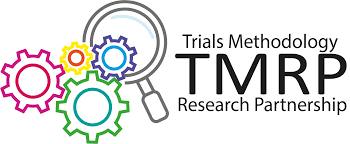
 

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| **PRESS Randomised Recruitment SWAT Master Statistical Analysis Plan Template** | | |
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**How to cite this master SAP template**

Sutton, C., Gkekas, A., Shiely, F., Treweek, S., Bruhn, H., Wilkinson, J. A., … Parker, A. (2025, March 29). PRESS Randomised Recruitment SWAT Master Statistical Analysis Plan Template. <https://osf.io/vqt6g/files/osfstorage>

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AI-generated content may be incorrect.**

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| **{Recruitment SWAT Title}** | | |
|  | | |
| SWAT Statistical Analysis Plan | | |
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**SWAT SAP Version date:**

**SWAT SAP Author(s):**

**SWAT identifier and registry name:**

**SWAT Chief Investigator/Lead:**

**Host Trial Chief Investigator:**

**Trial Coordinator**:

# Roles and responsibilities

## Signatures

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **SWAT or Host**  **Trial Role** | **Signature** | **Date** |
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# SAP Revisions

|  |  |
| --- | --- |
| **Amendment/addition to SAP and reason for change** | **New version number, name and date** |
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# Introduction

The [PRESS project](https://osf.io/xfkgp/) team has developed a set of resources for randomised SWATs looking at the effectiveness of a range of recruitment and retention SWAT interventions. This Statistical Analysis Plan (SAP) template is designed for *recruitment* SWATs and provides details on the analysis that is to be undertaken by any person analysing the results from an individually randomised Study Within A Trial (SWAT) implemented in the broad area of recruitment. It can be used for SWAT replications or for individual SWATs and should be read in conjunction with the [PRESS SWAT Master Protocol Template](https://osf.io/jmpyn/).

The SWAT SAP should normally be developed and agreed prior to the end of SWAT data collection, and before any SWAT data is presented to the person responsible for the analysis. This SAP template has been designed to ensure that analyses are undertaken in a relatively consistent way, although it is appreciated that some SWATs will have different priorities and outcomes. For replication of an existing SWAT, if a SAP is in existence, the team replicating the SWAT should review the SWAT SAP and conduct the analysis as prescribed. Should changes to the SAP be required, these should be incorporated in writing into a modified version of the SWAT SAP. When planning a SWAT replication, it is particularly important to ensure consistency with key aspects of the SAP of the existing SWAT to facilitate combining the results in a future meta-analysis.

Throughout this document, wherever curly brackets (‘ {...}’ ) appear, a deletion or edit of the text within the curly brackets is required. When finalising this SAP, please ensure that all such instances have been addressed and that all curly brackets have been removed from the document. This includes certain instances where guidance text is included inside the curly brackets (which may be retained, deleted, or edited as deemed appropriate for that SWAT). Please also remove this ‘Introduction’ section: the definition of terms/acronyms should then revert to Section 0. of the SWAT SAP. Finally, please update the Table of Contents.

# Definition of terms/acronyms

|  |  |
| --- | --- |
| PRESS | Protocol and resources development for prioritised recruitment and retention strategies |
| SAP | Statistical Analysis Plan |
| SWAT | Study Within A Trial |

# Objectives

This SAP provides details on the SWAT being undertaken in the {Host Trial Name} trial. The SWAT will assess the impact of {Details of the intervention being tested} on the recruitment rate for the host trial**.**

## Primary objective

The primary objective of this SWAT is to evaluate the effect of {insert SWAT intervention details} on the recruitment rate in the host trial.

# Outcomes

## Primary Outcome

The primary outcome for this SWAT is the recruitment rate. This is defined as the proportion of SWAT participants (i.e. potentially eligible patients approached for participation in the host trial during the SWAT) who are randomised in the host trial.

The numerator is the number of SWAT participants randomised in the host trial, and the denominator is the number of SWAT participants: in this instance this is the number of {insert details reflecting how patients are approached, {e.g. packs sent out; invitation letters sent out}}.

## Secondary Outcomes

Secondary outcomes for this SWAT include:

* Incremental Cost-effectiveness Ratio i.e. additional cost of SWAT intervention (relative to control intervention) per additional potential participant recruited, only to be reported if the estimated effect of the SWAT intervention on recruitment is positive;
* 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 (denominator) who {complete the chosen key outcome assessment/measure(s)/ attend the chosen key follow-up appointment} (numerator).
* Number of harms or unintended effects.

{Other secondary outcomes may be of interest for some recruitment SWATs. These include:

* Time (interval) from patient approach to participant randomisation;
* Proportion of patients not responding to invitation to take part in the host trial {(only applicable for certain methods of recruitment)};
* Time (interval) from patient approach to their consent {(only applicable for certain methods of consent)};
* Proportion of patients recruited into the trial {(if different from the proportion randomised)};
* Proportion of randomised SWAT participants who complete other chosen outcome assessment/measure(s)/attend other chosen follow-up appointments.}

# Study Methods; design, sample size and randomisation

{The study design, details of the recruitment strategies and population of interest can be found within the corresponding SWAT protocol. Full details on the aspects such as treatment allocation, randomisation, blinding, selection of study population, and details on the specified follow-up time points are given in the SWAT protocol; a brief overview should be given here.}

## Design

{Information on the design of the SWAT.}

## Sample Size

The sample size of this SWAT is restricted by the target sample size (and recruitment rate) of the host trial, and, as such, no formal sample size or power calculation has been performed. The {Host trial name} trial is expected to {approach or screen} {Sample Size expected/obtained patients} during the time-period that the SWAT is running: this is therefore the expected sample size of this SWAT.

## Randomisation

{Include details on how participants are randomised into the SWAT, including information such as individual or cluster randomised, allocation ratio and method of randomisation.}

# Data

Methods detailing data collection are detailed in the corresponding SWAT protocol.

## SWAT Population - Baseline Data

Number of patients included in the SWAT.

{Number of patients eligible for the SWAT (if different from the number included in the SWAT)}.

{Number of participants randomised into the host trial}.

{Number of SWAT participants randomised into the host trial (if different from the total number of participants randomised into the host trial)}.

{Demographic data (where available)

* mean (SD) age at randomisation into the SWAT;
* number (%) sex or gender;
* number (%) ethnic group;
* {other demographic, clinical characteristics}

Additionally, any characteristics deemed relevant either to the host trial or the SWAT intervention should be presented. Whenever relevant and possible, it is recommended that characteristics reported are consistent with PROGRESS-Plus (Kavanagh et al, 2008).}

{Note: For recruitment SWATS, some or all of these characteristics will not be available unless collected on screening logs and ethics approval is obtained for their usage in the SWAT. Consideration of the importance and feasibility of collecting these demographic characteristics is, therefore, important when designing recruitment SWATs. Being able to present recruitment rates (and secondary outcomes, where appropriate) by key demographic characteristics will allow subsequent future meta-analysis to be undertaken.}

{Note: Depending on the SWAT, the optimal procedure for collecting sex, gender or ethnicity data (e.g. in the case of UK-based SWATs, 5, 9 or 19-category UK ethnicity data) is likely to vary. Please refer to the Trial Forge diversity materials (<https://www.trialforge.org/improving-trial-diversity/>). Examples of resources available at that link are the INCLUDED project for ethnicity data collection at (<https://www.trialforge.org/trial-diversity/how-to-collect-ethnicity-data/>) and SAGER for sex and gender (<https://www.trialforge.org/trial-diversity/how-to-consider-sex-and-gender-in-trials/>).}

Total cost of the SWAT

{Note: Please refer to [Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies](https://osf.io/sebnk/). This may include direct costs (e.g. training, printing, postage, communication to non-responders, amount of financial incentives, reimbursement of members of the public) and indirect costs (e.g. staff time to prepare mailings, staff time to collect data). As SWAT evaluations generally need replication, it is useful for trialists to see the costs of both using the SWAT intervention and the cost of evaluating the SWAT should they wish to replicate the evaluation. Trial teams should identify the relevant cost components of both the SWAT intervention and the comparator strategy.}

# Analysis

## Software

The analysis will be undertaken using {Software name and version to be used}.

## Blinding

The statistician analysing the SWAT {will/will not – delete as applicable} be blinded to the SWAT allocation.

## Participant Flow

A CONSORT flow diagram will be created to detail the flow of the SWAT participants through the SWAT, including relevant details of the host trial wherever needed.

## Baseline

All available baseline demographics will be reported overall {, and by SWAT trial arm if possible}. Where available, these will include but may not be limited to: age; sex/gender; and ethnic group. In addition, details around the number of SWAT participants in each arm of the host trial, by SWAT arm, will also be given. No testing will be undertaken comparing baseline characteristics in the two arms.

## Primary Outcome Analysis

The primary outcome, recruitment rate, will be presented as the proportion in each arm (unadjusted) and both the absolute difference in proportions (Risk Difference [RD], unadjusted) and the relative difference in proportions (Odds Ratio [OR], unadjusted).

The primary outcome will also be compared between the two arms of the SWAT using logistic regression. The analysis will be two-sided and conducted at a 5% significance level. {Analysis will be adjusted for the SWAT minimisation/stratification factors {and the following covariates {include list of covariates}.} Results will be presented as p-value and both {adjusted} absolute (RD) and relative differences (OR) with associated 95% confidence intervals. Model assumptions will be checked. {Flexibility in choice of model is allowed where needed.}

## Secondary Outcomes Analysis

Similar to the primary analysis, any SWAT secondary outcomes that are proportions will be presented as proportion (unadjusted) by arm, and both absolute (RD) and relative difference (OR) (unadjusted) in proportions, and analysed using logistic regression. {Analysis will be adjusted for the SWAT minimisation/stratification factors {and the following covariates {include list of covariates}.} Results will be presented as {adjusted} absolute (RD) and relative difference (OR), with associated 95% confidence intervals, and p-value. Model assumptions will be checked. {Flexibility in choice of model is allowed where needed.}

{Time-to-event variables will be presented as medians, and analysed using a Cox proportional hazards regression model. {Analysis will be adjusted for the SWAT minimisation/stratification factors {and the following covariates {include list of covariates}.} Results will be presented as {adjusted} hazard ratio, with associated 95% confidence interval, and p-value. Model assumptions will be checked. {Flexibility in choice of model is allowed where needed.}

The ICER will be estimated as the additional cost of SWAT intervention (relative to control intervention) per additional potential participant recruited, *only* if the result of the primary analysis (in terms of the adjusted analysis is ‘positive’ (i.e. the estimated absolute or relative difference favours the SWAT intervention).

The number of harms or unintended effects will be presented descriptively, overall and by SWAT trial arm.

{Any secondary outcomes that are continuous, rates, or counts, or are not already covered in the above text should be analysed appropriately, with the methods documented here. It is expected that the above text should cover most outcomes for standard recruitment SWATs}

### Withdrawals, loss to follow-up and missing data

Any missing SWAT outcome data will be detailed per trial arm.

{Note: It is extremely unlikely that patients will withdraw from an individually-randomised SWAT as, for most SWATs, patients (as SWAT participants) are unaware that they are taking part in the SWAT.}

## Other analyses

{Although not anticipated for most SWATs, please include details of any sensitivity analyses or subgroup analyses for the SWAT in this section.}

{For SWAT replications, it may be useful to plan subgroup analyses for future meta-analyses, by including descriptive statistics for primary outcomes by key subgroup(s): in such cases, please include details here. It is, however, recognised that this information linked to SWAT outcome data may not be available for many recruitment SWATs.}

## References

Kavanagh J, Oliver S, Lorenc T. Reflections on developing and using PROGRESS-Plus. Cochrane Health Equity Field and Campbell Equity Methods Group 2008;2:1.

National Institute of Health Research. The INCLUDE Ethnicity Framework, 2020. Available: [**https://www.trialforge.org/trial-forge-centre/include/**](https://www.trialforge.org/trial-forge-centre/include/) [Accessed [29th March 2025]].

Bruhn H, Shiely F, Parker A, et al. PRESS SWAT Master Protocol Template. 2025.Retrieved from <https://osf.io/jmpyn/files/osfstorage>

Gkekas, A., Shiely, F., Wilkinson, J. A., Sutton, C., Treweek, S., Bruhn, H., … Parker, A. (2025, March 24). Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies. Retrieved from <https://osf.io/sebnk/>