

SWAT 22: Promoting Recruitment using Information Management Efficiently (PRIME)

Objective of this SWAT

Stepped wedge cluster randomised trial to investigate if a recruitment co-ordinator, providing software for hospital sites in a stroke prevention randomised trial (to extract lists of their own patients using criteria customised to the eligibility criteria of the trial), training investigators at each site via a telephone ‘recruitment review’ to use the reports and approach prevalent stroke survivors, and following-up the recruitment review 6 months later, improves the recruitment rate to a multicentre, randomised, parallel group clinical trial.

Study area: Recruitment

Sample type: Sites in a Cluster Randomised Trial

Estimated funding level needed: Low

Background

Under-recruitment to randomised controlled trials (RCTs) is a major source of inefficiency in the conduct of applied clinical research.¹ Recruitment is a challenge for trials of secondary prevention after stroke in the UK in general, and it has been a major challenge for the REstart or STop Antithrombotics Randomised Trial (RESTART, www.RESTARTtrial.org, ISRCTN71907627). Therefore, we set out to conduct a stepped wedge randomised trial of an intervention to boost recruitment at active sites in RESTART.

Interventions and comparators

Intervention 1: A questionnaire to be completed by the site in advance of a recruitment review, to collect information from the site about current sources of recruitment. This is followed by a teleconference recruitment review to be held within an allocated month (allocated via a stepped wedge cluster randomisation algorithm) involving the recruitment co-ordinator and each site’s principal investigator and site co-ordinator. The recruitment review involves training site staff in the use of the audit data export. The recruitment review is followed 6 months later by a follow-up teleconference with each site’s co-ordinator.

Intervention 2: Control

Index Type: Method of Recruitment

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Recruitment rate.

Secondary: To identify any potential disadvantages to implementing PRIME, which may include: potentially eligible patients being identified but not recruited; complaints from the Principal Investigators and Trial Co-ordinators about the intervention; costs of implementing the intervention.

Analysis plans

The primary outcome of site recruitment rate will be compared before and after implementing the recruitment reviews in a negative binomial generalised linear mixed model, adjusting for site, time since start of study, and season.

Possible problems in implementing this SWAT

Sites not adhering to the allocated time period of their recruitment review. Possible delays to implementing the SWAT if a substantial amendment is required, to the Trial Protocol, to include it if it was not originally approved when the Trial commenced.

References

- 1 Al-Shahi Salman R, Beller E, Kagan J, et al. Increasing value and reducing waste in biomedical research regulation and management. Lancet 2014;383(9912):176-85.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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