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Witham, M.D., Band, M.M., Price, R.J.G., Fulton, R.L., Clarke, C.L., Donnan, P.T., Soiza, R.L. and Cvorov, V., Effect of two different participant information sheets on recruitment to a falls trial: an embedded randomised recruitment trial, *Clinical Trials*.

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DOI: <https://doi.org/10.1177/1740774518803558>

# **Effect of two different participant information sheets on recruitment to a falls trial – an embedded randomised recruitment trial**

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Running head: Falls information sheet trial

Word count: 1995

Trial registration: [www.isrctn.com](http://www.isrctn.com) - ISRCTN18436190

Funding: Chief Scientist Office, Scottish Government grant number CZH/4/1100

## **Abstract**

### *Background/Aims*

Recruitment to trials of intervention for older people who fall is challenging. Evidence suggests that the word falls has negative connotations for older people, and this may present a barrier to engaging with trials in this area. We therefore tested whether a participant information sheet that minimised reference to falls could improve recruitment rates.

### *Methods*

We conducted a Study Within A Trial, embedded within a randomised controlled trial of vitamin K versus placebo to improve postural sway in patients aged 65 and over with a history of falls. Potential participants were identified from primary care lists in 14 practices and were randomised to receive either a standard participant information sheet or an information sheet minimising use of the word falls, instead focussing on maintenance of health, fitness and balance. The primary outcome for this embedded trial was the proportion of responses expressing interest in participating received in each arm. Secondary outcomes were the proportion of those contacted attending a screening visit, consenting at screening, and the proportion contacted who were randomised into the main trial.

### *Results*

4145 invitations were sent, with an overall response rate of 444 (10.7%). 2148 individuals received the new information sheet (minimising reference to falls); 1997 received the standard information sheet. There was no statistically significant difference in response rate between those individuals sent the new information sheet and those sent the standard information sheet (10.1% vs 11.4%; difference 1.3% [95%CI -0.6% to 3.2%];  $p=0.19$ ). Similarly, we found no statistically significant difference between the percentage of those who attended and consented at screening in the two groups (2.1% vs 2.7%;

difference 0.6% [95%CI -0.4% to 1.6%]; p=0.20), and no statistically significant difference between the percentage randomised in the two groups (2.0% vs 2.6%; difference 0.6% [95%CI -0.4 to 1.6%]; p=0.20)

### *Conclusions*

Use of a participant information sheet minimising reference to falls did not lead to a greater response rate in this trial targeting older people with a history of falls.

### **Keywords**

Falls; Study Within A Trial; Participant Information Sheet; Recruitment

## Introduction

Recruitment to clinical trials is challenging, and under-recruitment remains a major barrier to both the timely completion of trials and to recruiting a sample size with adequate power to answer the trial question.<sup>1</sup> Recruitment to trials of interventions to reduce falls risk is a particularly challenging area. The number needed to contact is high, and the number needed to screen (the number of participants screened for each participant randomised) is high across other studies, ranging from 1.5 to 5 depending on the type of intervention.<sup>2</sup> Systematic reviews have noted a lack of evidence-based interventions to improve recruitment to trials,<sup>3</sup> and initiatives including TrialForge<sup>4</sup>, the UK Medical Research Council START programme<sup>5</sup> and the UK Medical Research Council Trials Methodology Hubs recruitment working group<sup>5a</sup> have been launched to attempt to fill this evidence gap.

Patients do not engage well with the word 'falls' in clinical practice<sup>5b</sup> – they perceive it to have negative connotations, especially around fear of future falls and loss of independence. Previous work has highlighted that patients do not like the idea of attending 'falls clinics'; a focus on maintaining health, activity and wellbeing encourages much better engagement with clinical services.<sup>6-8</sup> It follows that similar concerns around language may be pertinent for recruitment to trials of interventions to reduce falls. A focus on the dangers of falls may not be the best way to engage patients in such trials, and a focus on the ability of interventions to preserve strength, balance, health and wellbeing may reap improve recruitment rates as well as engaging older people in research in a more positive manner.

Studies Within A Trial (SWATs) provide an efficient way to test methods to improve trial design and conduct, including tests of strategies to improve recruitment.<sup>4,8a,9</sup> No studies to date have attempted to test whether using a participant information sheet that minimises reference to falls and the consequences of falls enhances recruitment to a falls intervention trial when compared to a standard information sheet. We therefore conducted a randomised controlled trial to compare two participant

information sheets (PIS), nested within a multicentre pilot randomised controlled trial (RCT) of vitamin K for older people at risk of falls.

## **Methods**

### *Design:*

We conducted a single-blind, parallel-group, embedded randomised recruitment trial comparing two information sheets (referred to as the 'recruitment trial' in this paper). The trial was designed as a Study Within A Trial (SWAT) embedded in a RCT of vitamin K vs placebo to improve postural sway in older people at risk of falls (the K-SWAY trial).

### *Population and trial context:*

K-SWAY is a three-armed, double-blinded, parallel-group pilot RCT, conducted in the Tayside, Grampian and Fife regions of Scotland, UK. The trial aims to recruit 96 participants aged 65 and over, with at least two falls in the last 12 months, or one fall resulting in hospitalisation in the last 12 months. Participants receive one year of either 400mcg daily oral vitamin K2, 200mcg daily oral vitamin K2, or matching placebo. Participants are ineligible if taking more than 100mcg of vitamin K per day, have atrial fibrillation, taking warfarin, unable to stand without human assistance, or currently undergoing physiotherapy or other non-pharmacological interventions to reduce falls risk. The primary outcome for the K-SWAY trial is the between-group difference in anteroposterior sway at 12 months, measured using a sway platform. The main K-SWAY trial received ethics approval from the East of Scotland Research Ethics Committee (ref 15/ES/0197); approval was granted for the SWAT as a substantial amendment to the main approval. The trial is registered on the ISRCTN registry (ISRCTN18436190).

Recruitment was conducted via primary care; practices willing to assist with recruitment underwent a search of their records, performed by the Scottish Primary Care Research Network (SPCRN). Lists of

patients fulfilling the inclusion and exclusion criteria on primary care practice lists searches were then screened by a primary care practitioner from the practice to remove any patient that the primary care practitioner had concerns about contacting (e.g. terminally ill, unwilling to participate in research). The screened list was then returned to SPCRN, who sent out letters of invitation and participant information sheets on practice headed paper, on behalf of the primary care practice. The number of information sheets sent out per practice was capped at 300 by SPCRN if the list was longer than this. The research team had no contact with participants up to this point and no data were collected on individuals sent letters.

Reply slips were returned to the primary care practice and collected by SPCRN staff. Only replies indicating that a potential participant wished to be contacted by the study team ('positive replies') were passed to the study team. The study team then telephoned the participant, conducted a brief telephone prescreen for eligibility, and arranged a joint screening/baseline visit. Consent for the main K-SWAY trial was obtained at the screening visit.

#### *Intervention:*

Two information sheets were tested. One ('standard sheet') contained standard wording used in a previous trial describing the importance of falls and their adverse consequences as a preamble to the description of the trial. The other ('new sheet') minimised the use of the word 'falls' (including in the title) and instead emphasised maintenance of balance, health and wellbeing. The new wording was developed by the trial management group with advice from the local Older People's advisory group. Both information sheets are shown in the Supplementary material with the key changes highlighted.

#### *Randomisation, masking and distribution of information sheets*

Each pack to be mailed out was assigned a study code. 1:1 randomisation was performed via a computer-generated list, with each study code being assigned to either the new sheet or the standard

sheet and their respective cover letters. Randomisation was stratified by primary care practice. Randomisation and preparation of study packs was performed by staff not otherwise engaged in the study; sealed packs were then delivered to SPCRN who added address labels and posted them to potential participants. SPCRN were not aware of which pack contained which information sheet; nor were the study team. Each pack consisted of a cover letter, an information sheet, and a reply slip. Each reply slip carried the study code but no indication of pack allocation, thus allowing linkage to pack allocation at the end of the trial. Intervention allocation was masked from the study team for the primary outcome, but after first contact with potential participants, it was not possible to mask the study team from intervention allocation; the researcher taking consent had the potential to become aware of the allocation during the consent procedure.

#### *Selection of primary care practices:*

All primary care practices that had previously indicated a willingness to be involved in research in Tayside, Fife and Grampian areas of Scotland were contacted by SPCRN and given information on K-SWAY. For practices willing to take part, SPCRN then screened practice lists. Further practices were contacted in each area until the recruitment target for the main K-SWAY trial was met.

#### *Outcomes and data analysis*

At the end of the recruitment phase of the K-SWAY trial, lists of study codes were passed to the study team for each practice, and the study codes on positive replies were matched to the group allocation on the study code list for each primary care practice. The primary outcome for the recruitment trial was the number of positive replies returned to SPCRN and passed to study team in each group. Secondary outcomes were the number of patients agreeing to attend screening visit after telephone contact, the number of participants consenting at screening visit, and the number of participants randomised into the main KSWAY trial in each information sheet group.



For each comparison, the number of positive responses as a proportion of the total number of information sheets sent in each arm was compared using Pearson's chi-squared test. Subgroup analysis was performed by area of recruitment. Analyses using characteristics of letter recipients could not be performed, as data on age, sex and other patient-level variables were not available to the study team for reasons of confidentiality.

#### *Sample size calculation:*

We assumed a 10% positive response rate overall to initial letters, based on previous similar trials run in this study area<sup>10,11</sup> and we aimed to detect a 4% difference in initial response rate between the two information sheets – i.e. 8% vs 12% response rate. To do so with 80% power at an alpha of 0.05 requires 1000 letters per arm to be sent. The total number of letters sent was however dictated by the number required to recruit to the main trial, rather than being limited by the above sample size calculation.

## **Results**

A total of 4145 letters with participant information leaflets were sent out to potential participants, drawn from 14 primary care practices across the three study areas. No information was shared with the study team on the baseline characteristics of the 4145 individuals who were sent letters; we are thus unable to report this information. The flow of participants through the SWAT is given in Figure 1.

#### *Primary outcome*

The overall response rate was similar to that anticipated (444/4145; 10.7%). There was no statistically significant difference in response rate between those individuals sent the new sheet and the standard sheet (10.1% vs 11.4%; difference 1.3% [95%CI -0.6% to 3.2%]; p=0.19).

### *Secondary outcomes*

All participants who were eligible and willing to attend a screening visit did so (n=99). There was no statistically significant difference between the percentage of those eligible and willing to attend screening in the two groups (2.1% vs 2.8%; difference 0.7% [95%CI -0.3% to 1.7%]; p=0.14), no statistically significant difference between the percentage of those who actually attended screening in the two groups (2.1% vs 2.7%; difference 0.6% [95%CI -0.4% to 1.6%]; p=0.20), and no statistically significant difference between the percentage randomised in the two groups (2.0% vs 2.6%; difference 0.6% [95%CI -0.4 to 1.6%]; p=0.20).

Of those who responded to the original invitation, the conversion rate to screening was no different in those receiving the new sheet and the standard sheet (20.7% vs 23.8%; difference 3.1% [95%CI -5.0% to 11.0%]; p=0.44).

### *Subgroup analysis by site*

Table 1 shows the primary and secondary outcomes subdivided by site. Similar patterns of response were seen at all three recruitment centres. In Tayside, the response rate for the new versus the standard information sheet was 74/900 (8.2%) vs 85/845 (10.1%) (p=0.18); in Fife it was 49/626 (15.1%) vs 46/578 (8.0%) (p=1.0) and in Grampian it was 94/622 (15.1%) vs 96/574 (16.7%) (p=0.45)

### **Discussion**

The key finding from this study within a trial was that using a participant information sheet that minimised the use of the word 'falls' and promoted positive messages about strength and balance, did not produce a statistically significantly higher response rate in this falls trial. Indeed the opposite was true – the standard information sheet using the word 'falls' was associated with a higher response

rate and a higher progression to screening and randomisation, although these were not statistically significant.

Qualitative work suggests that older people dislike the idea of attending falls clinics or falls classes, and considerable stigma and negative emotional responses surround the use of the word 'falls'. Our results thus appear counterintuitive, and there are a number of possible explanations. Firstly, in contrast to those referred to clinical services, use of the word 'falls' may matter less to potential participants in falls trials. Given the statistically non-significantly higher response rate with the standard leaflet, it is possible that older people who fall engage better with a trial invitation when the topic under study is explicit; use of the word falls may appear more relevant to potential participants who have a history of falls than a less direct focus on balance and fitness.

Another possible explanation for the lack of effect may be that the information sheets were not sufficiently different. Much of the content was similar, driven in part by the requirements of the ethics committee, but also because much of the information sheet dealt with material that did not mention falls. Even in the sections where falls were mentioned, it was not possible to eliminate use of the word falls altogether, as this formed a key inclusion criterion that participants needed to know about. A more formal, structured approach to changing the content might have been more effective, but would still have been limited by the small percentage of the information sheet that mentions falls. Although the numbers included in our analysis were sufficient to show moderate to large differences in response rates, larger studies would be required to show small differences; conducting similar trials in different host trials and different populations would allow more robust conclusions to be drawn via meta-analysis.

Previous ineffective attempts to increase recruitment to falls trials have included directing favourable newspaper articles to potential participants together with the study information.<sup>12</sup> and use of a user-

optimised information sheet.<sup>13</sup> Although small differences in recruitment rates may not revolutionise recruitment rates within an individual trial, amending the design of a participant information sheet is a simple and inexpensive strategy that might have utility in some populations, and could form part of a series of strategies providing incremental gains. The simple approach tested in this analysis seems unlikely to be effective however, and more comprehensive redesign of information sheets, using a range of behaviour change techniques, may be needed.<sup>14</sup> Techniques that have been, or are being explored, include the use of language to prompt intention formation, use of action planning strategies, and using stories or anecdotes to role-model participation as a normative behaviour;<sup>15</sup> further trials are required to test if these strategies will produce gains in recruitment.

Acknowledgements: None

Conflicts of Interest: None to declare

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**Table 1. Outcomes by site**

Site	Tayside (6 practices)			Fife (4 practices)			Grampian (4 practices)			All (14 practices)		
	New	Standard	p	New	Standard	p	New	Standard	p	New	Standard	p
Information sheet sent												
Invitations sent	900	845	-	626	578	-	622	574	-	2148	1997	-
Positive replies received (%)	74 (8.2)	85 (10.1)	0.18	49 (7.8)	46 (8.0)	1.0	94 (15.1)	96 (16.7)	0.45	217 (10.1)	227 (11.4)	0.19
Agreed to attend screening visit (%)	18 (2.0)	17 (2.0)	1.0	14 (2.2)	18 (3.1)	0.34	13 (2.1)	21 (3.7)	0.11	45 (2.1)	56 (2.8)	0.14
Attended screening visit (%)	18 (2.0)	17 (2.0)	1.0	14 (2.2)	18 (3.1)	0.34	13 (2.1)	19 (3.3)	0.21	45 (2.1)	54 (2.7)	0.20
Randomised (%)	16 (1.8)	16 (1.9)	0.86	14 (2.2)	18 (3.1)	0.34	13 (2.1)	18 (3.1)	0.28	43 (2.0)	52 (2.6)	0.20
Response conversion rate (%)*	16/74 (21.6)	16/85 (18.8)	0.66	14/49 (28.6)	18/46 (39.1)	0.27	13/94 (13.8)	18/96 (18.8)	0.36	43/217 (19.8)	52/227 (22.9)	0.42

\*Number of positive replies that converted to randomised participants

p values derived from Pearson's chi-square test

Practices refers to the number of primary care practices used for recruitment in each site

**Fig 1. Flow through the embedded recruitment trial**