SWAT 112: Effects on recruitment of a personalised compared with a standard study invitation letter

Objective of this SWAT

To evaluate the effects of a personalised letter including the parent's name and address compared with a standard, non-personalised letter on recruitment to a prospective study.

Study area: Recruitment Sample type: Participants Estimated funding level needed: Very Low

Background

Trials delivered via the internet are an increasingly common and acceptable form of generating research evidence [1-3]. These studies often use invitation letters to recruit patients in the study and there is evidence that personalisation of study invitation letters may positively impact on recruitment rates [4]. Personalisation can take many forms, the simplest of which is adding the participants name in letters. The latest Cochrane Review of the effects of recruitment strategies for randomised trials did not identify any interventions focused on personalisation of invitation letters [5]. As such, there is a need to rigorously evaluate the effects of personalisation of study invitation letters into clinical research studies, including the recipient's name.

This SWAT is a collaboration between the University of Uppsala and the PROMoting THE USE of SWATs (PROMETHEUS) programme (Medical Research Council Grant number MR/R013748/1) (www.york.ac.uk/healthsciences/research/trials/research/swats/prometheus). It is being implemented in the non-randomised ENGAGE study (ISRCTN57233429) of an internet-administered, guided, CBT-based, self-help intervention for parents of children previously treated for cancer [6].

Interventions and comparators

Intervention 1: Personalised invitation letter, including the parent's name and address. The wording of this invitation letter has been designed in consultation with the parent research partners' group for the host trial.

Intervention 2: Standard invitation letter, not including the parent's name and address.

Index Type: Method of Recruitment

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of participants agreeing to join the host trial in each SWAT intervention group. Secondary: Proportion of parents in each group who express an interest in participating; proportion of parents in each group who opt out; proportion of parents in each group who complete the reasons for non-participation questionnaire; proportion of parents in each group who complete the eligibility interview; proportion of parents in each group who complete the baseline assessment; proportion of parents in each group retained at (a) 12-weeks and (b) 6-months follow-up; proportion of parents in each group who require a telephone reminder at (a) recruitment; (b) post-treatment (12 weeks); and (c) 6-months follow-up.

Analysis plans

Numbers and percentages within the personalised and non-personalised study invitation letter groups will be reported for categorical outcomes. Differences in the proportion of recruitment will be compared, using logistic regression. The results of the logistic regression model will be reported as an adjusted odds ratio with 95% confidence interval. Secondary outcomes of proportions will be compared adjusted using logistic regression. The results of the logistic regression model will be reported as an adjusted odds ratio with 95% confidence interval.

Possible problems in implementing this SWAT

No informed consent will be obtained before the SWAT intervention and patients will not be aware of the hypothesis being tested. However, due to the minimal risk and discomfort, this intervention was deemed to be ethical and ethical approval has been obtained from the Swedish Ethical Review Authority via a substantial amendment to the ENGAGE study (07/08/2019, ref: 2019-03083).

References

1. Mathieu E, Battatt A, Cater SM, Jamtvedt G. Internet trials: participant experiences and perspectives. BMC Medical Research Methodology 2012; 12: 162.

Mathieu E, McGeechan K, Barratt A, Herbert R. Internet-based randomized controlled trials: a systematic review. Journal of the American Medical Informatics Association 2013; 20: 568-76.
Brice A, Price A, Burls A. Creating a database of internet-based clinical trials to support a public-led research programme: A descriptive analysis. Digital Health 2015; 1: 2055207615617854.
Short CE, Rebar AL, Vandelanotte C. Do personalised e-mail invitations increase the response rates of breast cancer survivors invited to participate in a web-based behaviour change intervention? A quasi-randomised 2-arm controlled trial. BMC Medical Research Methodology 2015; 15: 66.

5. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018; 2: MR000013.

6. Woodford J, Wikman A, Cernvall M, et al. Study protocol for a feasibility study of an internetadministered, guided, CBT-based, self-help intervention (ENGAGE) for parents of children previously treated for cancer. BMJ Open 2018; 8(6): e023708.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Dr Joanne Woodford and Prof Louise von Essen Contact email address: louise-von.essen@kbh.uu.se Date of idea: 1/OCT/2018 Revisions made by: Date of revisions: