SWAT 58: Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC)

Objective of this SWAT
To investigate whether a teleconference re-visit with the study personnel accompanied with a commitment contract can enhance recruitment in a cluster randomised trial.

Study area: Recruitment
Sample type: Sites in a Cluster Randomised Trial
Estimated funding level needed: Low

Background
Many randomised trials fail to meet their recruitment goals within time.[1] In the UK, it has been identified as the highest priority to find methods to enhance recruitment in trials,[2] but few studies have been done to evaluate different strategies for recruiting patients.[3] These studies are small, and some are hypothetical, making the interpretation further unclear. The ongoing uncertainty about the barriers and facilitators for recruitment to trials (especially in multicentre clinical trials) means that trialists are advised to include study recruitment strategies within their trials (3).

The host trial for this SWAT, EFFECTS (www.effects.se; NCT02683213), investigates whether routine administration of fluoxetine (20mg daily) for 6 months after acute stroke improves patients' functional outcome.[4] It is a multicentre trial aiming to recruit 1500 patients in in Sweden, and collaborates with two other investigator led studies, FOCUS (UK) and AFFINITY (Australia/New Zealand/Vietnam). Each trial is funded independently and intend to report its own results.[4] The original plan was to close recruitment in October 2018 but current projections are that it will need to continue until at least July 2019 and ways to boost recruitment are needed. The original aim for EFFECTS was that each centre should randomise at least two patients per month, but huge differences have been found between centres. For example, in June 2016 to May 2017, only three centres achieved the recruitment goal and three centres came close. These six centres have included half of the participants as of 12 June 2017 and the five top recruiters have probably reached their full potential and little would be gained with the planned intervention. Important barriers to recruitment have been identified: lack of time for the responsible doctor to identify eligible patients and do the study specific procedures at baseline and lack of time for all other study personnel who have a high clinical burden at their clinic and do not have any time specially dedicated for work with clinical trials.

The aim of this SWAT is to investigate whether a teleconference re-visit with the study personnel at a site in the EFFECTS trial, accompanied with a commitment contract, enhances the recruitment 60 days after this intervention, compared to 60 days before it.

Interventions and comparators
Intervention 1: One person (Trial Manager, Trial Manager Assistant or a PhD student) will contact the site's principal investigator or research nurse 2-3 weeks before a planned meeting and suggest three possible dates for a one hour meeting. A document of consent is signed where the principal investigator agrees to participate in this SWAT and provides a telephone number for contact (including text messages). One week before the meeting, an email with the attached agenda and slideshow will be sent to all participants One day before, a text-message and an email will be sent to all participants as a reminder. The teleconference will be between the Chief Investigator and Trial Manager and the study personnel at the site. As a minimum, the principal investigator, one research nurse and the head of the department must attend the meeting or it will be rescheduled. Ideally, all members of the local team at the centre listed on the delegation list will attend the meeting. The proposed agenda and time schedule for the teleconference is
a) Opening of the meeting (1 min). Chair: Trial Manager. Secretary: Chief Investigator. Keeping track of the time: Chief Investigator.
b) Introductions for all at the meeting (2 min)
c) Presentation of the EFFECTS slideshow (4 min)
- Rationale of the study (1 slide)
- Update of the overall recruitment (1 slide)
- What we need to do: our aim (1 slide)

- Update of the recruitment at the local site (1 slide)
d) Discussion of local barriers (5-7 min)
e) What can we do at our local site (5-7 min)
f) Discussion with the head of department of barriers and what can be done. (5 min)
g) Where do we go from here? Formulate a commitment contract, minimum 1 item, maximum 3 items. (5-7 min)
h) Closing summary of the meeting (2 min)
After the meeting, the summary of the meeting and the Commitment Contract will be sent to the principal investigator to sign and return to the Trial Office. A text message will then be sent every Monday to the principal investigator and research nurse during the whole period as a friendly reminder.
Intervention 2: None of the elements in the intervention until the site is allocated to receive it.

Index Type: Visit, Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Recruitment 60 days after the teleconference compared to recruitment in 60 days before intervention.
Secondary: 1) Recruitment 61-120 days after the intervention; 2) Proportion of eligible patients who are not recruited.

Analysis plans
The EFFECTS study has been running since 20 October 2014, and data are available on the recruitment rate per site and month. We have started 35 centers, but a lack of principal investigaters meant that we have been forced to close three centers. Amongst the remaining 32 active sites, five have achieved the goal of recruiting two or more patients per month. These sites will not be included in this SWAT, leaving 27 sites for this SWAT. A stepped wedge cluster randomised study design will be used [5] for three reasons. First, it is not possible to do the intervention in 14-15 sites at the same time. Second, all sites might gain from the intervention, and a stepped wedge design means that all sites will have been exposed to the intervention by the end of the SWAT. Third, there is seasonal variation in the recruitment (with lower recruitment around Christmas, Easter, and especially in the summer) and this design will provide a realistic view of recruitment throughout a whole year. The 27 sites will be divided into two categories: medium and low recruiters to allow for stratified randomisation which will avoid, for example, all medium recruiters falling into the same step (such as the low-recruiting period in the summer). Randomisation of the intervention will be performed so that at least one medium and one low recruiter receives the intervention in each step, with two or three sites in each step. Participants in the EFFECTS study will not be aware of the SWAT. The intervention and the randomisation order will not be mentioned outside the group responsible for the SWAT. Although the intervention cannot be blinded, the sites will not be informed that we are measuring numbers of randomised patient before and after intervention. The exact numbers of recruitment per centre has been available at the public domain through a link that is updated in real time since the start of the EFFECTS study.

The analyses will compare the numbers of included participants 60 days before the teleconference with the numbers 60 days after the intervention. The null hypothesis is that it is no difference before and after the intervention, and we consider an increased recruitment rate of 20% as significant. The proportion of eligible participants who are not recruited will also be investigated in the two time periods. The following subgroups analyses are planned:
• Medium versus low recruiting sites
• Large stroke centres (> 500 strokes/year) versus small stroke units
• Stroke centres versus rehabilitation centres
• University hospitals versus non-university hospitals
• Experienced centres versus in-experienced centres

Possible problems in implementing this SWAT

1. The intervention might develop during the study. For example, the agenda or the content of the teleconference might change during the study period.
2. Participants in the host study (EFFECTS) might get know about the intervention and change their behaviour before the planned intervention.
3. The organization of the intervention will be challenging because it involves 27 sites over a period of one year and is likely to take approximately five hours for each intervention: three hours for preparation and meeting, one hour for reminding and text message, and one hour for post-meeting administration. This gives a total of 108 hours, or 14 days of work.
4. Some sites might refuse to be a part of the intervention and this will interfere will the results.

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;383:176–85.
2. Tudur Smith C, Hickey H, Clarke M, et al. The trials methodological research agenda: results from a priority setting exercise. Trials 2014;15:32.
3. Treweek S, Mitchell E, Pitkethly M, et al. Strategies to improve recruitment to randomised controlled trials. Cochrane Database of Systematic Reviews 2010;(4):MR000013.
4. Mead G, Hackett ML, Lundström E, et al. The FOCUS, AFFINITY and EFFECTS trials studying the effect(s) of fluoxetine in patients with a recent stroke: a study protocol for three multicentre randomised controlled trials. Trials 2015;16:369.
5. Hemming K, Haines TP, Chilton PJ, et al. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. BMJ 2015;350:h391.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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