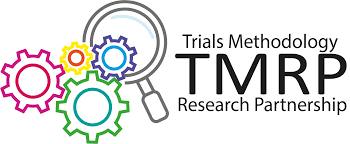
A purple and blue border

AI-generated content may be incorrect. 

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **PRESS Randomised Retention SWAT Master Statistical Analysis Plan Template** | | |
|  | | |
|  | | |
|  | | |

**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 Retention SWAT Master Statistical Analysis Plan Template. Retrieved from <https://osf.io/h73ke/files/osfstorage>

**A purple and white flag

AI-generated content may be incorrect.**

|  |
| --- |
|  |
| **{Retention SWAT Title}** |
|  |
| SWAT Statistical Analysis Plan Template V1.0 |
|  |

**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** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# SAP Revisions

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

**Contents**

[Roles and responsibilities 2](#_Toc193966714)

[Signatures 2](#_Toc193966715)

[SAP Revisions 2](#_Toc193966716)

[0. Introduction 4](#_Toc193966717)

[1. Definition of terms/acronyms 4](#_Toc193966718)

[2. Objectives 4](#_Toc193966719)

[2.1. Primary objective 4](#_Toc193966720)

[3. Outcomes 5](#_Toc193966721)

[3.1. Primary Outcome 5](#_Toc193966722)

[3.2. Secondary Outcomes 5](#_Toc193966723)

[4. Study Methods; design, sample size and randomisation 5](#_Toc193966724)

[4.1. Design 5](#_Toc193966725)

[4.2. Sample Size 5](#_Toc193966726)

[4.3. Randomisation 6](#_Toc193966727)

[5. Data 6](#_Toc193966728)

[5.1. SWAT Population - Baseline Data 6](#_Toc193966729)

[6. Analysis 6](#_Toc193966730)

[6.1. Software 7](#_Toc193966731)

[6.2. Blinding 7](#_Toc193966732)

[6.3. Participant Flow 7](#_Toc193966733)

[6.4. Baseline 7](#_Toc193966734)

[6.5. Primary Outcome Analysis 7](#_Toc193966735)

[6.6. Secondary Outcomes Analysis 7](#_Toc193966736)

[6.7. Withdrawals, loss to follow-up and missing data 8](#_Toc193966737)

[6.8. Other analyses 8](#_Toc193966738)

[7. References 8](#_Toc193966739)

# 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 *retention* 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 retention. 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 retention 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 retention rate in the host trial.

# Outcomes

## Primary Outcome

The primary outcome for this SWAT is the retention rate. This is defined as the proportion of SWAT participants who {complete the chosen key outcome assessment/measure(s)/ attend the chosen key follow-up appointment}.

The numerator is the number of {completed outcome assessments/measures/participants who attend the follow-up appointment}, and the denominator is the total number of participants randomised in the SWAT.

## Secondary Outcomes

Secondary outcomes of interest in this SWAT include:

* Incremental Cost-effectiveness Ratio (ICER) i.e. additional cost of SWAT intervention (relative to control intervention) per additional participant retained, only to be reported if the estimated effect of the SWAT intervention on retention is positive.

{Note: For some retention SWATs, it will be relevant to consider other costs in both arms when performing the analysis of costs. For example, estimating the impact of the intervention and control retention strategies on subsequent follow-up costs (e.g. due to number and type of reminders/calls) may be relevant in considering fully the cost-effectiveness of the SWAT intervention in terms of the ICER described above.}

* Number of harms or unintended effects.

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

* Time interval between the due date for the primary outcome assessment/measure/ follow-up appointment for the host trial and {completion of key chosen outcome assessment/measure**/**attendance at follow-up appointment};
* Number of follow-up {reminders/calls {method of contacting participants}} required to obtain the primary outcome measure for the host trial;
* Completeness of follow-up assessment/questionnaire;
* Proportion of 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 retention 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 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 randomise {sample size expected/obtained participants} 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 of patients included in the SWAT)}

{Number of participants randomised into the host trial (if different from the number of patients included in the SWAT)}

Demographic data

* {mean (SD) age at randomisation into the SWAT / mean (SD) age at randomisation into the host trial (if age at randomisation into the SWAT is not available);
* number (%) sex or gender;
* number (%) ethnic group;
* {other demographic, clinical characteristics}}

{Note: This will allow subsequent future meta-analysis to be undertaken, and differences in effects between different populations to be assessed. 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: 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: 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 baseline demographics will be reported by SWAT trial arm, and overall. These will include but are not limited to: age; sex; 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, retention 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}}. {Note: Consideration should still be given to including host trial arm as a covariate, even if not a SWAT minimisation/stratification factor.} 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 (e.g. proportion of SWAT participants who complete a later outcome assessment) will be presented as proportion by arm, and both the absolute (RD, unadjusted) and the 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 both {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 (e.g. time interval between due date and questionnaire completion date) 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 number of follow-up {reminders/calls} required will 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/minimisation} variable{s} that were used in the SWAT randomisation algorithm will be included as {a covariate/covariates}. 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 participant retained, *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.

### 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, host trial 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.}

## 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/>