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Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial

Natasha Mitchell[a], Catherine E. Hewitt[a], Elizabeth Lenaghan[b], Eleanor Platt[a], Lee Shepstone[b], David J. Torgerson[a,*], on behalf of the SCOOP study team

[a]*York Trials Unit, Department of Health Sciences, University of York, Heslington, YO10 5DD York, UK*
[b]*Norwich Medical School, University of East Anglia, Norwich, NR4 7TJ Norfolk, UK*

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Abstract

Objective: To assess the effectiveness of prenotification using a newsletter to increase questionnaire response rates within a randomized controlled trial (RCT).

Study Design and Setting: An RCT set within the context of the Medical Research Council's SCOOP trial of screening older women for fracture risk.

Results: A subsample of SCOOP participants were randomized in equal numbers to receive a newsletter approximately 6 weeks before the follow-up questionnaire or no newsletter. Of the 1,342 participants in the newsletter group, 1,291 (96.2%) returned their 24-month follow-up questionnaire compared with 1,271 of the 1,344 participants who were not allocated to receive the newsletter (94.6%). The difference of 1.6% was statistically significant ($P = 0.05$), with an odds ratio (OR) of 1.45 (95% confidence interval [CI]: 1.01, 2.10). The newsletter and no newsletter groups required a similar number of reminders (OR 0.88, 95% CI: 0.73, 1.06), had a similar number with a complete primary outcome (OR 0.95, 95% CI: 0.57, 1.58), and took a similar time to respond (log rank 1.30, $P = 0.25$).

Conclusions: This study supports previous research that suggests that prenotification increases survey response rate: albeit a small absolute increase. No previous study has shown this to be so within the context of patients enrolled within an RCT. Trials that use newsletters to keep their participants informed of the study's progress should use the newsletter as a prenotification device as this will increase overall response rates.

Keywords: Attrition; Randomized controlled trials; Prenotification; Newsletter; Osteoporosis; Screening

1. Introduction

Attrition in randomized controlled trials (RCTs) is an important threat to their internal validity [1]. In addition, attrition also affects the statistical power of the study by decreasing the effective sample size. Many, if not most, RCTs suffer some element of attrition. In particular, trials that rely on self-completed outcome measures, often delivered by post, from patients can have high levels of attrition and a 20% loss to follow-up in such trials is not uncommon [2]. Consequently, it is crucial that attrition is kept to a minimum.

There are a relatively large number of completed RCTs of different interventions that test different strategies to reduce attrition or increase response rates to surveys [3]. The literature on methods of reducing attrition from postal surveys has been summarized and synthesized in a Cochrane systematic review [3]. This review, however, has synthesized all the literature on improving survey response. A systematic review looking at the literature on improving health survey response (including responses within RCTs) found substantially fewer studies [4]. One approach that seems to improve responses rates to postal surveys is prenotification. Thus, over 40 RCTs in the Cochrane review [5] show that sending some form of prenotification (e.g., letter, postcard, e-mail) to alert the respondent that they would be shortly receiving a questionnaire did increase responses rates (OR, 1.45; 95% confidence interval [CI]: 1.29, 1.63). However, only nine of these studies were in a health care context and none were evaluated among patients within an RCT. It may be the case that participants to surveys respond differently when it is about their health or health care compared with surveys about nonhealth issues. Furthermore,

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* Corresponding author. +44-1904-321340; fax: 44 1904 321387.
E-mail address: david.torgerson@york.ac.uk (D.J. Torgerson).

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What is new?

- Prenotification of trial participants through a newsletter increases questionnaire response rates.
- Most previous studies have not been done in the health field. This is the first study within the context of questionnaire response rates within a clinical trial. This supports findings elsewhere that prenotification is effective at increasing response rates in randomized trials.
- To increase follow-up to randomized trials' study, newsletters should be sent out to participants before their follow-up questionnaires.

participants taking part in a clinical randomized trial may be more motivated to respond to trial-related questionnaires, as they have already consented to do this before they were randomized, than the general population who may be mailed as part of an epidemiological study.

To assess whether prenotification would increase the response rates to the usual postal follow-up within the Medical Research Council's funded SCOOP trial (ISRCTN 55814835) of a screening program for fracture prevention [6], we decided to undertake an RCT of prenotification using a study newsletter.

2. Methods

The SCOOP trial is evaluating a screening program that aims to identify women aged between 70 and 84 years who are at high risk of osteoporotic fractures. One method of data collection within the trial is to send out six monthly questionnaires to ascertain incident fracture status as well as participants' quality of life and resource use. The trial has recruited over 12,000 participants across seven centers. In this study, two of the centers (Norwich and York) developed a generic newsletter about the trial, which was tailored to each site.

The newsletter took the form of an A5 single sheet, which was folded into a booklet. The newsletter gave the participants an update on the trials progress, and reminded them about the importance of returning their questionnaires whether or not they were in the control or intervention group. On the back of the newsletter, there was a brief description, with a photograph, of the local study team, with a reminder of the local trial coordinator's contact details if they had any queries or questions. The newsletter was sent out to the intervention participants approximately 6 weeks before they were due to receive their 24-month questionnaire.

The sample size was arbitrary in that it was limited to the numbers of SCOOP patients recruited at the two sites. Nevertheless, we expected to randomize approximately 2,700 participants from Norwich and York, which would give us 80% power to observe a difference of 2.1% assuming a control response rate of 95%. Because we planned to send participants a study newsletter anyway, any improvement in response rates would be worth detecting. In addition, the larger the trial the more precise the estimates of the intervention effects are. Hence, we sought as large a sample size as possible within the constraints of the existing workload of the trial. All participants at the York and Norwich centers, who had not formally withdrawn from the SCOOP study, were eligible for inclusion.

The randomization was undertaken by the York data manager who randomized to two equally sized groups in one single block allocation (the block was the size of all the potential participants), a computer program randomly divided the total numbers of participants into two equally sized blocks. The allocation was independent and concealed. The newsletter was mailed out to half the participants, with the control group receiving the newsletter after they had returned their follow-up questionnaire.

The newsletter trial was aimed at the 24-month data collection point for the SCOOP study during 2010. Both arms of the SCOOP trial were included in this methodological study.

The primary outcome measure was the overall questionnaire response rate, which was calculated as the number of patients who returned the 24-month follow-up questionnaire divided by the number of patients who were sent a questionnaire. The secondary outcome measures were as follows: whether a reminder was required (number of patients requiring a reminder mailing divided by the number of patients who were sent a questionnaire); completeness of the primary outcome (number of patients with a complete primary outcome divided by the number of patients returning a questionnaire); and time to response (length of time taken to return the questionnaire).

All analyses were conducted in Stata version 9 (StataCorp, College Station, TX, USA) using two-sided significance tests at the 5% significance level on an intention-to-treat basis. Univariate odds ratios (ORs) were calculated for each response rate. The log rank test was used to compare the time to response between the two groups.

Participants who withdrew consent for follow-up questionnaires or who did not want to receive a questionnaire at this time point were included in the analysis as nonresponders. However, nonresponders in the control group who had not withdrawn from the trial received the newsletter after the study was complete.

3. Results

A total of 1,352 (50.0%) were randomized to receive a newsletter (intervention group) and 1,352 (50.0%) were randomized not to receive a newsletter (control group).

One hundred twenty-three participants had withdrawn from questionnaire follow-up and were not randomized. A number of individuals were excluded from the analysis presented here: died before or within 1 month of mailing ($n = 16$, intervention; $n = 9$, control $n = 7$); participant followed-up by telephone only ($n = 1$, control participant); or lost to follow-up ($n = 1$, intervention participant).

3.1. Increasing overall response rate

The total number of participants returning a 24-month follow-up questionnaire in the SCOOP study was 2,562 out of 2,686 (95.4%). Univariate analysis showed that there was an evidence of a difference in response rates between those receiving a newsletter and those not receiving a newsletter (newsletter: 1,291 out of 1,342, 96.2% and no newsletter 1,271 out of 1,344, 94.6%; OR, 1.45; 95% CI: 1.01, 2.10; $P = 0.05$).

3.2. Reducing the number of reminders required

The total number of participants requiring a reminder in a 24-month follow-up questionnaire in the SCOOP study was 538 out of 2,686 (20.0%). Univariate analysis showed that there was a little or no evidence of a difference in the number of patients requiring a reminder between those receiving a newsletter and those not receiving a newsletter (newsletter: 255 out of 1,342, 19.0% and no newsletter 283 out of 1,344, 21.1%; OR, 0.88; 95% CI: 0.73, 1.06; $P = 0.18$).

3.3. Increasing the completeness of the primary outcome

Of those individuals returning a 24-month follow-up questionnaire, the total number with a complete primary outcome measure was 2,502 out of 2,562 (97.7%). Univariate analysis showed that there was a little or no evidence of a difference in the completeness of the primary outcome between those receiving a newsletter and those not receiving a newsletter (newsletter: 1,260 out of 1,291, 97.6% and no newsletter 1,242 out of 1,271, 97.7%; OR, 0.95; 95% CI: 0.57, 1.58; $P = 0.84$).

3.4. Reducing the time to response

The median time to response in the newsletter group was 9 days (interquartile range [IQR]: 7−18 days) and in the no newsletter group was 9 days (IQR: 7−16 days). There was a little or no evidence of a difference in the time to response between those receiving a newsletter and those not receiving a newsletter (log rank 1.30, $P = 0.25$).

4. Discussion

We have undertaken a large RCT of a newsletter acting as a prenotification to older women taking part in a screening study of osteoporosis. The absolute effect of an increased response rate of 1.5%, while statistically significant, was small. However, it should be noted that the response rate from the control group was nearly 95%. Consequently, the scope for an increased response rate is relatively limited. Nevertheless, our observed OR was exactly the same as the meta-analysis in the most up-to-date Cochrane review (Fig. 1).

4.1. Comparison with previous studies

Taking data from the latest Cochrane review (Fig. 1), we have added this study to the Cochrane meta-analysis. The OR of our study is exactly the same as the pooled OR of the Cochrane review. Our study is also the third largest study in the updated review and the largest study in the area of health care research and the only one nested within an RCT.

There is considerable heterogeneity within the original Cochrane review and the updated review. This is not surprising given the differences in study populations and interventions. Nevertheless, our findings are not inconsistent with the literature as a whole.

There are some strengths and limitations to our study. The study was large, which allowed us to have substantial power to observe relatively small differences. We used concealed randomization and as response rate was the outcome measure, there were not potential biases because of attrition. Furthermore, as far as we are aware, this is the first trial of prenotification within the context of a randomized clinical trial allowing us to speculate that this approach would help minimize attrition within randomized clinical trials. In addition, our results are generalizable only to an older female population and the effects of prenotification may differ in other populations. Furthermore, our control response rate was extremely high limiting the absolute effect that prenotification could have.

There are a number of forms of prenotification ranging from a simple postcard or letter to our more complex newsletter. We do not have evidence that a newsletter would work better than a postcard or letter. We chose to use a newsletter because we were going to routinely send this out in the hope this would increase study retention in this long screening study. Given that was the case, we found that timing the mailing of the newsletter to a short time before sending out a postal quality-of-life questionnaire increased response rates. Therefore, for studies that include routine newsletters we recommend that the timing is optimized to help response rates.

Prenotification may have some drawbacks. It will increase the cost of the study, which if the absolute difference is small may not be cost-effective. Also in some studies, it may cause anxiety by unduly reminding patients that they are at risk.

In summary, this trial shows that prenotification is effective at increasing the response rate within the context of an RCT of osteoporosis screening in older women.

Study or Subgroup	Pre-contact Events	Total	No pre-contact Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Albaum 1989	92	300	105	300	2.2%	0.82 [0.58, 1.16]
Bergen 1957	70	149	41	149	1.8%	2.33 [1.44, 3.78]
Chebat 1991	352	996	331	996	2.5%	1.10 [0.91, 1.32]
Childers 1979	1540	1900	169	200	2.0%	0.78 [0.53, 1.17]
Cycyota 2002	102	600	114	600	2.3%	0.87 [0.65, 1.17]
Dillman 1974b	233	348	224	348	2.2%	1.12 [0.82, 1.53]
Drummond 2008	356	715	343	743	2.5%	1.16 [0.94, 1.42]
Duhan 1990	120	1003	65	994	2.2%	1.94 [1.42, 2.66]
Eaker 1998	522	1000	453	1000	2.5%	1.32 [1.11, 1.57]
Etter 1998b	376	471	425	483	2.1%	0.54 [0.38, 0.77]
Faira 1990	147	326	55	163	2.0%	1.61 [1.09, 2.38]
Ford 1967a	188	474	156	474	2.3%	1.34 [1.03, 1.75]
Ford 1967b	165	786	120	786	2.4%	1.47 [1.14, 1.91]
Furst 1979	38	50	27	50	1.1%	2.70 [1.15, 6.34]
Gillpatrick 1994	187	419	32	200	2.0%	4.23 [2.77, 6.47]
Hansen 1980	179	400	46	200	2.1%	2.71 [1.85, 3.98]
Harrison 2004	92	307	67	320	2.1%	1.62 [1.12, 2.32]
Heaton 1965	20	41	11	41	1.0%	2.60 [1.03, 6.54]
Hornik 1982	308	540	36	100	1.9%	2.36 [1.52, 3.67]
Jobber 1983	215	400	243	400	2.3%	0.75 [0.57, 0.99]
Jobber D 1985	48	111	81	300	1.9%	2.06 [1.31, 3.24]
Kephart 1958	53	100	52	100	1.6%	1.04 [0.60, 1.81]
Kindra 1985	61	106	166	460	1.9%	2.40 [1.56, 3.69]
Mann 2005	1206	5415	1089	5415	2.6%	1.14 [1.04, 1.25]
Martin 1989	311	1000	152	1000	2.4%	2.52 [2.02, 3.13]
Murphy 1991	61	241	43	240	1.9%	1.55 [1.00, 2.41]
Myers 1969	129	350	101	350	2.2%	1.44 [1.05, 1.98]
Napoles-Springer 2004	127	300	88	300	2.2%	1.77 [1.26, 2.48]
Newby 2003	143	716	100	808	2.3%	1.77 [1.34, 2.33]
Nichols 1988	146	252	153	252	2.1%	0.89 [0.62, 1.27]
Osborne 1996	141	199	116	198	2.0%	1.72 [1.13, 2.61]
Parsons 1972a	80	105	99	131	1.5%	1.03 [0.57, 1.89]
Parsons 1972b	114	200	375	600	2.2%	0.80 [0.57, 1.10]
Pirotta 1999	252	399	234	407	2.3%	1.27 [0.96, 1.68]
Pucel 1971	50	100	42	100	1.6%	1.38 [0.79, 2.41]
Scott 1957	78	175	73	175	2.0%	1.12 [0.74, 1.72]
Shiono 1991	4310	5018	4340	5029	2.6%	0.97 [0.86, 1.08]
Spry 1989a	141	400	57	200	2.1%	1.37 [0.94, 1.98]
Stafford 1966	317	634	118	614	2.4%	4.20 [3.26, 5.42]
Sutton 1992	615	913	127	205	2.2%	1.27 [0.93, 1.74]
Taylor 1998	3242	4996	11690	18040	2.6%	1.00 [0.94, 1.07]
Temple-Smith 1998	329	383	112	137	1.7%	1.36 [0.81, 2.29]
This study 2011	1291	1342	1271	1344	2.1%	1.45 [1.01, 2.10]
Waisanen 1954	81	200	27	100	1.7%	1.84 [1.09, 3.11]
Whiteman 2003	290	750	149	450	2.4%	1.27 [1.00, 1.63]
Wiseman 1972	50	75	107	245	1.7%	2.58 [1.50, 4.44]
Wright 1995	74	156	80	160	1.9%	0.90 [0.58, 1.40]
Wynn 1985	119	245	57	324	2.1%	4.42 [3.02, 6.47]
Total (95% CI)		**36106**		**46231**	**100.0%**	**1.45 [1.29, 1.62]**
Total events	19161		24162			

Heterogeneity: Tau² = 0.13; Chi² = 419.70, df = 47 (P < 0.00001); I² = 89%

Test for overall effect: Z = 6.30 (P < 0.00001)

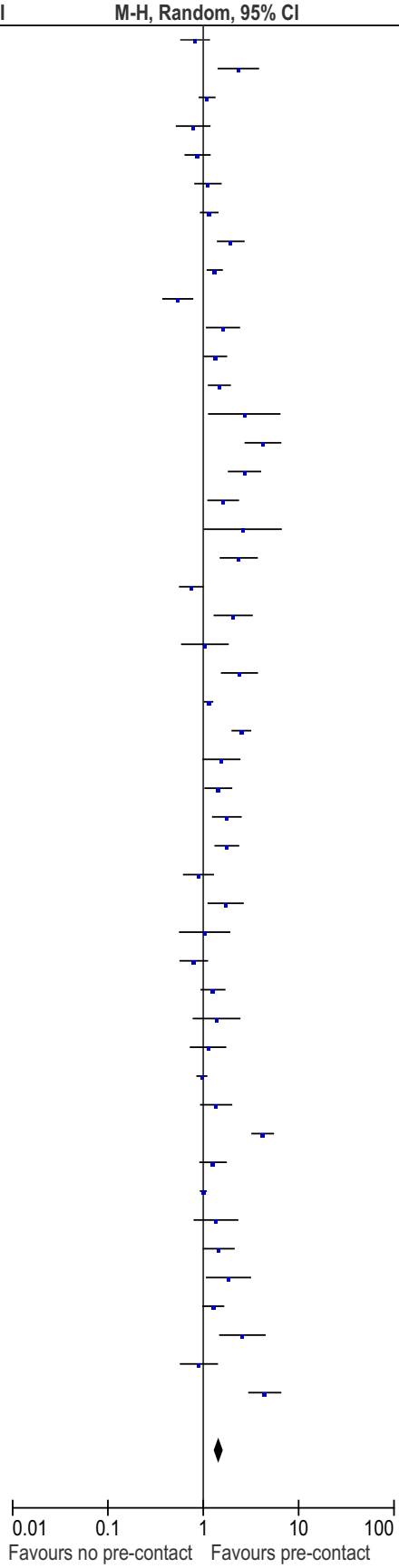

Fig. 1. Meta-analysis of previous studies and present study of prenotification.

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