

An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers: CASH Study Within A Trial protocol

How to cite this template SWAT protocol

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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.In this SWAT protocol we have used Love2Shop vouchers as an example as they are available as both physical and electronic vouchers in the UK and can be used with a wide range of retailers. We recommend you consult with PPI partners about which type of voucher and value will work best in your SWAT. In our experience, based on consultation with PPI partners, the minimum value of vouchers should be £10. Please see Appendix 2 for a list of monetary incentive values and comparators that have been tested or are currently being tested. For the cash-based incentive, the SWAT team will need to consider when the cash can be transferred to SWAT participants and how in consultation with PPI partners. This monetary incentive SWAT protocol is a conditional incentive, paid to participants after randomisation rather than unconditionally upfront on invitation to take part in the trial. Both conditional and unconditional approaches need evaluation, but you will need to amend the protocol if you want to evaluate an unconditional approach. Although the SWAT question focuses on people experiencing socioeconomic disadvantage, for reasons of equity and clarity, the template protocol assumes that all potential participants invited into the host trial during the SWAT implementation period, will be offered the allocated incentive regardless of socioeconomic status; the distribution of socioeconomic status across the recruited participants is assessed after they are recruited into the host trial, not before. However, SWAT teams may adapt this template, for instance, to target specific socioeconomically disadvantaged groups (including via postcode linked with indices of multiple deprivation or primary care practice list), at the point where they are invited into the trial.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/)
* [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/)
* [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)
* [An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers (CASH): guidance on applying for ethical approval for a Study Within A Trial (SWAT)](https://osf.io/hfvpn/)

\*\*\*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 cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers: CASH 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 to use financial incentives to support recruitment?’ was selected by the [Trial Forge SWAT Network](https://www.trialforge.org/2021/06/swat_network/) and the NIHR-funded Implement SWATs programme working group as a priority recruitment strategy for evaluation1. To answer the SWAT question, this SWAT study was chosen by three patient and public partners as part of the PRESS project2. **Rationale for this intervention**This strategy has been identified as high priority for evaluation in PRIORITY I (question 17)1,3.There is evidence that monetary incentives probably increase recruitment. There is currently no evidence of whether the monetary transaction mode of incentives (e.g. cash, electronic payment card, vouchers) make a difference. Bearing in mind the urgent need to make trials more inclusive this needs to be tested as it is likely to be of importance to people experiencing socioeconomic disadvantage. **Research question**Do cash-based monetary incentives increase recruitment of people experiencing socioeconomic disadvantage compared to vouchers with the same face value? |
| 4b | **Comparators** |
|  | Vouchers have mainly been used as monetary incentives and can therefore be viewed as ‘usual care’ and are therefore the chosen comparator.  |
| 5 | **Objectives** |
|  | To evaluate the effect of same value cash-based monetary incentives compared to vouchers on host trial recruitment of people experiencing socioeconomic disadvantage.  |
| 6 | **Design** |
|  | The SWAT design is parallel group, with allocation ratio of 1:1, using a superiority framework.  |
| **Methods: Participants, interventions, and outcomes** |
| 7 | **PPI partner involvement** |
|  | There has been PPI involvement in selection of this SWAT for evaluation. Patient and public involvement partners were asked to rank suggested SWATs for each of 11 SWAT questions, including this one1. SWATs ranked first were taken forward if PPI partners agreed on the ranking while disagreements were discussed until agreement was reached. [Add further details as per your SWAT patient and public involvement]. |
| 8 | **Study setting** |
|  | **How to complete:** Describe the setting(s) relevant to your SWAT.  |
| 9 | **Who can take part** |
|  | All potentially eligible host trial participants will be randomised in this SWAT. The host trial invitation letter and/or participant information leaflet will describe the personal socioeconomic conditions to be fulfilled in order to receive an incentive. [SWAT team should describe conditions here].  |
| 10a | **Interventions** |
|  | **Intervention**: A cash payment (of the same value as the control) on meeting the necessary conditions to trigger eligibility for payment [such as attending a screening appointment and/or signing a consent form].**Control**: A voucher payment on meeting the necessary conditions to trigger eligibility for payment. The timing of this SWAT is at first contact for recruitment (where potential participants are informed of the conditions for receiving an incentive) and after randomisation when the monetary incentive is transferred to SWAT participants. The mode of delivery of the intervention is whatever way the SWAT team and PPI partners think it is appropriate to transfer the incentive. The providers are the staff responsible for transferring cash or vouchers to SWAT participants. [The SWAT team should list any relevant co-interventions e.g., reminders. There are some ethical issues to consider for this SWAT. Offering monetary incentives may be perceived to disproportionately influence individuals experiencing socioeconomic disadvantage, potentially leading to the perception of undue inducement where people may feel pressured to participate for financial reasons rather than informed choice. However, guidance from the UK Health Research Authority states that: “Financial or other incentives, of themselves, are not considered coercive, nor present an undue inducement to a potential participant where the risks and burdens involved are those that a competent, adult participant might reasonably accept for no payment”. Although the SWAT question focuses on people experiencing socioeconomic disadvantage, for reasons of equity, ALL potentially eligible participants being invited into the host trial during the SWAT implementation period will be allocated to one of the two incentive strategies regardless of socioeconomic status. However, SWAT teams may adapt this template, for instance, to target specific socioeconomically disadvantaged groups (including via postcode linked with indices of multiple deprivation or primary care practice list), at the point where they are invited into the trial]. |
| 10b | **Additional interventions that can be used at the same time** |
|  | **How to complete:**There are no limitations on permitted or prohibited concomitant interventions/recruitment strategies in this SWAT, though any additional recruitment strategies used need to be administered to both SWAT arms. |
| 11 | **Outcomes** |
|  | Primary outcome:-Numbers randomised in the host trial, defined as the proportion of SWAT participants experiencing socioeconomic disadvantage who are randomised into the host trial. *[Measuring socioeconomic disadvantage in this SWAT may present challenges, particularly in collecting relevant data (e.g., postcode) for participants who are not recruited and randomised into the trial. SWAT teams should carefully consider how they will address this].*Secondary outcomes:- Overall participant recruitment rate, defined as the proportion of participants randomised in the host trial across all socioeconomic groups. - 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/)]. -Numbers retained in the two groups being compared at the most feasible follow-up point in the host trial, defined as the proportion of those SWAT participants randomised in the host trial who complete the most feasible follow-up in the host trial. -Harms or unintended effects to be collected.  |
| 12 | **Economic evaluation details** |
|  | **How to complete:**[The SWAT team should complete this section if appropriate as per [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/). We encourage SWAT teams to report the costs of the SWAT, even if a full economic evaluation is not undertaken. Please report both direct and indirect costs associated with the intervention - please see table below for a breakdown of potential costs. To calculate the costs, all relevant costs associated with each intervention should be aggregated to estimate the average cost per participant in each SWAT group. Unit costs - both direct and indirect - should be presented, including costs of the intervention (i.e., cash, vouchers). These unit costs should be reported in the currency of the relevant country of the SWAT team and adjusted to current price levels, with any necessary inflation adjustments made5. To estimate the unit costs, SWAT teams should estimate the total costs for each cost component, then aggregate all relevant components for each intervention and divide them by the number of SWAT participants allocated to the respective intervention group. Where relevant, the cost-effectiveness outcome should be reported as the incremental cost per additional participant recruited (if the effect of the intervention is positive), calculated as: * Incremental cost per additional participant randomised = (unit cost of Cash - unit cost of voucher)/ (recruitment rate in cash group- recruitment rate in voucher group).

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Intervention development staff** | **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, value of incentives and mode of transfer.  | 1 hour | £25 |
| **Intervention delivery** | **Unit cost** |  |  |
| Financial incentives | Value of incentive | N/A | [=number of incentives needed x value of incentives] |
| Postage or transfer cost (e.g. cost of payment card) | e.g. cost of payment card |  | [=number of payment cards needed] |
| Cost of any secure storage (e.g. safety box) for storage of incentives.  | Cost of one unit | N/A | [=cost of one unit x number of units 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 SWAT team should add necessary details as per the SWAT protocol template and use the PRESS Health Economic Guidance for a full breakdown of potential costs associated with this SWAT].  |
| 14 | **Data to be collected and characteristics of SWAT participants** |
|  | Data relating to which group participants were randomised to i.e., which incentive [cash or voucher] they were paid and whether the final follow up was completed will be collected for the SWAT. [All other data are collected as part of the host trial]. The following data will be collected in addition: [insert relevant data as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)]. [While participant characteristics might not be available pre-trial consent, the SWAT team should be able to describe who is taking part in the SWAT and in the host trial in relation to how representative they are of the population the trial is relevant for. Given the nature of this SWAT, please specific socioeconomically disadvantaged groups/geographic areas, etc., being targeted. This could include specific localities identified using the indices of multiple deprivation. Please also describe the sex, gender, age, and ethnicity of your SWAT participants].  |
| 15 | **Participant timeline** |
|  | Please see the flow diagram in appendix 1, showing participants’ movement through the SWAT.  |
| **Methods: Assignment of interventions (for controlled trials)** |
| 16a | **Sequence generation** |
|  | Individual randomisation. [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/)]. |
| 16b | **Allocation concealment mechanism** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)]. |
| 16c | **Implementation** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)]. |
| 17 | **Blinding (masking)** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/) and [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/). Describe who will and won’t be blinded after the assignment of participants to the intervention (e.g., recruiters, data analysts), and, if blinded, how this will be achieved]. |
| **Methods: Data collection, management, and analysis** |
| 18 | **Data management** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Describe plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values)]. ***Guidance:*** *It is sufficient to provide ‘light touch’ details.* |
| 19 | **Statistical methods** |
|  | [Please see [Randomised Recruitment SWAT Statistical Analysis Plan Template](https://osf.io/vqt6g/) and [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/)].An ‘intention-to-treat’ analysis should be performed. The primary outcome will be the absolute (risk difference) and relative difference (odds ratio) in the recruitment rate (i.e., proportions randomised to the host trial between those experiencing socioeconomic disadvantage and receiving the cash-based incentive (intervention group) and those receiving the voucher incentive (control group) [please specify socioeconomically disadvantaged groups/geographic areas, etc., being targeted, and how you will obtain the data on socioeconomic disadvantage. This could include specific localities identified using the [Indices of multiple deprivation](https://data.cdrc.ac.uk/dataset/index-multiple-deprivation-imd)]. 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 deprivation [*e.g., using the* [*Index of Multiple Deprivation decile*](https://data.cdrc.ac.uk/dataset/index-multiple-deprivation-imd)], age and ethnic group should be presented descriptively as mean (standard deviation) or number (%), as appropriate. For secondary outcomes: 1. Overall participant recruitment rate, regardless of participants’ socioeconomic status: comparison of the recruitment rate between the two SWAT groups should use logistic regression.
2. 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 presented, including costs of the intervention (i.e., cash, vouchers). 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 recruited (if the effect of the intervention is positive). This should be calculated by dividing the difference in unit costs between the intervention and comparator groups by the percentage point difference in recruitment rates between these groups.
3. 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.
4. Harms or unintended effects should be reported descriptively in terms of any feedback from potential participants in relation to the incentive they have received, such as number of participants who have provided feedback and a short description of the feedback, as negative or positive.
 |
| **Methods: Monitoring** |
| 20 | **Interim analysis and stopping rules** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/). Describe any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the SWAT].  |
| 21 | **Ethical approval** |
|  | **How to complete:**[Please refer to [An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers (CASH): guidance on applying for ethical approval for a Study Within A Trial (SWAT)](https://osf.io/hfvpn/). 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 incentive is provided as part of the host trial process and is participant facing. The SWAT team should add details as to which option suits their SWAT and host trial].  |
| 22 | **Consent or agreement to participate**  |
|  | 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. In this SWAT seeking individual consent, prior to the person considering whether to join the host trial, is not appropriate as it may confuse potential participants as to what they are consenting to. It might also impact on their behaviour if they are aware that different incentives 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]. |
| 24 | **Confidentiality and access to Data** |
|  | **How to complete:** [The SWAT team should complete this section as appropriate as per [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/)]. |

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

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

# Please share your SWAT findings

If you undertake this SWAT, please share your findings so your results can be included in future updates of the [Cochrane systematic review of recruitment strategies](https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000013.pub6/full). Please email Dr Adwoa Parker at: swats-group@york.ac.uk

## Funding statement

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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**

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

