

Randomized trial within a trial of yellow 'post-it notes' did not improve questionnaire response rates among participants in a trial of treatments for neck pain

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Abstract

Rationale Attrition is a threat to the validity of randomized trials. Few randomized studies have been conducted within randomized trials to test methods of reducing attrition.

Aim To test whether using yellow post-it notes on follow-up questionnaires in the ATLAS treatment trial for neck pain reduces attrition.

Method Nested trial within a trial. ATLAS participants were randomized to have their 6-month follow-up questionnaire have a 3' yellow post-it note with a handwritten message encouraging return of questionnaire.

Results 499 participants were independently randomized using simple allocation to receive the post-it notes or not. Two hundred fifteen of the 256 (84.0%) participants in the intervention group returned their questionnaire compared with 205 of the 243 (84.4%) in the control group. There was no difference in time to response.

Conclusion Yellow post-it notes do not enhance questionnaire return rates for participants in a randomized trial of neck pain.

Introduction

Attrition or loss to follow-up is a serious concern for many, if not most, randomized controlled trials. Attrition can lead to bias and will lead to loss of statistical power. Consequently, maintaining a low attrition rate of trial participants is crucial to reduce the possibility of post-randomization selection bias and maintain statistical power.

Many strategies are used to reduce attrition but relatively few have been evaluated by using a randomized controlled trial. While Edwards and colleagues have found many randomized trials assessing the impact of interventions to improve response rates to postal questionnaires, the majority of the evidence was not in the context of reducing attrition to randomized controlled trials in health care [1]. Recently, Brueton and colleagues systematically reviewed the evidence for strategies to reduce attrition within randomized trials and found 38 studies [2]. This review found little evidence for the effectiveness of commonly used strategies, apart from financial incentives. A key recommendation was for more trials to assess techniques to improve response rates within randomized trials.

In this study, we have undertaken a 'trial within a trial' looking at the role of putting a handwritten yellow 'post-it note' on the front of patient postal questionnaire for participants taking part in

a randomized controlled trial of treatments for neck pain. In four small trials to improve response rates to surveys among university students and employees, in the United States, it was shown that adding a small post-it note to the front of the questionnaire encouraging early response led to an increase in response rates [3]. However, these studies were not within randomized trials of health care treatments and they were not even a survey of health status or needs. Therefore, its generalizability to the setting of a clinical trial may be doubtful. Nevertheless, it is a relatively simple and straightforward intervention that has promise and we deemed it worthwhile to test within a health care trial.

Methods

We undertook a trial within a trial, that is, we nested the randomized trial of 'post-it notes' within the ATLAS trial, which is a large pragmatic randomized controlled trial of acupuncture or Alexander training or usual care for the treatment of neck pain [4]. The aim of this trial within a trial was to assess whether the use of a simple intervention, post-it notes, would result in a decrease in study attrition. Additionally, as a secondary outcome, we also sought to ascertain whether post-it notes would reduce the time to questionnaire response.

Participants

These were ATLAS trial participants who were due to receive either their 6-month follow-up questionnaire or who had not fully or partially withdrawn from the ATLAS trial nor withdrawn from treatment. Full withdrawal means the participant had withdrawn from the treatment and had withdrawn from follow-up. Partial withdrawal means the participant had withdrawn from questionnaire follow-up, but had still consented for data to be collected from medical records.

Questionnaire follow-up

All consenting participants in the ATLAS trial were sent a paper, postal, questionnaire to their home address 6 months after they had been randomized to either usual care, acupuncture or the Alexander technique for the neck pain. Each participant, who provided a valid mobile phone number, was also sent an SMS message 7 days before they were due to receive the questionnaire encouraging them to return the questionnaire as soon as possible. For initial non-responders, an SMS message was sent 7 days after questionnaire receipt encouraging questionnaire return. Fourteen days after receipt of the questionnaire, those who had not responded were sent a postal reminder, which was followed by a further postal reminder 10 days later. We phoned those who had still not responded 7 days later to encourage return by post or completion over the telephone.

Intervention

The intervention was given in addition to the 'standard' contact procedures listed above. The intervention was: a yellow 3' square 'post-it notes' with handwritten text, in black ink (by four researchers) with the wording 'Please complete and return to us as soon as possible. Thank you. [Signed with the first name of the person whose name was on the cover letter accompanying the questionnaire, which was Helen]', was placed at the top right hand corner of the questionnaire. The intervention was only used on the first questionnaire sent out and was not used on any reminder questionnaires.

Randomization

We used simple randomization with no restrictions (e.g. no blocking or stratification was used).

Statistical analysis

All statistical analyses were conducted in Stata (StataCorp. 2013, Stata Statistical Software: Release 13, StataCorp LP, College Station, TX, USA) using two-sided significance tests at the 5% significance level on an intention-to-treat basis. Baseline data were summarized by randomized group. The 6-month questionnaire response rates were compared by randomized group using a chi-square test. Odds ratios (ORs) and 95% confidence intervals (CI) were also calculated. Time to return of questionnaire was plotted using Kaplan–Meier survival curves and the log-rank test was used to compare the two randomized groups. Cox regression was used

to adjust for age, gender and treatment allocation (Alexander technique, acupuncture or usual care).

Sample size

There was no formal sample size calculation for this nested trial as the sample size of approximately 500 was governed by the numbers available for the main trial.

Blinding

The response rate was determined by York Trials Unit data clerks who were not aware to which group the participants belonged. The randomization sequence was generated by computer and was conducted by one of the York Trials Unit's data managers so allocation concealment was achieved.

Results

Of a total of 517 participants in the ATLAS trial, 499 were eligible to be randomized, 256 (51.3%) were allocated to receive a handwritten post-it note with the 6-month follow-up questionnaire and 243 (48.7%) were randomized to control (Fig. 1). The trial was undertaken between September 2012 and December 2013. Baseline characteristics of the study population are presented in Table 1.

A total of 420 out of 499 participants (84.1%) returned the 6-month questionnaire within 42 days, 215 of 256 (84.0%) in the post-it note group and 205 of 243 (84.4%) in the control group (difference -0.4% 95% CI of difference -6.8% to 6.1%). There was no significant difference in questionnaire response rates

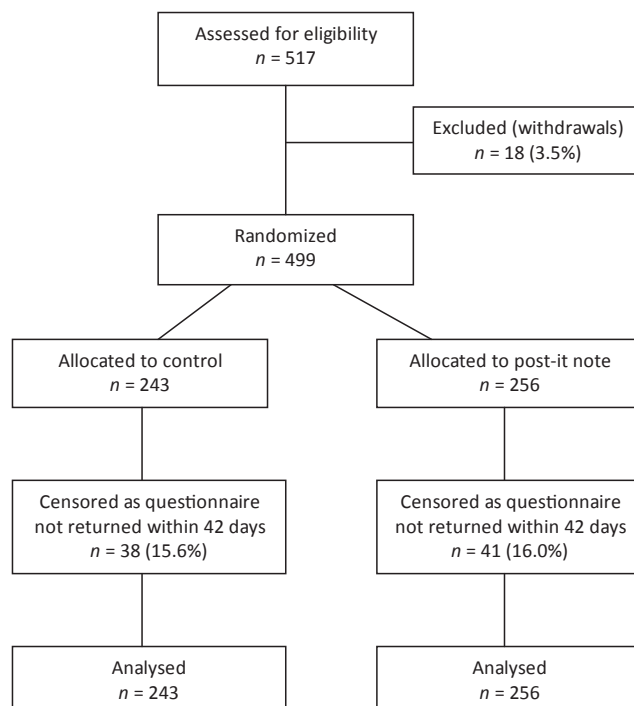


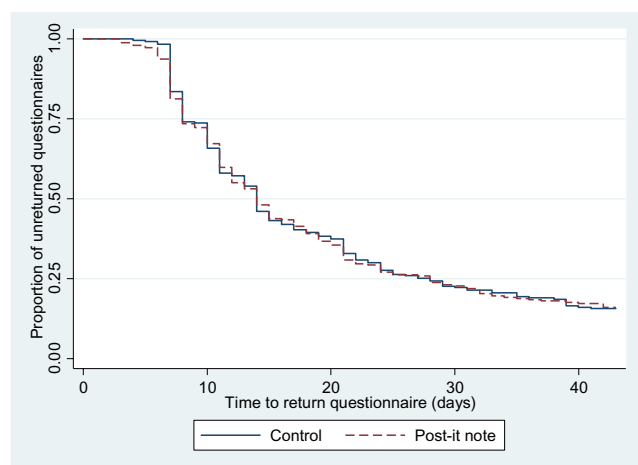
Figure 1 Flow of participants through the trial.

Table 1 Baseline characteristics

Variable	Group allocation	
	Control	Post-it note
Treatment, <i>n</i> (%)		
Alexander technique	72 (30.0)	90 (35.2)
Acupuncture	89 (36.6)	78 (30.5)
Usual care	82 (33.7)	88 (34.4)
Gender, <i>n</i> (%)		
Male	64 (26.6)	89 (34.8)
Female	177 (73.4)	165 (64.5)
Age (years)		
Mean (SD)	52.9 (13.2)	53.1 (14.3)
Median (range)	53.4 (18–86)	53.0 (18–100)

Table 2 Time to return 6-month questionnaire (days)

Group allocation	<i>n</i>	Median	Interquartile range
Control	243	14	8–25
Post-it note	256	14	8–25

**Figure 2** Kaplan–Meier survival curve of time to return 6-month questionnaire.

between the two randomized groups: $\chi^2 = 0.01$, $P = 0.91$. The OR for the post-it note group compared with the control group was 0.97, 95% CI (0.60, 1.57).

The median time to return the 6-month questionnaire was 14 days in the control group and 14 days in the post-it note group (Table 2). The Kaplan–Meier survival curve presents the proportion of unreturned questionnaires against time to return the questionnaire (Fig. 2). The log-rank test revealed no significant difference in the time to return the questionnaire between the two randomized groups ($\chi^2 = 0.01$, $P = 0.91$). A Cox regression adjusting for gender, age and randomized treatment gave a hazard ratio of 1.03, 95% CI (0.85, 1.25).

Discussion

Previous trials of yellow post-it notes in a different setting and among survey participants appeared to show improvements in response rate to a survey [3]. However, our trial of using yellow post-it notes to reduce attrition in this randomized of treatments for neck pain showed no evidence of reducing non-response or a lower time to response. The sample size was relatively large and the 95% CI excluded a 6.8% improvement in response rates. Although the intervention was simple, it was not cost free as it required the researchers to hand write several hundred post-it notes. Our control response rate was relatively high at 84% and we used a variety of methods to enhance this, such as reminder letters and SMS messages. It might be that this relatively minor intervention would not have an effect on participants who had already ignored postal reminders and SMS messages.

Although we found no effect because there are relatively few ‘trials within trials’ testing methods to reduce attrition, we should encourage their wider use. In this instance as we found no effect, we will not be implementing the use of post-it notes for our 12-month follow-up.

In summary a reasonably sized trial of yellow post-it notes did not enhance questionnaire response. However, it is important that we continue testing methods to improve participant retention, using random allocation, within randomized controlled trials.

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