. | | |
| 6 | **Design** | | | | |
|  |  | | | The SWAT is a parallel group, cluster, superiority design with a 1:1 allocation ratio.  ***Guidance:*** *Depending on the design of the host trial, the SWAT design could be modified to be an individual-level, superiority design.* | | |
| **Methods: Participants, interventions, and outcomes** | | | | | |
| 7 | **PPI partner involvement** | | | | |
|  |  | | | **How to complete:**  Three PPI partners were involved in selecting this specific SWAT question and co-producing the intervention. They 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 was ranked first. PPI Partners decided to focus on fostering ‘trust’ as the key mechanism of action, and a PPI Partner generated a sample participant biography (See [‘Guide to Creating a Trial Participant Biography for the BIOREC SWAT’](https://osf.io/dqv9j/)), which other PPI Partners provided feedback on. All PPI Partners contributed to developing this protocol and support resources.  [Add further details regarding PPI involvement in your SWAT. This may include identifying diverse potential trial participants to produce the biography and the input of your host trial PPI partners in developing the biography and SWAT]. | | |
| 8 | **Study setting** | | | | |
|  |  | | | **How to complete:**  Describe the setting(s) relevant to your SWAT. | | |
| 9 | **Who can take part** | | | | |
|  |  | | | Due to the need to identify enrolled host trial participants to provide the biography, not all potential host trial participants will be randomised into this SWAT. Once the SWAT all eligible potential host trial participants will be randomised into this SWAT. Host trial enrolment materials, including the participant biography in the intervention group, will be provided to potential host trial participants by recruiting staff. | | |
| 10a | | **Interventions**  **How to complete:**  **Intervention**: The host trial team and/or recruitment sites will approach host trial participants to provide a biography. These participants will be asked if they are willing to work with the trial team to produce a biography regarding their recruitment to the host trial, including the reasons they chose to take part. The host trial team will facilitate production of the participant biography in an accessible format that can be distributed to participants identified as eligible for the host trial and randomised to the SWAT intervention group.  ***Guidance****:**, along with any relevant materials required for this approach.*   * Informed Consent: *It is important to note that approaching a host trial participant to develop the biography may need to be included in the host protocol from the outset and included in the main trial ethical application, or an ethical amendment approval will need to be sought to allow this approach. The participant providing the biography will need clear information about the study, their rights, and data protection measures. They will need to provide fully informed consent and understand how their information will be shared and used. Clear agreements will need to be established on how the biography can be used and whether the participant can withdraw consent after publication.* * *You may wish to choose some biographers who are from under-served groups of particular relevance to your trial ((e.g., women, ethnic minorities, those with a disability).* * *The biographers should be reimbursed in line with the relevant patient and public involvement guidance for the host trial team.*   **Control**: Usual trial enrolment materials (no participant biography) will be provided by [insert method(s) of provision] to patients identified as eligible for the host trial.  The timing of this SWAT is at first contact for recruitment. The mode of delivery of the intervention can be via postal letter or email, via separate paper copy given by hand alongside the participant information leaflet, as a QR code on participant invitation letter to access video biography, etc. The SWAT team should add details as to the mode used or if mixing modes, how this is decided. The providers are the staff inviting potential trial participants 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** | | | | |
|  |  | | | There are no limitations on permitted or prohibited concomitant interventions/recruitment strategies in this SWAT, although any additional recruitment strategies used need to be administered to both SWAT arms. If the SWAT plans to assess the impact of the biography on retention rates as a secondary outcome, any additional retention strategies will also need to be delivered to both arms. | | |
| 11 | **Outcomes** | | | | |
|  |  | | | Primary outcome:  Recruitment rate, defined as the proportion of SWAT participants who are randomised into 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. Proportion of randomised SWAT participants retained in the trial (i.e. retention rate), defined as the proportion of SWAT participants randomised into the host trial who complete the chosen key outcome assessment/measure(s)/ attend the chosen key follow-up appointment *[host trial to edit as appropriate]* at the *[Please specify the follow-up time point(s)*] 3. Harms or unintended effects, to be collected in terms of any feedback from potential participants in relation to the biography they have received (i.e., number of participants who have provided feedback and a short description of the feedback as negative or positive). | | |
| 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 the biography (including video biography where relevant) 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 a biography and staff time for administering the intervention and managing SWAT data collection; please see table below 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 biography and no biography, 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 biography - unit cost of no biography)/ (recruitment rate in biography group- recruitment rate in no biography 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 biography intervention will be direct and associated with the trial team’s budget)].  ***Guidance****:*  *Example costs to report:*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | ***Intervention development*** | ***Applicable to*** | ***Description*** | ***Task*** | ***Time*** | ***Total*** | |  | *Trial participant biography group* | *Trial participant providing biography* | *Time to create biography; review biography drafts and agree format; training (as required).* | *2 days* | *£150 (per day) x 2 days X number of trial participants (biography subjects)* | |  | *Trial participant biography group* | *Patient and public partners involvement*  *Payment per NIHR guidance:*  [*https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals*](https://www.nihr.ac.uk/payment-guidance-researchers-and-professionals) | *Review drafts and format of biography* | *3 hours* | *[=£25 (per hour) x 3 hours x number of PPI partners]* | |  | *Trial participant biography group;*  *No biography 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 sites to identify host trial participants willing to share their biography; support of biographers; production of distributable biography; managing PPI input on biography; seeking ethical approval for biography, distributing biography to sites; distributing trial materials to sites; SWAT data collection* | *X hours* | *[=hourly pay x time in hours per staff member]* | | ***Intervention delivery*** | ***Applicable to*** | ***Description*** | ***Unit cost*** |  |  | |  | *Trial participant biography group;*  *No biography group* | *Cost of printing* | *Number of biographies printed;*  *Number of trial materials printed* | *N/A* | *[=cost of one printed biography x numbers needed]* | |  | *Trial participant biography group;*  *No biography group* | *Postage costs* | *Number of biographies posted;*  *Number of trial materials posted* | *N/A* | *[=cost of one posted biography x numbers needed]* | | ***Total*** |  |  |  |  | *[TOTAL COST]* | | | |
| 13 | **Resource** | | | | |
|  |  | | | **How to complete:**  Modest.  [The development of the intervention can add to the host trial cost depending on the trial participant providing the biography and PPI Partners’ involvement. 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.  Any indirect costs will involve staff time in managing the development of the written trial invitation, liaising between different contributors (e.g. PPI Partners), developing the biography, obtaining ethics approval, and setting up the SWAT]. | | |
| 14 | **Data to be collected and characteristics of SWAT participants** | | | | |
|  |  | | | Data relating to potential eligible host trial participants randomised to each SWAT arm (i.e., whether they received the biography or just usual study materials), and whether they were randomised into the host trial, will be collected for the SWAT. Where relevant, data relating to trial participants completing the host trial primary outcome assessment in each SWAT arm will be collected.  [All other data are collected as part of the host trial/The following data will be collected in addition: (insert relevant data as per [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/)).  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** | | | | |
|  |  | | | Cluster randomisation.  [Whilst individual randomisation can be used for this SWAT, cluster randomisation at the level of recruiting site (e.g., hospitals, GPs) may be more pragmatic and easier to implement. 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 the method to be used to generate the random allocation sequence for sites for the SWAT (e.g., computer-generated random numbers), and list any factors for stratification (e.g., size of site). If there are any planned restrictions (e.g., blocking) identify that these will be provided in a separate document that is unavailable to those who enrol sites]. | | |
| 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/). 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 [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/). Describe who will and won’t be blinded after the assignment of sites 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 should be performed. All statistical analyses should be conducted using a named computer programme. The primary outcome analysis is of the difference in recruitment rate between those receiving a participant biography alongside usual enrolment materials and those receiving the standard enrolment materials (no participant biography). Demographic characteristics, including age and ethnic group should be presented descriptively as mean (standard deviation) or number (%), as appropriate.  [For secondary outcomes:   1. Costs [Please see - [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 calculated and 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). Cost-effectiveness (the incremental cost per additional participant recruited) 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 (proportions) 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 biography 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 see [The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): guidance on applying for ethical approval for a Study Within A Trial (SWAT)](https://osf.io/c4pr2/). Describe the requirements for ethical approval in your jurisdiction. For this SWAT, trial teams must identify enrolled host trial participants to provide the biography. Therefore, the host trial must be actively recruiting before the biography intervention can be developed. Approaching a host trial participant may need to be included in the host protocol from the outset. Otherwise, a substantial amendment must be sought before any participant is approached. We recommend obtaining approvals for this SWAT as part of a substantial amendment to the host trial’s ethics approval. For a consideration of some of the ethical issues related to this SWAT, please see [The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): guidance on applying for ethical approval for a Study Within A Trial (SWAT)](https://osf.io/c4pr2/)]. | | |
| 22 | **Consent or agreement to participate in the SWAT** | | | | |
|  |  | | | It will not be possible to ask potential participants for informed consent to be randomised into this SWAT. We do not consider this a major ethical issue as this is a low-risk study. The SWAT is conducted as part of the host trial recruitment process, and individual participants are not being randomised as they are receiving the SWAT intervention allocated to the recruiting site; rather, they will be receiving the standard recruitment approach for that site. Additionally, potential trial participants will already have been included in the SWAT before they are approached to participate in the host trial, so this would require retrospective consent, which is not feasible, and may also cause patients confusion about what they are being asked to consent to. It might also impact their behaviour if they are aware that different recruitment materials are being tested, which may adversely affect the integrity of the SWAT evaluation. The key information being recorded for the SWAT is whether or not the patient is being recruited into the host trial (anonymously), so there are no ethical or data protection issues. | | |
| 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

* Kamil Sterniczuk, Michele Powponne, Philip Bell – Patient and Public Involvement partners on the [PRESS project](https://osf.io/xfkgp/).
* 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/).

## 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

PRESS participant biography recruitment SWAT flow diagram

