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Does personalising a study invitation letter by including a potential participants' name and address improve study recruitment?

Submission date
19/11/2019

Recruitment status
No longer recruiting

Registration date
25/11/2019

Overall study status
Completed

Last Edited
11/11/2022

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recruiting participants into trials can be challenging and many trials fail to recruit in time and to the target sample size. Recruiting into mental health trials can be particularly difficult. Recruitment difficulties may result in a waste of public funding, reduce statistical power and validity and impact negatively on patient health. Despite this, little is known about how to design efficient recruitment strategies and the identification of evidence-based recruitment strategies is therefore needed. A potential solution is to combine results from similar well-designed and well-reported recruitment studies with a trial (SWATs) embedded in different trials.
Research indicates that addressing people by name may increase the likelihood of the person responding, which has been shown for different populations and in different settings, for example breast cancer survivors invited to partake in a behaviour change intervention, persons encouraged to pay a delinquent fine via text message, and members of the public invited to complete postal questionnaires. However, few of these studies have used a randomised controlled design (RCT) in the area of clinical healthcare research. In addition, the latest review of strategies to improve recruitment into RCTs did not identify any interventions evaluating the personalisation of study invitation letters.
This SWAT will evaluate the effectiveness of a personalised study invitation letter including the potential participant's name and address, compared with a standard, non-personalised study invitation letter (without name and address), on participant recruitment rates into the ENGAGE study, a feasibility study of an internet-administered, guided, CBT-based, self-help intervention (ENGAGE) for parents of children previously treated for cancer.

Who can participate?
Parents of children diagnosed with cancer when aged 0-18 years, who have completed cancer treatment three months to five years previously, residing in Sweden

What does the study involve?
Two approaches will be used for recruitment into host study ENGAGE: (1) postal study invitations packs and; (2) advertisements placed on websites and social media (e.g., Facebook,

Twitter, and Instagram). Target sample size is 50 participants. The embedded SWAT will be implemented only for postal invitations and all parents invited via postal invitation will be included.
Participants will be randomly allocated to receive one of the following interventions:
Intervention (1): Standard ENGAGE study invitation letter not including their name and address (control group)
Intervention (2) A personalised study invitation letter including their name and address (intervention group). The wording of the personalised invitation letter has been designed in consultation with the ENGAGE Parent Research Partners group, consisting of parents with lived experience of being a parent of a child treated for cancer.

What are the possible benefits and risks of participating?
Potential participants will not be aware they are part of an embedded trial evaluating a recruitment strategy and receiving a personalised or non-personalised letter. The researchers do not anticipate any risks associated with being part of this trial.

Where is the study run from?
Clinical Psychology in Healthcare, Department of Women's and Children's Health, Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
February 2020 to December 2020

Who is funding the study?
1. Vetenskapsrådet (Sweden)
2. Barncancerfonden (Sweden)
3. Cancerfonden (Sweden)

Who is the main contact?
1. Prof. Louise von Essen (scientific)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1

Study information

Scientific Title
Study within a trial (SWAT) protocol. Investigating the effect of personalised versus non-personalised study invitations on recruitment: an embedded randomized controlled recruitment trial

Acronym
ENGAGE: SWAT

Study objectives
This SWAT aims to evaluate the effectiveness of a personalised study invitation letter including the participant's name and address compared with a standard, non-personalised study invitation letter on participant recruitment rates into the ENGAGE study (ISRCTN57233429). The researchers will examine a two-tailed hypothesis that sending the personalised study invitation letters to potential participants could cause benefit or loss to recruitment for the host trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/08/2019, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, SE-750 02 Uppsala, Sweden; Tel:+46 (0)10475 08 00; Email: registrator@etikprovning.se), ref: 2019-03083

Study design
Randomised controlled embedded trial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet.

Health condition(s) or problem(s) studied
Recruitment to trials

Interventions
Children's personal identification numbers will be obtained from the Swedish Childhood Cancer Registry (National Quality Registry) and linked to parents' names and addresses via NAVET, a population registry held by the Swedish Tax Agency. Invitation packages, including invitation letters and information about the study will be sent to parents via post. Parents will be invited to participate randomly by the research team, using blocks of 100 until the target number of 50 has been reached. Invitations will not be sent to parents of deceased children.

Participants will be randomised to receive one of the following interventions:
Intervention (1): Standard ENGAGE study invitation letter not including their name and address (control group)
Intervention (2): A personalised study invitation letter, including their name and address (intervention group)

The wording of the personalised invitation letter has been designed in consultation with the ENGAGE Parent Research Partners group, consisting of parents with lived experience of being a parent of a child treated for cancer.

Intervention Type
Other

Primary outcome measure
The effectiveness of the personalised invitation letter compared with the standard invitation letter, defined as the recruitment rate, being the proportion of participants in each intervention group that are enrolled into the ENGAGE study.

Secondary outcome measures
The proportion of parents in each group:
1. Expressing an interest in participating in the ENGAGE study
2. Opting out of the ENGAGE study
3. Completing the reasons for non-participation questionnaire
4. Completing the eligibility interview
5. Completing the baseline assessment
6. Retained at (1) 12 weeks and (2) 6 months follow-up
7. Requiring a telephone reminder at (1) recruitment; (2) post-treatment (12 weeks); and (3) 6-months follow-up

Overall study start date
01/01/2019

Completion date
02/03/2021

Eligibility

Key inclusion criteria
Parents of children diagnosed with cancer when aged 0-18 years, who have completed cancer treatment three months to five years previously, residing in Sweden

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
56

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment

02/03/2020

Date of final enrolment
02/09/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Clinical Psychology in Healthcare
Department of Women's and Children's Health
MTC-building
Akademiska sjukhuset Uppsala
Uppsala
Sweden
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Organisation
Uppsala University

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Sponsor type
University/education

Website
http://www.uu.se/

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Barncancerfonden

Alternative Name(s)
Swedish Childhood Cancer Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Publication and dissemination plan
The SWAT protocol is prepared and planned to be submitted to an open access journal in autumn 2019 (November 2019). Results from the embedded SWAT are planned to be submitted to open access journals in March 2021. Anonymised data from this SWAT will ultimately be combined in a meta-analysis with data from similar host studies participating in the UK Medical Research Council-funded PROMETHEUS programme, which is promoting the use of SWATs.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Repository name: Promoting the use of SWATs (PROMETHEUS) Programme. PROMETHEUS is a major national programme of research funded by the Medical Research Council (MRC) to facilitate the routine embedding of a methodology research study within a planned or ongoing trial.
Link: https://www.york.ac.uk/healthsciences/research/trials/research/swats/prometheus/. After trial end date, a copy of the anonymised aggregate recruitment data will be shared with the PROMETHEUS team to allow a meta-analysis with data from similar host studies participating in the PROMETHEUS programme. Identifiers will be removed, and data will be randomly sorted to ensure that it would not be possible to re-identify participants in the dataset, in line with General Data Protection Regulation (GDPR) requirements. Potential participants included in the embedded recruitment trial will be blind to the study hypothesis and unaware they are part of an embedded trial. As such, consent to participate in the host trial will be obtained from participants, however, not for this embedded trial. Swedish Ethical Review Authority has granted approval for the embedded recruitment trial, 07/08/2019. ref: 2019-03083.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/04/2020	19/05/2020	Yes	No
Results article		06/03/2022	08/03/2022	Yes	No