

SWAT 3: Gender of the person signing an invitation letter for a prospective study

Objective of this SWAT

To examine the effect on recruitment of the gender of the person signing 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 the gender of the person signing 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 signed by a female.

Intervention 2: Invitation letter signed by a male.

Intervention 3: Invitation letter with a gender neutral signature (e.g. 'The --- trial team').

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. Subgroup analyses will be done for the gender of the participant.

Possible problems in implementing this SWAT

A possible problem is that participants might not recognise the gender of the person signing 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.

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