

The Effect of the Method of Invitation on Recruitment of Participants from GP Practices to a Trial of a Smoking Reduction Intervention: a Study Within A Trial

Introduction

The TARS study is a definitive, multi-centre randomised controlled trial (RCT) of tailored support as an aid to reducing smoking, funded by NIHR HTA programme (HTA 15/111/01; ISRCTN 47776579). The trial aimed to recruit 900 participants from GP practices across four English cities. Six months into the TARS trial, the corresponding recruitment rate was 1-2% and not 5% as anticipated. Discussions with the funder led to a recommendation to compare the GP invitation methods

Aims

To compare the efficiency of three invitation methods sent from GP practices in terms of key recruitment parameters

Methods

Study design: Randomised (1:1:1) study within a trial (SWAT)

Participants: Six GP practices in one recruiting city. A search was conducted of GP records to identify current smokers who met the inclusion/exclusion criteria

Invitation methods: The TARS trial protocol described three different general practice invitation methods, as shown in **Table 1**. Postal invites were sent via DOCMAIL, a secure online mail management system used by GP practices. The Single page invitation letter included four methods to contact the trial team (telephone, text message, email, study website), with the Full pack also including the Participant Information Sheet, reply slip and pre-paid envelope. The text message invite included contact telephone number, email and study website addresses

SWAT procedures: Shown in Figure A

Outcomes: Number of invitations sent, number of expressions of interest received, number of participants recruited and initial research costs attributed to sending invites

Sponsor, HRA & REC approvals: The three methods and accompanying patient-facing documents had all previously been approved by REC and HRA for use as selected by local sites. The Sponsor and HRA agreed that the SWAT study could be undertaken without the need for any protocol amendments; HRA requested the SWAT was documented in a study file note

Table 1: Invite method details and approximate research costs

Initial invite method	Details	Approximate research cost per initial invite
Full pack postal invite	1 page letter listing four contact methods + full participant information sheet + pre-paid reply slip	£1.00
Single page postal invite	1 page letter listing four contact methods	£0.55
Text message	Short text message with three contact methods	£0.00*

* GP practices pay up front for text messaging services, with varying packages; however no practice requested research funding for text message invites

Results

- ~40,000 patients in participating practices
- 1377 patients identified as potentially eligible for TARS
- Numbers of invitations sent and expressions of interest received shown in **Figure A**

(a) Research costs for initial invites (Table 1):

- GP practices sent text messages using their usual text messaging service
- Full pack invite cost ~£1/invite
- Single page initial invites cost ~£0.55/invite

(b) Recruitment rates (Figure A, Table 2):

- Full invitation pack resulted in the highest recruitment rate (2.8%)
- Only one individual was recruited following text invite (0.03%)

(c) Efficiency of invite methods (Table 2):

- Whilst text invite method incurred zero cost to the trial, it only resulted in one recruit
- The most efficient method (by invite cost per recruit) was the Full pack postal invite method - even before including additional costs for sending further information following the Single page invite or text message invite

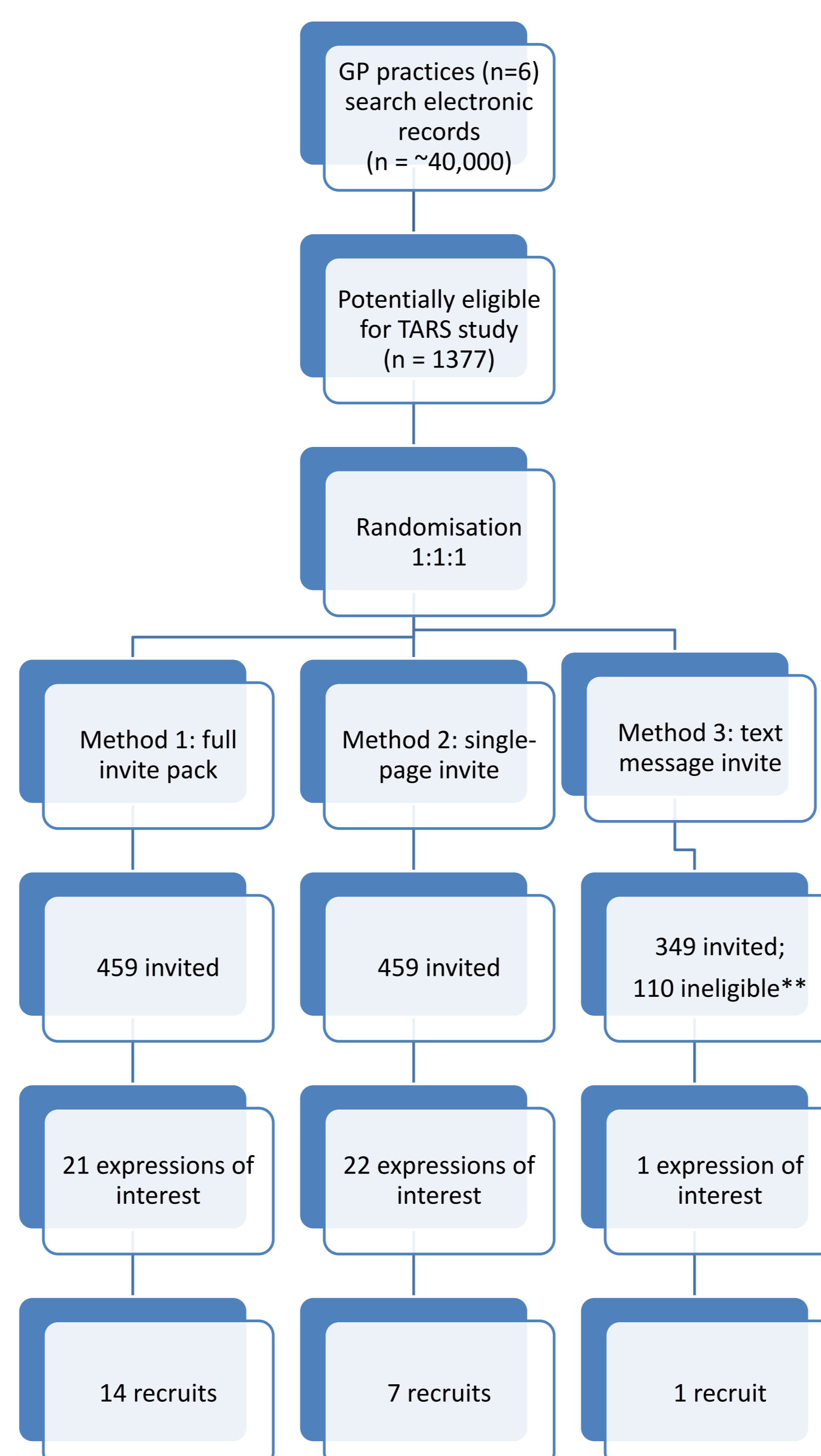
Discussion

- Sending the Full invitation pack was the most efficient, despite the cost
- Whilst there was no cost to the research team for text messages, GP practices used part of their usual text messaging package; in future trials, practices may require researchers to cover associated costs
- Changes, for example in smoking behaviours, during the time between completion of the pilot trial and commencing the definitive trial may have contributed to observed changes in recruitment parameters
- The pragmatic approach by the Sponsor and HRA enabled the SWAT to be quickly implemented
- This work contributes evidence to answer PRioRiTy questions #2 and #10 (<https://priorityresearch.ie>)

Conclusions

Contrary to sometimes common thinking, providing more information (at a higher cost) in the first instance can be cost-effective in recruiting patients from GP practices

Figure A: Flow diagram of SWAT



** Potentially eligible patients allocated to receive text invite but who had no mobile number or had requested not to be contacted by text were excluded

Table 2: Recruitment and costs per method

	Recruits (% of invites sent)	Total cost of method	Cost per patient recruited
Full pack postal invite	14/459 (2.8%)	£459.00	£35.31
Single page postal invite	7/459 (1.5%)	£252.00	£36.06
Text message	1/349 (0.03%)	£0.00	No cost to research team

* In memory of Helen Hancocks, TARS Trial Manager