

SWAT 5: Influence of explicit discussion of confidentiality in an invitation letter for a prospective study

Objective of this SWAT

To examine the effect on recruitment of discussing and guaranteeing confidentiality for the participants in the invitation letter.

Study area: Recruitment; retention.

Sample type: Participant.

Estimated funding level needed: None.

Background

Methods to boost recruitment in trials are top priorities for methodological research, as identified by the directors of UK Clinical Trial Units.[1] Indeed, studies of recruitment suggest that at least 50% of trials fail to achieve their recruitment targets,[2] which may result in an underpowered trial thereby increasing waste and the risk that an effective intervention will be abandoned before its true value is appreciated, or delays in demonstrating the benefits of an intervention while further trials are carried out. Poor recruitment can also lead to a trial being extended, increasing costs; and might affect any prospective study that involves invite people to join the study. More research is needed to identify strategies which, even if they are only moderately effective could have an important impact on the costs or duration of a study.[3] This SWAT explores the effects of discussing and guaranteeing confidentiality for the participants in the invitation letter, on the recruitment to a study and on whether those who are recruited remain in the study.

Interventions and comparators

Intervention 1: Invitation letter includes an explicit guarantee that the participant's data will be kept confidential.

Intervention 2: Invitation letter includes an explicit guarantee that the participant's data will be kept confidential.

Index Type: Method of Invitation

Method for allocating to intervention or comparator

Randomisation.

Outcome measures

Primary outcomes: Proportion of recipients of the invitation letter who join the study.

Secondary outcomes: Proportion of recruited participants who remain in the study.

Analysis plans

The primary analysis will compare the proportion of participants recruited to the study in the different randomised groups. Secondary analyses will examine retention in the study and the extent of the recruited person's participation in the study.

Possible problems in implementing this SWAT

The participant's data are likely to be kept confidential regardless of the content of the invitation letter, and this is likely to be explained to them in the participant information leaflet and when their consent is being sought. This might subvert the potential impact of the inclusion, or not, of the information in the invitation letter.

References

1. Tudor Smith C, Hickey H, Clarke M, Blazeby J, Williamson P. The trials methodological research agenda: results from a priority setting exercises. *Trials* 2014; 15: 32.
2. McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, Elbourne DR, Francis D, Garcia J, Roberts I, Snowdon C. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006; 7: 9.
3. Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK, Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2010; (4): MR000013.

People to show as the source of this idea: Lisa Maguire and Mike Clarke.
Contact email address: lisa.maguire@qub.ac.uk.
Date of idea: 21 January 2014.