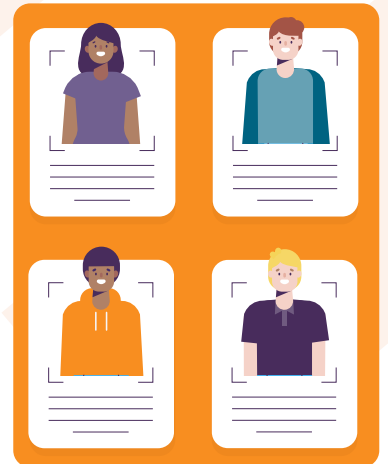


SWAT DESIGN

Studies within a trial (SWATs) help researchers find answers to important questions, such as how to make some parts of clinical trials work better. Here, we discuss some things you may consider when designing a SWAT.

A: Randomisation. Randomisation (i.e., randomly assigning someone to a group) is a fair method that researchers use to assign people to treatment groups – like tossing a coin. Sometimes SWATs will be randomised, other times they may not - this depends on the question the SWAT is trying to answer.



Randomised SWATs: Let's explore some scenarios where two types of randomisations may be useful to answer questions:

1. If the SWAT treatment includes participants, **individual randomisation** (where you randomise each person) is usually most suitable. Imagine you are trying to see if sending text messages before questionnaires leads to more of them being completed.

With individual randomisation, participants randomly receive either the SWAT treatment (text messages) or control (no text messages). It is as simple as that!

Both methods could be done separately to how we randomise in the main study, and participants can be randomised either when the study starts or closer to when the event is happening.

Non-randomised SWATs

Not all SWATs use a randomised study design. SWATs can also discuss topics with participants to see if common thoughts occur (qualitative SWAT). An example of this would be understanding what motivates people to join a clinical trial.

SWATs can also compare what was happening before and after a new treatment was introduced (before and after SWAT).

2. If the focus is on processes at a group level (e.g., a GP Practice/Hospital/School) **randomisation by group** may be more useful. Imagine you are trying to see if giving extra training to hospital nurses will lead to more participants joining the trial.

Randomly assigning nurses within the same hospital to different groups can cause issues if they talk to their non-trained colleagues about the training they received. To avoid this, randomising all nurses in the same hospital to receive either the SWAT training or no training would be the best approach.

B. SWAT Replication: SWATs are often repeated (or replicated) across various trials. By carefully planning and testing the same SWAT across multiple trials, research teams can get enough information to answer the SWAT question. So, it is useful when designing your SWAT to have this in mind.

SWAT replication is important because it can help ensure that we can confidently say the SWAT treatment works, and that it works for a wide range of people.

For example, if the SWAT is completed with 200 25-year-old women, it doesn't tell us if the SWAT treatment works for men or

older people. So, doing the SWAT across various groups helps researchers know if the SWAT can be effective for a wide range of people, not just those 200. This way, researchers get a better idea of how well it works for different people.

So, when is it appropriate to replicate a SWAT? Let's consider some factors suggested by the **Trial Forge Guidance 2:**

- What is the quality of the evidence available?
- Is there already enough quality evidence to answer the SWAT question?
- Can the SWAT be repeated in various types of host trials?
- Is there a balance of pros and cons of the SWAT for participants and the new host trial?

It is also useful to weigh the benefits of the SWAT with how much it would cost to deliver it before deciding on replication.

C. Outcomes and analysis: When replicating a SWAT, it is important that the same outcomes (i.e., study goals) and tests used in the first/previous SWAT are used again so that the results can easily be combined to answer the SWAT question.

But first, let's look at some outcomes commonly used in SWATs and how we test these:

SWAT Type	Outcomes	Analysis
Recruitment	How many people joined the study	You can count this and compare across groups
Retention	How many reminders it took for people to fill out surveys	You can count this and compare across groups
Qualitative	Participant experiences (e.g., of the recruitment process)	Document themes that come out of individual experiences

D. Costs: Having a clear idea of the associated costs of a SWAT is very important. Some SWATs do not cost much. An example is a SWAT testing how using different coloured paper for the same questionnaire affects how people complete them.



Here are some costs to consider when planning a SWAT:

- Materials and resources required.
- Staff time to design the SWAT, randomise participants, prepare and/or deliver the intervention and complete the analysis.
- Cost to publish the results of the SWAT.

Overall, if you apply these principles, you can design SWATs that are both impactful and cost-effective.

