The effect of personalised versus non-personalised study invitations on recruitment: An embedded randomised controlled recruitment trial

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Background
Recruitment into clinical trials is challenging and there is a lack of evidence on effective recruitment strategies. Personalisation of study invitation letters might increase recruitment and retention rates.

A Study Within a Trial (SWAT) is a study that is embedded in a larger host trial, with the aim to investigate different trial processes and trial components. A SWAT can help evaluating the effect of personalised study invitation letters.

Methods
A SWAT to investigate the effect of personalised versus non-personalised study invitation letters on recruitment and retention rates into ENGAGE, a study of an internet-administered, guided, self-help intervention for parents of children previously treated for cancer.

Primary outcome:
The proportion of participants in the intervention group and the control group enrolled into the ENGAGE trial.

Secondary outcomes:
Relating to recruitment and retention, e.g. screened for eligibility and follow-up rates.

Results
Of 509 potential participants, 56 (11.0%) were enrolled into the ENGAGE host trial.
Enrolled in intervention group: 30/254 (11.8%)
Enrolled in control group: 26/255 (10.2%).
No statistically significant effect on personalisation of enrolment was found (OR 1.18, 95% CI 0.68 - 2.06). No statistically significant differences were found for any secondary outcome.
Visual inspection of numbers indicated a non-significant positive effect on recruitment of personalised study invitation letters.

Conclusions
Visual inspection of numbers indicated a non-significant positive effect of personalised study invitation letters, and a larger sample might show statistical significant differences.
No statistical significant effect of personalised study invitation letters on recruitment or retention
Additional SWATs to examine the personalisation of study invitations are warranted, as sample size was small.