

SWAT 84: Same-day Consent vs Delayed Consent in a Randomised Trial

Objective of this SWAT

To compare the effects of same-day versus delayed consent on recruitment and retention rates in a randomised trial.

Study area: Recruitment, Retention

Sample type: Patients

Estimated funding level needed: Low

Background

Randomised trials are widely acknowledged as the preferred design to evaluate the effects of healthcare interventions and methods to increase recruitment in randomised trials are priorities for methodology research.[1] The success of randomised trials relies on the recruitment and retention of a sufficient number of participants.[2] However, recruiting to trials can be challenging and at least 50% of trials fail to recruit the target number of participants.[3,4] Poor recruitment can have a negative impact on the allocated budget and estimated completion date of the study and may result in an underpowered study that will not adequately answer the original research question.[2]

The consent process for trials is a delicate and crucial process. Not all patients have the same capacity to understand all the information divulged by the investigators, at the same rate. According to the International Conference on Harmonization Guideline for Good Clinical Practice (ICH GCP),[5] trialists should ensure that patients being recruited to a study should be given reasonable time to think, before giving their consent to join the study. But, there is no clarification as to what is considered to be reasonable time.

It is unclear whether participants who consent on the same day could be more determined to join the trial, because as they already understand the potential benefits, while undecided patients might delay their joining and not be fully convinced of the benefits, which may cause lower retention rates. On the other hand, it is possible that patients who take longer to give their consent have more carefully studied the trial material, making them more determined to continue with the study with better retention.

More studies are required to identify strategies to improve recruitment and the consent process within randomised trials. Even though these studies may identify interventions that are only moderately effective, they may have a vital impact on the duration or cost of a study.[2]

Interventions and comparators

Intervention 1: Same-Day Consent: The patient is willing to give consent on the same day after the pre-designed information leaflet; for the host trial has been fully explained by the investigator.

Intervention 2: Delayed Consent: The patient feels they still need further time to think after the pre-designed information leaflet for the host trial has been fully explained by the investigator. They are given an unsigned consent form, with an addressed and stamped envelope. The investigator will telephone the patient on the third day after the initial meeting (if the return envelope has not arrived), to ask if they have decided to join or not.

Index Type: Method of Recruitment

Method for allocating to intervention or comparator

Non-Random

Outcome measures

Primary: Proportion of patients who withdraw consent, following same-day consent or delayed consent

Secondary: 1. Attrition rate following commencement of host trial

2. Compliance with host trial intervention

3. Reason for withdrawing consent

4. Reason for drop-out from host trial

Analysis plans

The primary analysis is the proportion of patients who withdraw consent, following same-day consent or delayed consent. The secondary analysis will examine the attrition rate at the end of the intervention and the compliance with host trial's intervention.

Possible problems in implementing this SWAT

Recruiting and delivering the intervention within the trial timeline.

References

1. Smith CT, Hickey H, Clarke M, et al. The trials methodological research agenda: results from a priority setting exercise. *Trials*. 2014;15:32.
2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2018;(2):MR000013.
3. Bower P, Wilson S, Mathers N. Short report: How often do UK primary care trials face recruitment delays? *Family Practice*. 2007;24:601-3.
4. Raftery J, Bryant J, Powell J, et al. Payment to healthcare professionals for patient recruitment to trials: systematic review and qualitative study. *Health Technology Assessment* 2008;12.
5. Phillips A, Ebbutt A, France L, Morgan D. The international conference on harmonization guideline, statistical principles for clinical trials: issues in applying the guideline in practice. *Drug Information Journal* 2000;34:337-48.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Marah Elfgi, Fionnuala Jordan, Wael Tawfick

Contact email address: marahelfgi@gmail.com

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Revisions made by:

Date of revisions: