SWAT 64: Identifying opinions on the features needed for making a study successful

Objective of this SWAT
To identify what study personnel involved in randomised trials consider to be important for making a study successful.

Study area: Recruitment, Data Quality, Follow-up
Sample type: Trial Team, Researchers
Estimated funding level needed: Low

Background
Many randomised trials fail to meet their recruitment goals (1-2) and, in the UK, recruitment was identified as the highest priority for research into the methods of trials (3). However, little is known about the barriers and facilitators for recruiting patients, especially to multicenter clinical trials. We will use the EFFECTS (www.effects.se; NCT02683213) study of fluoxetine for acute non-depressed stroke patients (4) as a host study for this survey to identify what personnel involved in a randomised trial RCT consider to be important for making a study successful using WIMSS-q (What is Important for Making a Study Successful questionnaire). The WIMSS-q begins with some general questions (age, gender, the role in the host trial, and how accustomed they are to taking part in randomised trials), followed by questions about potential barriers for inclusion and about ways to improve inclusion. The WIMSS-q takes approximately 15 minutes to complete and is available from the corresponding author of this SWAT. It is not specific to the EFFECTS trial.

Interventions and comparators
Intervention 1: The WIMSS-q will be sent to all healthcare personnel (doctors and nurses) actively involved in the EFFECTS trial (approximately 150 people). The study personnel at each of the active centers in the EFFECTS trial consist of at least one principal investigator and one research nurse.

Index Type: Questionnaire Format

Method for allocating to intervention or comparator
Given to all

Outcome measures
Primary: Most important barrier for recruitment to a randomised trial
Secondary: Other important barriers for recruitment to a randomised trial
Most important measure to increase recruitment to a randomised trial
Other important measures to increase recruitment to a randomised trial

Analysis plans
Preliminary analysis plan: The main purpose is to describe and understand barriers for recruitment and to find strategies to overcome them. The results will used descriptive statistics and graphical methods.

Possible problems in implementing this SWAT
As always with questionnaires, the answering rate could be low. In a pilot study, we had a 67% response rate after three reminders via the SurveyMonkey system. Based on that, we will administer the questionnaire as follows. Measures marked with an asterix (*) are additional to, or changed from the pilot study.
1. Pre-notification with a personal email – advising that a survey will be sent out and its purpose *
2. Via mail, using the SurveyMonkey service
3. Sending the questionnaire and reminders on a Tuesday *
4. Up to three consecutive reminders via SurveyMonkey's system
5. Personal email to non-responders (not SurveyMonkey) *
6. Reminder by phone or text message to non-responders*
7. Responders who provide a full answer, will receive compensation in the form of a cinema voucher (worth approximately SEK 120) *

All participants are already involved in the EFFECTS trials and they might feel pressure to answer because this, but they do not need to enter a reason if they say no. On the other hand, they may find it satisfying to express their opinion on this subject and share their experience from working with clinical trials.

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;383:176–185.
2. Treweek S, Lockhart P, Pitkethly M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. BMJ Open 2013;3. (doi: 10.1136/bmjopen-2012-002360)
3. Tudur Smith C, Hickey H, Clarke M, et al. The trials methodological research agenda: results from a priority setting exercise. Trials 2014;15:32.
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.

Publications or presentations of this SWAT design

This SWAT was approved by the Ethical Review Board in Stockholm (8 August 2017, Diarie number 2017/1284-31/1). It should start in late 2018 and be analyzed and published in 2019.

Examples of the implementation of this SWAT

People to show as the source of this idea: Erik Lundström, Eva Isaksson, Per Wester, Ann-Charlotte Laska, and Per Näsman
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Date of idea: 23/MAY/2017
Revisions made by:
Date of revisions: