Recruitment strategies for a clinical trial of community-based water therapy for osteoarthritis

Rachel Davey, Sarah Matthes Edwards and Tom Cochrane

SUMMARY

This study compares the efficiency of two methods of recruitment into a randomised controlled trial examining the cost-effectiveness of water therapy for elderly people with lower limb osteoarthritis. The direct cost of recruiting patients via general practice was £27.66 per patient (1.1 personnel hours/patient). The cost per recruited patient from a local newspaper article was £2.72 (0.2 personnel hours/patient). The cost differential between the two recruitment methods was largely owing to poor administration practices, difficulties in accessing patient information, and difficulties in contacting patients from the general practice computer database.

Keywords: *randomised controlled trial; patient recruitment; osteoarthritis.*

R Davey, BSc, MMedSci, PhD, senior lecturer; S Matthes Edwards, BSc, MSc, lecturer; and T Cochrane, PhD, associate dean; Department of Sport, Health and Exercise, School of Health, Staffordshire University.

Address for correspondence

Dr Rachel Davey, School of Health, Brindley Building, Staffordshire University, Leek Road, Stoke on Trent ST4 2DF. E-mail: r.davey@staffs.ac.uk

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Introduction

SUFFICIENT recruitment of participants into randomised controlled trials is critical to ensure adequate statistical power and external validity of research in primary care. In some cases trials have been terminated, owing to low recruitment and insufficient sample size.[1] This paper describes recruitment of elderly patients using two methods: the GP patient database and a local newspaper article.

Method

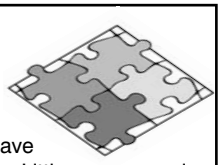
Sample requirements of the randomised controlled trial (RCT)

The study was designed to have an 80% statistical power to detect an expected difference of 2.66 on the WOMAC[2] pain score — the critical outcome measure — with a false-positive rate of 1%. Assuming a 50% loss of subjects owing to drop-out or non-compliance, approximately 300 patients were required in the study (151 in each arm).

Patients and recruitment methods

Ethical approval was granted by North Staffordshire Research Ethics Committee and all patients gave their written consent to participate in the study. Recruitment of patients into the trial (with cost per patient) is shown in Figure 1. Recruitment took place initially via GPs in Stoke on Trent, in the North Staffordshire health region. Although all practices that agreed to participate were computerised, there was great variation in ease of access to patient information from the database. Only one of the 16 (out of the 67 contacted) practices willing to participate was able to identify patients who had osteoarthritis of the knee or hip from the computerised database. The others were not able to run disease-specific osteoarthritis searches (or identify patients' prescribed non-steroidal anti-inflammatory drugs). Thus, all patients who were aged over 60 years in these practices had to be contacted with an initial screening questionnaire, to identify those likely to have osteoarthritis. There was difficulty in accessing patients by letter as some of the practices were unable to print address labels. In order to comply with the Data Protection Act (1998), one of our research staff visited each practice to assist with the printing of address labels and mailing letters on site. In some cases, letters had to be addressed by hand, which proved to be a considerable burden. A signed letter from the main partner at each practice was sent to patients with information on the trial, and a reply-paid envelope for patients willing to be contacted by the research team. This phase of recruitment took six months, with 242 eligible patients agreeing to participate.

HOW THIS FITS IN



What do we know?

The recruitment of older patients into clinical trials, particularly those who may have poor health, is difficult and time consuming. Little is reported in the literature comparing the efficiency and costs of different recruitment strategies.

What does this paper add?

We report two complementary recruitment strategies; one through general practice, the other using an article and call for volunteers in a local newspaper. The direct costs of recruiting through general practice were approximately ten times more per patient than the local newspaper article. Thus, it may be more practical in future to recruit directly through the local newspaper.

Recruitment via GPs was lower than anticipated; thus, a call for volunteers was printed alongside a health article about the benefits of exercise for osteoarthritis on one day in the week in a local newspaper (at no charge). This phase of recruitment took one month and 66 eligible patients were recruited.

Results

The age distribution of recruits was similar to that of people aged over 65 years in Stoke on Trent. No statistically significant differences ($P<0.05$) in any of the main outcome measures were found at baseline between the two recruitment methods (Table 1). Comparing on the basis of the time taken and the direct cost of recruiting, the newspaper article was less expensive and more efficient than using the general practice database.

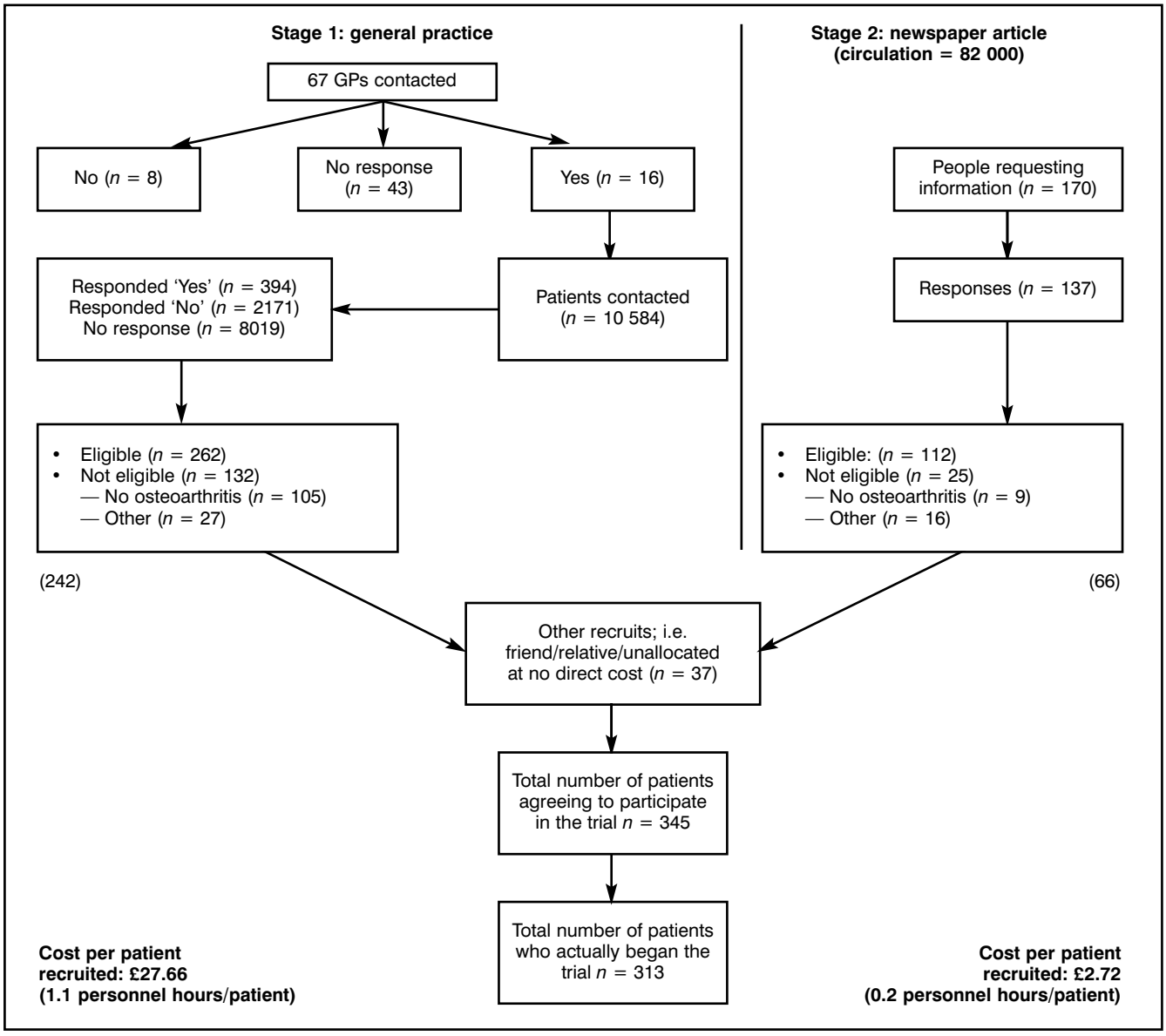


Figure 1. Recruitment of general practitioners and patients into the trial.

Table 1. Baseline characteristics of the study participants by recruitment strategy. Inclusion criteria: age 60 years or older; confirmed osteoarthritis of the knee and/or hip by GP or orthopaedic surgeon; willingness to be randomised into a water-exercise group or control placebo group; community-dwelling. Exclusion criteria: not ambulatory without personal assistance; already participating regularly in an exercise programme; severe visual impairment or hearing loss; dementia; currently receiving physiotherapy or hydrotherapy; stroke, myocardial infarction, hip/knee replacement (in the past six months); expecting major surgery (hip/knee replacement (in next six months); unstable angina; contraindications to exercising in water (e.g. incontinence, urinary infection, open wounds, skin disease).

Primary outcome measures (mean ± SD)	Recruitment method	
	GP	Newspaper
Age (years)	69.84 ± 6.78	69.35 ± 5.56
BMI (kg/m^2)	30.03 ± 4.99	28.73 ± 5.32
Sex (% male/female), $P<0.05$	41.5/58.5	22.4/77.6
SF-36[3] score (arbitrary units)		
Physical functioning	51.18 ± 22.80	48.36 ± 20.99
Social functioning	64.81 ± 28.55	60.77 ± 28.80
Physical role limitation	24.89 ± 35.54	19.70 ± 31.17
Mental role limitation	46.81 ± 44.80	41.41 ± 46.06
Mental	68.46 ± 17.29	69.76 ± 14.95
Energy	43.43 ± 20.66	43.26 ± 18.84
Pain	42.69 ± 20.66	39.23 ± 19.12
General health	51.49 ± 20.17	49.34 ± 17.17
Change in health	41.11 ± 19.10	39.62 ± 22.49
WOMAC score (arbitrary units)		
Pain	8.82 ± 3.37	9.39 ± 3.27
Stiffness	3.90 ± 1.57	4.17 ± 1.37
Physical function	30.10 ± 12.21	32.65 ± 11.53

Discussion

Other researchers have suggested many reasons why GPs may or may not be willing to participate in trials, such as limited time or motivation of recruiting physicians, staff shortages, involvement in other research studies, the research question not perceived as relevant, and inadequate support by researchers.[4-6] The newspaper article generated fewer participants, but was faster and less expensive. However, since the article was only placed on one day in the week, it is not possible to estimate how many people were exposed to this, so overall response rates cannot be determined. Nor is it possible to determine how many more volunteers could have been recruited using repeat articles or a sustained media campaign.

When comparing the main outcome measures at baseline, no statistically significant differences ($P<0.05$) were found between the two methods of recruitment except in the sex balance of the respective samples: 59% women via the GP and 78% via the newspaper article. The article appeared in the Health section, and women may be more interested than men in health issues and in socialising in a group exercise. There are problems associated with relying on general practice, rather than researchers, to recruit patients. There is a risk of introducing selection bias if potentially eligible subjects are excluded by a practice that does not wish to participate (for whatever reason) in the trial — in this case, 76% of GPs in the area. There are ethical dilemmas in relying on such 'gatekeepers' who may be denying patients potentially beneficial treatments. Lack of staff support and time has been identified as an important barrier to the recruitment of GPs in other studies. If lack of time and staff is the main problem then it augurs badly for those hoping to encourage more evidence-based practice and networks of research in primary health care. The solution may lie in encouraging primary research capacity in general practice, with an emphasis on opportunities for research training and academic attachments for health professionals, and for financial compensation to cover the costs of developing networks for research in primary health care.

Conclusions

Success in reaching target recruitment depended largely on being able to directly contact patients with osteoarthritis through the general practice database and the willingness of GPs to participate. The lower than anticipated response rate and underdeveloped research infrastructure in a majority of practices made recruitment more difficult, time-consuming, and costly. Based on the consideration of disease distribution and main outcome measures, recruitment via the newspaper did not result in a significantly different group of patients. Thus, it may be more practical in future to recruit directly through local newspaper advertisements.

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