

Studies within a trial (SWAT): Frequently Asked Questions

What is a SWAT?

A SWAT is a self-contained study embedded within a host trial, which aims to test different ways of delivering a trial process, such as recruitment or retention.

What is a SWAT?

Trials are central to improvements in health care, but delivering trials is hard work. Despite this, we have little evidence to help us make good decisions about how best to deliver trials.

What SWAT should I do?

The possibilities are endless, because the evidence for trial processes is so sparse. However, it would be a good idea to look at the issues that people think are a priority in recruitment.

Although you can choose the subject of your SWAT, a single SWAT of a single intervention may not change practice. It may be more helpful to do a SWAT on a subject that other people are also exploring, answering important questions quickly by working together.

There is a repository of SWATs to help you link with the work others are doing.

For specific advice about which SWAT might work for your trial, you can contact the SWAT Team based at York Trials Unit.

How much does a SWAT cost?

SWATs don't have to be expensive; our experience is that many are likely to cost between £5000 and £10,000. Very ambitious SWATs may need more significant funding.

When do I start a SWAT?

A useful rule is that early is better, but it is never too late.

Embedding a SWAT from the start is easier. That is why the new HTA process is so useful.

However, a SWAT can be run during a limited period of a trial (towards the beginning or end), or in some sites across a trial.

What are the Key features of SWATs?

- Seek to resolve uncertainties about how to do trials.
- Are embedded within a host trial, but do not affect the integrity of the host.
- Should have a formal protocol, just like the host trial.
- Can be evaluated in a single trial, but is preferably run across many trials.
- Will inform how we do future trials, and might inform decisions about the host trial.



www.hrb-tmrn.ie



TRIAL FORGE

www.trialforge.org



@hrbtmrn @Trial_Forge #trialmethodology

How do I randomise people in a SWAT?

Whether randomisation is needed depends on the question being asked. Randomisation can be by a separate process to that used for the host trial randomisation.

Although individual randomisation is preferable, our experience is that sometimes that might not be possible for practical reasons. It is possible to randomise SWATs as clusters (for example, some sites use one recruitment method, and some sites use another).

What about ethical approval for SWATs?

Ethical regulations vary, and you need to check the relevant guidelines. It is likely that some, but not all, SWATs will need appropriate approvals. If the SWAT was planned at the same time as the host trial, it could be included in the approval for the host trial. Otherwise a substantial amendment to existing approvals for the host trial can be sought.

SWATs are generally low risk, and for scientific and practical reasons, it will not usually be possible to get individual consent from participants - it may confuse patients as to what they are consenting to, and may impact on their behaviour.

Trial Forge has a collection of material that has been used before to obtain ethical approval for a SWAT (info@trialforge.org for more details).

What about sample size for SWATs?

There are three key issues with sample size.

SWATs are constrained by host trial size - a separate power calculation may not be useful.

For some SWATs (such as recruitment SWATs), the sample for the SWAT will actually be much larger than the host trial.

While an individual SWAT may lack power, a meta-analysis of several SWATs testing the same intervention using a standard protocol can provide compelling evidence.

How do I disseminate SWATs?

Whether randomisation is needed depends on the question being asked. Randomisation can be by a separate process to that used for the host trial randomisation.

Registering your SWAT

If your SWAT is a novel idea, you can register it with the SWAT repository, so other researchers become aware of it. If your SWAT is randomised you can also register it on other trials registries such as ISRCTN.

Where to get support for your SWAT

For help and support, you can contact the SWAT team at York Trials Unit (Dr Adwoa Parker - adwoa.parker@york.ac.uk).

Useful References

Adamson et al (2015). Producing better evidence on how to improve RCTs. *BMJ*, 351, h4923.

Brueton et al (2014). Use of strategies to improve retention in primary care randomised trials: a qualitative study with in-depth interviews. *BMJ Open*, 4(1), e003835.

Healy et al (2018). Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiTy study. *Trials*, 19, 147.

Treweek S et al (2018). What is a Study Within A Trial (SWAT)? *Trials*, 19(1), 139.

Treweek et al. Strategies to improve recruitment to randomised trials. *The Cochrane Library*.

Madurasinghe et al (2016) Guidelines for reporting embedded recruitment trials. *Trials*. 2016;17:27.

For further information or support on embedding a SWAT contact:

HRB-TMRN hrb-tmrn@nuigalway.ie
(Ireland)

Trial Forge info@trialforge.org
(UK)

