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Recruiting patients to randomized trials in primary care: principles and case study

Sally EM Bell-Syer and Jennifer A Klaber Moffett[a]

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Background. There are many factors affecting recruitment to trials in primary care, and trials are often jeopardized due to the inability to enter sufficient patient numbers. It is generally agreed that the interest in and commitment of GPs to the project are important, and their forgetfulness and time pressures are major factors which mitigate against maximal recruitment.

Objectives. The aim of this study is to focus on maximizing recruitment of patients to a randomized controlled trial of exercise classes for back pain patients.

Methods. Two distinct methods of recruitment were used. One practice provided a computerized list of names and asked patients' permission, by letter, to be contacted by the researchers. The other 18 practices manually recorded referrals after the consultation by the GP.

Results. Referral rates were slower than expected. Many patients either did not fit the inclusion criteria or excluded themselves due to domestic commitments or work. During 24 months, 1588 patients were referred. A total of 187 patients (12%) met the criteria and could be included in the study. The practice which referred patients through a computerized listing contributed 44% of the patients successfully included in the study.

Conclusions. Recruitment rates depended on the method and rate of GP referrals, the proportion of referrals meeting the entry criteria and the proportion of patients available to attend the exercise classes.

Keywords. Back pain, primary care, randomized controlled trial, recruitment.

Introduction

There is a great need to carry out randomized controlled trials (RCTs) in the primary care setting to provide evidence for the effectiveness of different methods of management for specific conditions. In practice, however, there are many obstacles to overcome before an RCT can be completed successfully. One of the key issues is that of patient recruitment to the study. Obtaining sufficient recruitment rates of eligible patients can be a major problem for clinical trials.

The literature covering problems of recruitment to trials is limited. An electronic search of several databases was carried out and relevant papers identified; in turn, their individual bibliographies were searched for further references. From this review, several principles emerge.

In the first place, negotiating access to research settings and subjects is a very important step which needs to be handled carefully in order to avoid compromising the project. The quality of access obtained is just as important as the quantity. When presenting the research project to prospective collaborating GPs, the practical implications of the research need to be emphasized. It has been shown that topics which have clear clinical relevance and are of concrete daily interest are much more acceptable to the GPs,[1] although the majority are not interested in research.[2]

It is recommended that GPs should be recruited by an initial letter of introduction followed by a personal practice visit where the research issues can be freely discussed and the protocol clarified. This meeting should encourage a sense of collective ownership of the project which increases the chances of it being completed successfully. A robust initial commitment and a positive attitude by the GPs tends to lead to a lasting loyalty and is especially important for longer term projects. Usually the pressure of time and forgetfulness are major factors which work against maximal recruitment.[1,3,4] Peto *et al.* (1993)[3] found that regular contact maintained throughout the recruitment period, usually with the practice manager, and the use of regular progress reports and reminders were effective in improving recruitment. Richmond[4]

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Centre for Health Economics, University of York, York YO1 5DD and [a]Institute of Rehabilitation, University of Hull, Hull, UK.

went further, placing a researcher in the practice itself and instituting a payment by results system for the practice staff. These methods improved recruitment rates, but usually are precluded by the additional costs or ethical considerations.

Jonker and Sumajow (1992)[5] in The Netherlands advocate personal contacts and visits to practices participating in a trial. They suggest that personal contact with the individual GP and not just the practice staff is necessary in order to encourage compliance with the protocol. They also noted that personal attention was probably a stronger incentive than financial compensation.

Richmond *et al.* [4] and Tognoni *et al.* [6] found that many GPs have problems with compliance with the study protocol. It seems that this may be the case even if the GPs themselves are instrumental in drawing up and agreeing the original protocol. It is essential, therefore, that the protocols are simple and that data collection forms are easy to use and administer.

Wodak *et al.*[7] in Sydney found that the recruitment rate usually 'plateaus' after ~3 months, when saturation of new eligible patients who visit the GP is reached. Charlson *et al.*[8] in the UK showed that 66% of trials never achieve their projected sample size. Largest losses before randomization occurred as a result of the study criteria and not the refusal of patients or their physicians to participate. They felt that the problem of large losses before randomization cannot be solved easily. Minimizing the pre-randomization losses requires the use of less restrictive entry criteria. Collins *et al.*[9] (1984) in the USA examined 10 studies, the majority of which showed an underestimation of the number of patients to be included in a study due to excessively stringent study criteria. They also reported that many GPs felt that they were referring adequate numbers of patients to the research studies, but badly underestimated the number of patients who would be excluded because of the entry criteria. Rigorous recruitment criteria are adopted because they enhance the RCT's internal validity but at the expense of the external validity where the RCT subjects are less representative of the population experiencing the condition.

The issues surrounding recruitment of patients to an RCT in primary care were explored thoroughly in a trial carried out in York. This trial forms the basis of a case study which illustrates the general principles.

Case study of low back pain: I. Method of recruitment

An RCT was set up to evaluate the effectiveness of an exercise class for primary care patients with sub-acute low back pain.[11] GPs who were invited to participate in the study were sent a copy of the study protocol, procedure and background information. After initial telephone contact with the practice manager, a personal visit was arranged by the project leader in order to explain the study in more detail. Emphasis was put on the need for all GPs plus the practice manager or key reception staff to be present, in order to have the opportunity to air any concerns prior to deciding on their participation in the study. Only two practices declined to participate. In this way, 87 GPs from 19 practices were recruited gradually in four waves over a period of 18 months.

The time and effort required by GPs involved in the study was kept to a minimum in recognition of their pressurized schedule. They were asked to record on a carefully designed referral form the names of any patients they saw with an episode of low back pain lasting for not more than 6 months. The GPs were asked to: (i) tell the patients that the practice was participating in a trial with researchers at the University who were looking at different methods of managing back pain; (ii) obtain the patient's consent to referral; and (iii) record the patient's date of birth, time of onset of back pain and, if possible, the treatment plan on the referral forms provided.

All the practices except one large practice (Practice H) recruited the patients in this way. Practice H with 12 partners was fully computerized and agreed to use a computer printout to identify patients who had presented to the practice with a back pain condition. A letter from the GPs was then sent to all contacts on the list who satisfied the age criteria (i.e. between the ages of 18 and 60 years old). The letter informed them that they would be contacted by telephone unless they returned the letter of invitation within 5 days indicating that they did not wish to be contacted.

After initial telephone screening, patients were invited to the University for an interview with a researcher to establish that they satisfied the study criteria. This was followed by a physical assessment and data collection through administration of questionnaires at the GP's surgery by a research physiotherapist blind to treatment allocation. Patients were randomized to either the exercise programme or the control group. Those in the control group were asked to continue following their GP's advice. Each patient knew that they had a 50% chance of being allocated to the exercise programme.

Six weeks later, a follow-up assessment was carried out by the same research physiotherapist at the GP's surgery. All study participants subsequently were followed up at 6 months and 1 year by a postal questionnaire.

Over the course of the trial, several strategies were developed with the aim of maximizing recruitment, such as project logo, information updates, seminars and local publicity.

A survey was carried out after recruitment to the study had ceased. This sought information from all the participating GPs and focused on: (i) factors which might have encouraged or prevented patient referral to the

trial; (ii) their understanding of the inclusion/exclusion factors; and (iii) the effectiveness of recruitment strategies implemented during the trial.

Case study of low back pain: II. Results of recruitment

Over a period of 24 months, 1588 names of patients with low back pain as their main complaint were referred to the study. A total of 1050 referrals were made by Practice H through their computerized lists and, of these, 83 patients were included in the study. The remaining 74 GPs made 538 referrals resulting in 104 patients being included. Table 1 shows how the referrals were classified.

The pie charts (Figs 1 and 2) also display the different reasons for not including patients. Figure 1 displaying patient distribution in Practice H shows that ~30% of patients were either unable to attend the programme or declined to participate for some other reason which, in many cases, was not made known to the researcher. This may have been due to domestic or work commitments, possibly they had no back pain by the time they were contacted, or their back pain was not confined to their lower back or was not their predominant complaint. In the other practices where the gap in time between referral and inviting patients

TABLE 1 *Classification of referrals*

Classification	Practice H (computerized referral)	All other practices (personal referral)	Total
Patients included in the study	83	104	187
Included in the exercise class but not the study	29	36	65
Back pain better	287	130	417
Unable to attend class	83	75	158
Declined to participate— reason unknown	239	24	263
Ineligible for the study:			
Chronic back pain	91	37	128
Pregnant/disabled/too fit	38	27	65
Physiotherapy/other treatment	48	40	88
Contact problems	92	46	138
Back pain intermittent	60	19	79
Total	1050	538	1588

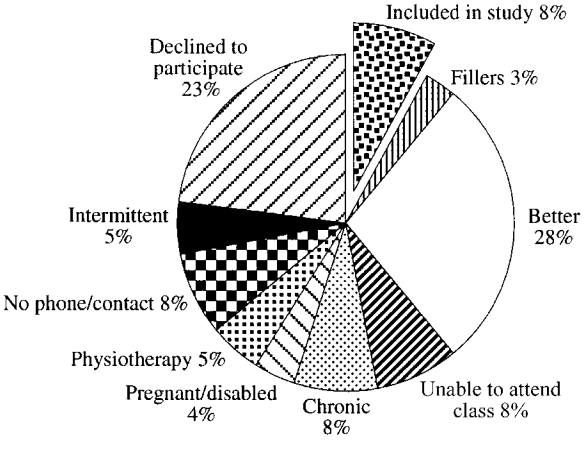

FIGURE 1 *Back pain referrals from Practice H*

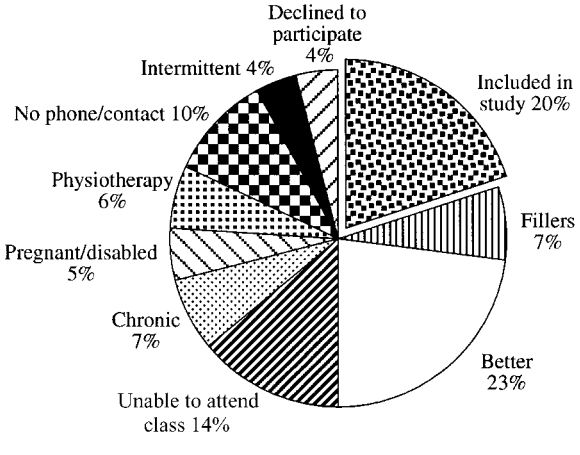

FIGURE 2 *Back pain referrals from all practices (excluding Practice H)*

to participate in the study may have been shorter, and where the GP would have mentioned the study to the patient at the consultation, the group of non-participants was reduced to 18%.

In other respects, the proportions of patients who could not be included were similar. In both cases, ~25% were better by the time they could have been included, 5% were attending physiotherapy or another hospital service, 8% were too chronic, 9% had no telephone and did not respond to written invitations to initiate contact, 5% could not be included for miscellaneous reasons such as pregnancy or major disability, or were already very fit through regular exercise. A further 5% had an intermittent problem with their backs.

Personal referral by GPs required seven referrals for one patient to be successfully included, whereas the computerized, less specific, referral method needed 87 referrals for every patient included. However, the computerized practice contributed 44% of the total number successfully included in the trial.

The survey of GPs at the end of the study achieved a 73% response rate. Pertinent observations and findings are included in the following discussion.

Discussion

On the whole, GPs did not have any problems complying with the protocol, but the follow-up survey showed that 43% had difficulty remembering the entry criteria. Practices which referred patients paying attention only to the broader entry criteria leaving researchers to establish eligibility tended to have a higher success rate, more of their patients being included in the study. This was also true for the single large Practice H which made referrals directly from its computer records. Their patients comprised 44% of the total number included in the study.

Practices who were recruited early in the study were on the whole more efficient at referring patients to the study than those recruited later. These GPs may have felt more involved in the study compared with those who were recruited later and felt less sense of ownership. This was confirmed by the follow-up survey. As expected, those GPs who had a special interest in back pain were significantly better recruiters, so were GPs who were personally known to the researchers. In fact, the recruitment rate was influenced greatly by personal contacts, as noted by previous researchers.[10]

Including patients in the programme at the appropriate time is another major issue. In 25% of cases, the patient's condition had improved by the time of the next exercise class, but may well have recurred some days or weeks later. A further 10% of patients were not able or willing to participate, often due to domestic or work commitments. With hindsight, some of these problems could have been overcome by running a continuous exercise programme including patients immediately after they were referred.

Conclusions and recommendations

Recruitment of patients is a particularly difficult problem in the primary care setting across a number of practices. It is important to encourage maximum engagement of GPs in the study, especially at the outset. Maintaining personal contact and sending frequent project reminders also help to combat natural forgetfulness and time pressures. Maximizing the number of GPs involved with the project and also encouraging referral via computerized lists, allowing informed researchers to apply the inclusion criteria, was a very successful recruitment strategy.

Future trials of this type in the primary care setting should note these observations and should consider:

- allowing initial referrals which satisfy fairly wide entry criteria and using experienced researchers to apply the more detailed entry criteria before entry to the trial
- sending frequent reminders and project updates
- recruiting as many GPs as possible
- using nurse practitioners to tell patients about the study
- obtaining an agreement to use computerized practice lists where feasible.

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