

Optimizing recruitment from primary care: methods of recruiting older people with depression

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Participant recruitment is often the rate-limiting step in clinical trials, but the methods used and the processes involved in recruitment are rarely reported. Although various methods will often be adopted, there is a dearth of information about the factors which facilitate or impede recruitment to trials. Such information is potentially very valuable to researchers. The present pilot study aimed to recruit a minimum of 30 participants through primary care to a randomized controlled trial (RCT) of three interventions for older adults with depression. The aim was to determine how recruitment to RCTs in primary care may be optimized. A wide range of recruitment methods was used, including both direct general practitioner (GP) referrals and self-referrals. Potential participants were informed about the study in a variety of ways, including GP recruitment when attending surgeries, contacting suitable patients identified from the GP database, posters and leaflets in the GP surgery, and the specific targeting of older people by the distribution of leaflets at 'flu clinics. Both GP referrals and direct referrals were successful. Interestingly and rather unexpectedly, the greatest numbers of individuals were recruited by self-referral. No differences were found between these two groups as to the severity of their depression. Recruiting from primary care can be successful, if primary health care teams are willing to work in partnership with researchers, and if researchers are willing to be flexible and try many approaches. In particular, the study found that cultivating self-referrals was a profitable strategy, which was not what had been initially expected with this particular target group of older people with depression. These self-referrals were a cost-effective method of recruitment, each costing around one-third less than those recruited by other methods, and without them the recruitment targets would not have been met.

Key words: cost-effective; methodology; primary care; randomized controlled trial; recruitment; referral

Received: February 2005; accepted: December 2005

Introduction

The demand for quality randomized controlled trials (RCT), which are generalizable to a general

population, is increasing; therefore the number of trials conducted in primary care is growing. Anecdotaly however, recruiting an adequate number of participants, which is an integral part of any research, can be particularly difficult. The current feasibility study intended to look at the acceptability and efficacy of cognitive behavioural therapy (CBT) with older adults in primary care and particularly

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the ability to recruit sufficient participants. CBT is an increasingly popular psychological intervention based on identifying and modifying dysfunctional thoughts and behaviours. There are several possible factors that may contribute to the difficulty of recruiting from this source: general practitioners (GPs) often have major time constraints, volunteers may have reservations about participating, screening can be time-consuming and people may fail to meet selection criteria.

One of the primary distinctions of recruitment methods is active versus passive recruitment. Sarkin *et al.* (1998), studied health promotion and reported on two methods of recruitment. Directly approaching potential volunteers (active) was found to lead to a higher rate of recruitment than mail-outs (passive). Nazemi *et al.* (2001) published a study of depression in primary care, and utilized both physician referrals and waiting room recruitment. Twenty-three per cent of those referred by their GPs and 12% recruited directly by research staff participated. Waiting room recruitment was more intensive in terms of researcher input but yielded higher numbers, whereas physician referral yielded a higher percentage of eligible participants. Physician referrals were more likely to be more depressed than waiting room referrals. Nazemi *et al.* (2001) recommended that using both methods simultaneously is the best practice. Using multiple methods of recruitment has also been identified as a key to success in other trials as well (Boult *et al.*, 1998).

Recruitment from primary care in a trial designed to increase physical activity has also been discussed (Margitic *et al.*, 1999). Forty-three per cent of participants entered the study through patient mailing, 33% were recruited through approaching them in the waiting room with a questionnaire, 22% came from 'cold calling' (calling patients who have not yet heard of the study and given consent) patients on doctors' list, while physician referral only yielded 1.4% of participants. It was concluded that approaching patients in the waiting room was the most effective.

Although some controversy surrounds cash payments to participating practices, their importance must not be ignored. Deehan *et al.* (1997) found that responses to surveys increased incrementally to levels of payment. Furthermore, as Foy *et al.* (1998) point out, pharmaceutical companies offer monetary compensations to GPs, which they

would not do unless it had a positive impact on recruitment. Although researchers from universities or the National Health Service (NHS) may find it hard to compete financially with pharmaceutical companies, in many cases funds can be devoted to at least covering costs.

The recruitment methods used in the present trial are described and the potential strengths and difficulties of the methodologies adopted are highlighted.

Method

Research into the optimal methods of recruitment into a RCT to investigate the potential effectiveness of CBT in older people with depression in primary care was undertaken between May 2002–03. People were randomized to one of three interventions: treatment as usual (TAU), CBT and attention control (AC). The selection criteria were: being over 65, a minimum of 14 on the Beck depression inventory (BDI) (Beck *et al.*, 1961) as well as a diagnosis of depression on the geriatric mental state (Alden *et al.*, 1998).

Recruiting GPs

GPs who had previously indicated an interest in research were approached – this was done through the North Central Thames Primary Care Research Network (NoCTeN). Initial information was brief and GPs could indicate further interest by return post. A contact person in the surgery was identified, who was usually the practice manager or GP/nurse with a special interest in the study. GP surgeries were informed that they would be financially compensated through NoCTeN for the time spent making referrals, as well as for the use of any rooms.

In order to facilitate minimizing the load placed on GPs, a quick reference guide in which key project information was listed with contact details was developed. The referral sheets listed inclusion/exclusion criteria in a bullet point fashion. Surgeries were also given leaflets the staff could hand out to those who expressed an interest in the study (see Figure 2).

Periodically updating practices on the progress of the trial was also considered vital. Newsletters were mailed to all staff involved in the trial, and included information such as the number of participants

recruited/required and feedback from other GPs. This also served to remind practices about the project, with the aim of prompting referrals. When GPs referred patients, the research team thanked them for each referral. If a referral was unsuccessful, the GP was informed why.

Self-referrals

Potential recruits were made aware of the study with posters and leaflets displayed in the waiting rooms. The language was designed to be clear and simple to account for possible language/literacy difficulties. Words such as ‘feeling down’ and ‘stress’, which are terms most people understand and use in everyday language, and which may be less stigmatizing than ‘depression’, were used.

The leaflet asked: ‘Are you or someone you know feeling down?’ As pilot work suggested that admitting directly to feeling down was more threatening and embarrassing, whereas picking up a leaflet for a friend was less direct and appealed to people’s altruism. Screening questions were formulated into a ‘quiz’ that was attached to the patient leaflet left in GP surgeries. Attaching pre-paid envelopes allowed interested individuals to return their details and this was followed up with more information being sent to them.

Targeted leaflet distribution

Leaving leaflets in waiting rooms and doctors’ offices does not ensure that people will read them, so where possible members of the research team handed them out. Many surgeries had designated ‘flu clinics’ when those over 65 were offered ‘flu injections. These clinics mean a large throughput of patients in the right age group for the study, so the researchers visited at those times and introduced the project to patients.

Database recruitment

It is possible to use surgery databases to gather information about potential recruits who can then be contacted by letter offering them an opt-in to the study. Individuals were sent a brief letter explaining why they were being contacted, a copy of the leaflet, and invited to contact the research team. Targeting individuals who meet certain criteria (eg, over 65s only) in this way may be particularly useful.

This enables potential access to those who do not visit their GP’s often and do not get a chance to see the leaflets in the surgery or get a doctor’s direct referral via a surgery attendance.

Results

Recruitment of GPs

Twenty-four general practices with a total of 95 GPs were recruited.

Recruitment

Twenty weeks were allocated for recruitment. As surgeries became familiar with the study, researchers developed their recruitment skills, and leaflets and posters were modified, recruitment accelerated. The average weekly recruitment was 0.58 participants, with a range from zero to four.

Recruitment

The breakdown of recruitment (illustrated in Figure 1), presented in the order of most referrals, was as follows.

Self-referrals and targeted leaflet distribution

Recruitment through leaflets and posters yielded the largest number of people. As the study progressed, several revisions of the leaflets and posters were undertaken. A minor, yet important change was using much brighter paper and bigger posters so that they would be eye-catching. Approximately 3000 leaflets, of which 750 were handed out personally during ‘flu clinics, were left at surgeries (see Figure 2). Where possible, the researcher tried to explain the study briefly to potential participants and answer any questions.

Most individuals approached by the research staff had positive reactions. Even those who told the researchers they did not feel down said they thought that the study was researching an important area. A common statement made was that they were ‘glad to see research being conducted on those over 65’, as they felt that the NHS often overlooked the concerns of older individuals.

Three thousand leaflets were made, of which 750 were handed out individually, mostly at ‘flu clinics. Fifty-two individuals responded to the flyer, of which 45 were contacted for assessment, each

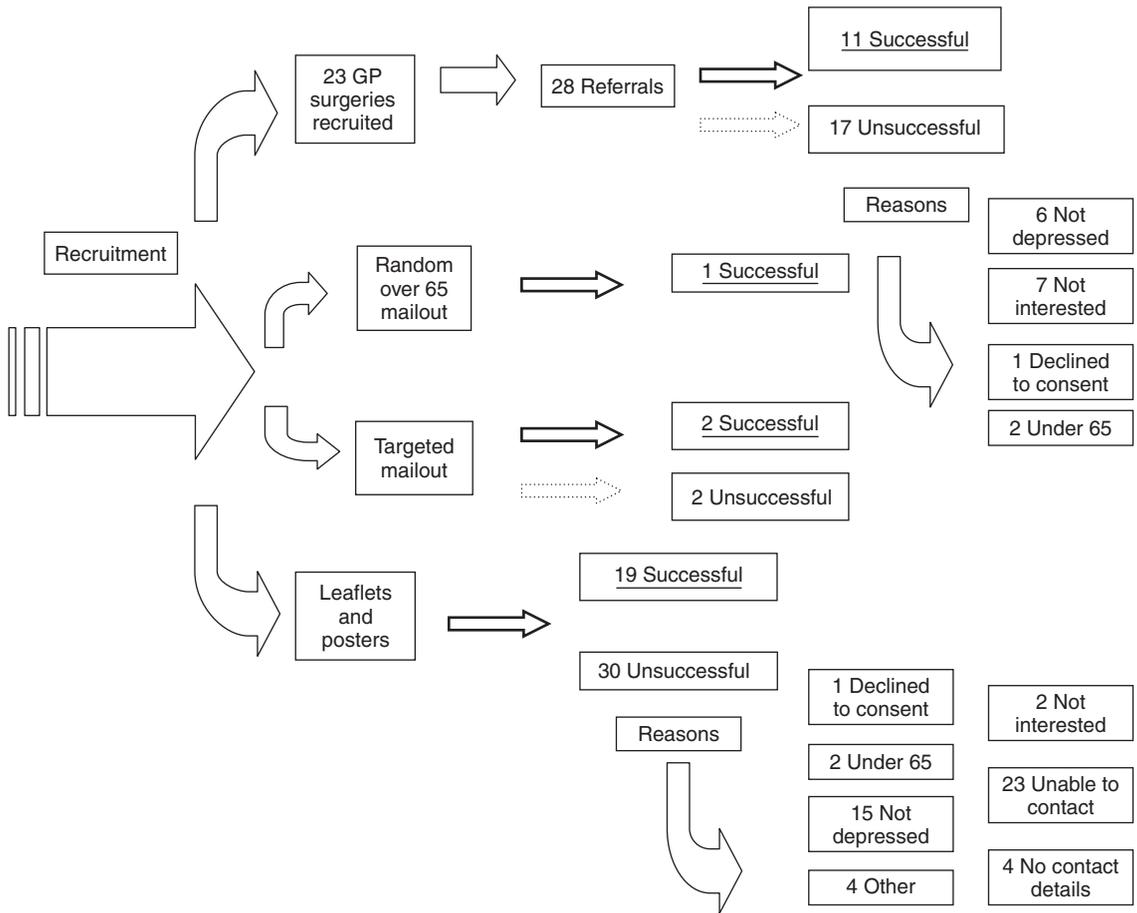


Figure 1 Recruitment flowchart

**Are you or someone you know
FEELING DOWN?**

Over 65? Have you or a friend/relative lost interest in things? Feeling fed up? Feeling lonely? Lacking in energy? Anything getting you down including physical problems? If the answer is yes, talking therapy might help change negative thinking and what to do about it, leading to a happier and more positive outlook.

Why not fill in the quiz to see if you/they could benefit from some support? **University College London** with the **Royal Free Hospital** are studying talking therapies **in people over 65 years of age**. This might result in free local support from a trained professional, in your own time without any risks.

For information, please call office number or mobile number and ask for Em or Rose or return the quiz and we will contact you.

Figure 2 Recruitment Leaflet

Table 1 Costs associated with self-referrals and GP referrals

	Self-referrals	GP referrals
Materials	3000 leaflets × £0.10 = £300	95 reference cards × £0.25 = £23.75 300 referral sheets × £0.10 = £30
Labour	50 hours construction of leaflets × £13 = £650 80 hours distribution time × £13 = £1040 £1990	28 GP referrals × £40 = 1120
Total	£1990	£1537.75
Assessments	45 assessments × £13 = £585	28 assessments × £13 = £364
Successful referrals	22	11
Final cost of each successful referral	£117	£173

Note: Rates for research staff were £13/hour.

assessment averaging one hour. A breakdown of costs is presented in Table 1.

GP referrals

GPs and nursing staff were also asked to refer potential candidates. Thirty-nine percent (11/28) of those referred by GPs were successfully recruited to the study. GPs were compensated for their time, and given materials and reminder letters to prompt referrals. These costs are presented in Table 1.

Database searches

Using the practice database was adopted late in the recruitment period in a bid to boost patient numbers. Leaflets and a brief letter of introduction were sent. Two such mail-outs were completed, and each GP practice was paid £50 for their time:

- Information was sent to 50 individuals. The practice manager identified those with a history of anti-depressant use and GPs were asked to eliminate any individuals who were inappropriate for the study. Two individuals elected to join the study as a result.
- Information was sent to a random sample of 200 individuals over 65 at a particular practice. This led to several people requesting more information, and only one individual joining.

Differences between referral sources

T-tests were conducted to explore differences between those referred by their GP and those who self-referred. No differences were found in the gender or age (see Table 2).

Table 2 Age and gender of those who self-referred and those referred by their GP

	Self-referral (n = 22)	GP referral (n = 11)	t or χ^2	P
Mean age	75.1	77.2	t = 0.8	NS
Gender				
Male	7	3	$\chi^2 = 3.7$, df = 5	NS
Female	15	8		

Table 3 Mean depression, social functioning and general health scores for those who self-referred or those referred by their GP

	Self-referral (n = 22)	GP referral (n = 11)	t or χ^2	P
BDI	24.2 (SD 6.5)	23.6 (SD 8.9)	t = 0.2	NS
SFQ	9.7 (SD 3.3)	9.1 (SD 4.1)	t = 0.4	NS
Euroquol (Q7)	50 (SD 19.1)	46 (SD 21.3)	t = 0.54	NS

Note: BDI = Beck depression inventory; SFQ = Social functioning scale.

The main and subsidiary outcome measures taken at baseline for self-referral or GP referrals were compared, but no significant differences were found, although the small sample size must be taken into consideration. This is given in Table 3.

Discussion

This paper highlights the challenges of recruiting from GP surgeries and gives suggestions as to how these may be overcome. Our study was successful

in recruiting the requisite number of participants, 33% of whom came from GP referrals and 66% came from self-referrals. Recruiting through primary care is desirable for research to be generalizable, as well as informing service providers which treatments are acceptable and effective in specific populations. Overall, this study demonstrated that it was possible to recruit sufficient numbers of participants from this population base, even for an area of research which might be perceived as less popular with potential participants (ie, older people with depression).

Both these findings and those of others suggest that researchers cannot expect GP referrals alone to provide participants, and indeed recruiting via GPs was more costly. The primary obstacle for GPs was that GPs reported simply not having enough time to devote to research, which may have led to a reluctance to accept new projects. Researchers must therefore try to minimize the time that surgery staff are likely to spend involved in the project, and financial reimbursement for any time spent is important. In the case of treatment trials, it may be useful to explain that the research may be of direct and immediate benefit to patients, beyond what current resources can provide, which was also stressed by Pringle and Churchill (1995). All the GPs who elected to participate in this study expressed the belief that such research was important and could be an addition to their services. This was in contrast to the findings of a study by Leader and Neuwirth (1978), who experienced hostility when recruiting the directors of senior citizens centres. This may be in part that the GPs who were approached by the research team were all members of NoCTeN, an organization which promotes GP involvement in research. Indeed, not only did NoCTeN provide lists of member GPs; compensation for their services was met by the organization as well. Recruiting primary care practices into the study initially may have taken considerably longer if the researchers had simply approached GPs according to NHS Primary Care Trust (PCT) lists. Furthermore, this primary care research network allows GPs to work with their colleagues and many expressed an interest after finding out who else was collaborating. Sellors *et al.* (2002) also found that involving a GP in the research team itself was a boost to more general GP involvement.

Participating GPs were certainly enthusiastic, but only 39% (11/28) actually then made referrals.

However, this study recruited better via GP referrals than others in the literature, since a third of our final sample were obtained this way. Margitich *et al.* (1999) actually abandoned this method as it yielded only 1.4% of their total recruitment, while Nazemi *et al.* (2001) recruited just over 20% in this manner. Both studies were larger than the present study, and it is possible that with continued recruitment, GP referrals may have been exhausted. Two main reasons were given by GPs to account for their low-referral rate. First, because of the limited consultation time allotted for each patient, GPs often forgot about the project, which was understandably not their main priority. Second, some GPs reported that they simply did not see people they considered suitable during their regular appointments. Indeed, Tognoni *et al.* (1991) also found that many eligible patients are often missed in the recruitment process. It is possible that those individuals who are depressed are actually less likely to attend GP appointments. Database recruitment may be particularly useful in catching individuals who do not regularly consult their GPs.

Updates were regularly sent to GPs and liaison made with practice managers informing them how the study was progressing. Regular visits to the surgeries were also undertaken, in order to keep a visible presence. Interestingly, over 60% of patients referred by their GPs did not proceed into the study. Several individuals expressed no interest in taking part in the study, despite their GP encouraging them to take part. Furthermore, quite a few were not significantly depressed by the time they were interviewed, and this may have been because the GPs had referred patients whose low mood was transient, but where the doctor had been concerned enough to offer some form of therapeutic help.

This study found recruiting via self-referrals considerably more effective than anticipated. The researchers were surprised by the interest that leaflets and posters within the surgery initially generated. Seeing this as a good opportunity, 'flu clinics for those over 65 were used to promote the study to further potential participants. Many individuals approached this way, even if they said that they weren't themselves depressed, nevertheless expressed their enthusiasm for research pertaining specifically to those who are over 65. Furthermore, this recruitment method was found to be more cost-effective, costing more than £50 less per participant recruited than GP referrals. This is a significant

saving, something that is of particular importance in larger trials.

Over the course of the study, various techniques were developed, such as modifying the screening questions into a 'quiz'. This served the dual purpose of screening out those ineligible, while participants found it easy to complete. Knowing the importance of making study materials accessible and appropriate to target individuals, we used large fonts for leaflets and posters to make them easier to read. Creating leaflets with contact details, envelopes and quizzes attached was more time-consuming than anticipated, but it was felt to be very effective and was a cost-effective method of recruitment. Without these self-referrals, the recruitment targets would not have been met.

As reported in other studies (Leader and Neuwirth, 1978), recruitment picked up momentum over time (from four to five weeks in this case). Seasonal variations and the familiarity of referral staff with the project both have an impact on recruitment. For example, in the summer, both patients and GPs may be away on holiday, and this should probably be taken into account. Given that the recruitment rate per surgery is often low, increasing the number of practices involved to increase the potential pool of participants is recommended. Also, not all partners in any particular practice will be equally committed to the project, so increasing the number of practices should increase the number of those who are highly committed.

The present study was not designed to recruit large numbers of individuals into the trial, since it was a feasibility study organized to address recruitment issues for a larger full-scale study. In a longer trial, recruitment fatigue may become a possibility in both GPs and researchers, but the variety of methods recommended can be used and adapted to longer studies. Wilson *et al.* (1999) reported that their recruitment rate fell sharply in the first year but became steady in the second. They point out that it may not simply be recruitment fatigue, but also that the pool of potential participants may be shrinking.

In summary, when researchers are recruiting from primary care they must be adaptive and proactive. Minimizing the workload for those one relies on for referrals is vital, as are reminders to them about the importance of the study. Studies in primary care should not rely on GP referrals only. Self-referrals are a rich source of participants and

our experience showed that it was very helpful to distribute leaflets or other information at times or venues when a high percentage of potential participants may be available, such as speciality clinics. Adapting posters or leaflets throughout recruitment not only allows for the fine-tuning of such materials, but new forms of presentation are likely to attract more attention.

This message about different effective methods of recruiting study participants, and the need to continually adapt recruitment strategies, needs to be passed on by educators and researchers to their research students and assistants and to study managers. The new Mental Health and other Clinical Research Network initiatives taking place in the UK, together with the reorganization of Primary Care Research Networks, indicate how important the recruitment of suitable research participants from within primary care settings will be in the near future (Department of Health, 2005). Disseminating advice about suitable recruitment methods between different network members will be an important part of making this work. This study has demonstrated that it is possible to recruit using surgeries as a source of referral, without significantly increasing the time GPs dedicate to the study, by using a variety of other recruitment strategies, particularly encouraging participants to refer themselves.

Key findings and recommendations

- Self-referrals can be an excellent source of participants and are a cost-effective form of recruitment where possible.
- Adopt user friendly, age-appropriate study materials/recruitment methods.
- Make the referral process as easy as possible for surgery staff.
- Remind and update surgery staff on progress of project.
- Utilize specific appropriate opportunities, such as 'flu clinics for the over 65s.
- Be flexible and pro-active in seeking referrals.

Acknowledgements

We would like to thank the participants who took part, the practices who aided us in recruitment, the North Central Thames Primary Care Research

Network, Camden and Islington Primary Care Trust and Barnet, Enfield and Haringey Primary Care Trust. We wish to thank Rose Donno for her untiring work on recruitment. We also wish to thank Professor Michael King, Dr Martin Blanchard and Robert Blizard for their support.

We especially wish to thank the Health Foundation (formerly PPP Foundation) who provided the funding for this work. The views and opinions expressed do not necessarily reflect those of the Health Foundation.

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