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Publicity does not increase recruitment to falls prevention trials: the results of two quasi-randomized trials

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Abstract

Objective: To test the effect of publicity on recruitment to a randomized trial. Recruitment is often poor in trials. Publicity within recruitment packs might be an inexpensive method of increasing recruitment. We tested this in two quasi-randomized trials.

Study Design: In a primary care setting, within the context of a randomized trial of falls prevention, we allocated participants to receive a newspaper article about the study with their information sheet. The first trial compared one newspaper article against no article; the second compared a more favorably written article against the original.

Results: In the first study 4,488 participants were allocated into two groups. The response rate was 102 and 97 in the intervention and control groups, respectively (4.55% vs. 4.32%, 95% confidence interval [CI]: −0.98, 1.43); the recruitment rate was 73 and 71, respectively, the difference not being statistically significant. In the second study 2,745 were allocated into two groups with a response rate of 75 and 69 for the control and intervention groups, respectively (5.46% vs. 5.03%, 95% CI: −1.24, 2.09); the recruitment rate was 57 and 54, respectively, the difference not being statistically significant.

Conclusion: These two large experiments revealed no evidence of effect of publicity on recruitment rates.

Keywords: Patient recruitment; Family practice; Randomized controlled trial; Falls prevention; Publicity; Response rates

1. Introduction

Recruitment into randomized trials is widely recognized as being challenging. Two recent systematic reviews of randomized controlled trials (RCTs) evaluating the effectiveness of various strategies to enhance recruitment to trials have revealed that there is a paucity of evidence in this area [1,2]. Indeed, to date only 15 published trials evaluating recruitment strategies exist, despite most of the RCTs experiencing recruitment difficulties to the extent that around a third under-recruit and a half require extensions [2−4]. Poor recruitment leading to inadequate sample sizes introduces the risk of type II error whereby a randomized trial fails to find an effect that actually exists [1]. Other dangers of under-recruitment include—increased cost through trial extensions, delays in people receiving effective interventions, and the danger of commissioners opting for cheaper, albeit less robust, study designs that are less susceptible to poor recruitment [1]. Despite the obvious ethical, practical, and fiscal merit of incorporating an evaluation of recruitment strategies into research studies, researchers rarely do this [2].

Often researchers encourage media publicity about their trial in the belief that this may aid recruitment to their study. However, to date there is little evidence to support this view. A small opportunistic nonrandomized study noted that in an epidemiologic study publicity increased questionnaire response rate, which increased still further when researchers deliberately included photocopies of press articles in their recruitment materials. This led to a significant reduction in nonresponse (odds ratio [OR]: 0.79; 95% confidence interval [CI]: 0.66, 0.96, $P = 0.02$) [5]. This post hoc study was reported in a "*Letter to the editor*" investigating the effect of a newspaper article on response rates to a postal questionnaire. As far as we are aware there has been no randomized trial of evaluating the impact of press coverage on recruitment to randomized trials.

2. Methods

The context of this study was a randomized trial of evaluating occupational therapy for the prevention of falls

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What's new ?

There are few trials of recruitment strategies to randomized trials and none looking a the role of bringing newspaper articles to the attention of potential participants. This is the first trial to look at this and we have shown that it does not improve recruitment or response rates.

among men and women aged 70+ years who had at least one fall in the preceding 12 months. Participants were recruited by mailing out to all people aged 70 and over and who were registered with a participating general practitioner (GP) in the North and West Yorkshire area. GPs were asked to notify the research team of the number of people on their practice lists aged 70 and over. This same number of packs was taken to the practices for mailing. The actual number of packs sent out might have varied marginally from the numbers quoted by the practices (as some patients may have died between producing the list and mailing out); however, this would have been slight and should have been equivalent between groups.

Participation in the trial involved being randomized to receive an environmental assessment aimed at falls prevention or to a usual care control group. Falls were prospectively monitored for a year. The other outcomes were re-measured by questionnaire at 3, 6, and 12 months. Therefore, the demands placed on respondents were far greater than in the Salvesen and Vatten study [5]. However, recruitment to the main trial at 3% reflected that of previous fracture prevention trial aimed at a similar population [6].

The trial received favorable media attention from the local newspaper, which interviewed the principal investigator (A.P.) and published an article along with a picture of a participant with an occupational therapist. The article was photocopied and used with the other recruitment materials.

Half of the recruitment packs taken to all practices contained newspaper clippings publicizing the trial and the covering letter drew participant's attention to these articles. The covering letter was not personalized and was signed by the principal investigator (A.P.) rather than the GP. The envelopes containing the articles were marked with a small red dot in the bottom left hand corner and the control group envelopes were left unmarked. This enabled the exact number of each type of recruitment pack sent to be calculated by counting the number of residual packs after all eligible people on practice lists had been mailed. The title of the consent form was underlined in the packs containing the press article to distinguish those who had received the publicity from controls when they returned the forms indicating consent to participate. There were no other differences between the recruitment packs.

When delivered to general practices the recruitment packs were placed in boxes with the "*control*" and "*intervention*" packs stacked alternately so that an equal number of each was sent out. Although the packs were allocated using alternation this approach is as effective as randomization for forming equivalent groups if the schedule is not interfered with and if participant characteristics are not related to the ordering [7]. In this instance, for practical reasons alternation was easier to perform and there was no reason to suppose that the ordering would not be interfered with by GP practice staff as they were unaware of the study.

Once practices had sent out the packs, the remainder were collected and the number of residual packs in each category counted to check whether numbers had been equally distributed between groups. Our sample size was predetermined by the requirement to recruit to the main trial, therefore, we did not formally determine a power calculation for the trial. However, a sample size of 4,500 would have more than 90% power to show an increase rate of recruitment from 5% to 8% with a P value of 0.05.

The tone of the original newspaper article included in the intervention packs was not as favorable as had been hoped because despite the press being provided with text for the article, this was edited to create a more "dramatic" tone. Publicity that portrays older people in an adverse manner can be regarded as offensive by older people [8]. Within the original article there were references to older people being "*quizzed*" about falls and this may have conveyed negative connotations. Therefore, a second study was carried out in which recruitment as a consequence of a more "*upbeat*" article was compared with the less "*upbeat*" one. The more favorable published article was included in half of the subsequent 2,745 packs posted out and the original article was included in the remaining packs, to act as controls (this sample would have had marginally less than 90% power to demonstrate a 3% absolute difference in recruitment). The sample sizes for both of the studies were driven by the need to achieve a given sample size for the main trial. Consequently, the quantity of packs sent out for the second wave of recruitment was dictated by the need to attain the remaining numbers for the main trial.

2.1. Analysis

The data were analyzed using the chi-square test to compare the group proportions between those who responded and received the article and those who did not receive it.

3. Results

For the first study 4,488 recruitment packs were sent out, 2,243 containing the article and 2,245 had no article enclosed. Of these 102 people who received the article responded and 73 were recruited. Of these who did not receive the article, 97 responded and 71 were recruited. Figure 1 below is a flowchart