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Achieving target recruitment in a primary care trial: lessons from PRIDE*

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Background: Failure to reach recruitment targets is a widespread problem in RCTs (randomized controlled trials). This paper presents experience of recruiting patients into the PRIDE trial which was carried out in one Primary Care Trust (PCT) in the North West of England. **Aim:** The aim of this feasibility study was to test the effectiveness of a new model of care for the management of late-life depression. **Method:** GPs (general practitioners), PNs (practice nurses) and community nurses were invited to refer patients into the study. Over 100 patients were needed (at least 50 in each arm of the trial) for the study to be sufficiently powered. On-target recruitment of over 100 patients over 18 months was achieved. **Findings:** Data obtained from conversations and from semi-structured interviews with health professionals is presented to give possible explanations for this successful recruitment. Not all practices in the PCT engaged with the study, and the most common reasons given by GPs and their staff for non-participation was being single handed or already having a heavy work-load. All community nurses spoken to agreed to refer patients to the study but only five referrals were made by this group over the course of the study. The main reasons primary care professionals did agree to participate and continue to refer patients was that they felt the trial was offering a local and relevant service to an under-served patient group. The very simple referral process was also an important factor. In addition, the Trial Nurse was perceived to be responsive, responding quickly to referrals made and providing regular and detailed feedback which was perceived to help and support the health professionals in the future management of the patient.

Key words: recruitment to trials; referral process; trials; under-served groups

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Introduction

Failure to recruit is a common problem in RCTs (randomized controlled trials) in primary care (Tognoni *et al*., 1991; Hunt *et al*., 2001) and is the main reason for the failure of trials. It is reported that 66% of trials never reach their projected sample size and the losses are often due to refusal of doctors or patients to participate (Charlson and Horowitz, 1984). Factors such as overwork and forgetfulness are reasons which are often given for general practitioners' (GPs) refusal to participate in the first instance or to fail to recruit any patients even if they have originally agreed to participate in a study (Murphy *et al*., 1992).

It has been claimed that the majority of GPs are not interested in research (Silargy and Carson, 1989), and it is suggested that RCTs are much

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better supported when they are perceived to be relevant, in a concrete and everyday way, to the concerns of the GP (Murphy *et al*., 1992). It is also the case that GPs who are personally known to the researchers and GPs with a special interest in the topic are more likely to recruit patients than others (Bell-Syer and Klaber Moffett, 2000).

Specific recruitment strategies that are suggested to be effective are: setting out a clear and simple protocol, making a personal visit to the GP, sending regular progress reports and reminders, and having a very straightforward referral form (Jonker and Sumajow, 1992; Murphy *et al*., 1992; Peto *et al*., 1993; Bell-Syer and Klaber Moffett, 2000). Scant evidence exists to demonstrate the effectiveness of any one recruitment strategy over another. Foy *et al*. (2003) looked at seven RCTs in an attempt to determine an evidence base for recruitment strategies. In all of the trials the most important contributor to successful recruitment was reported to be 'favourable organizational characteristics,' such as broadening the eligibility criteria and reducing the work-load for primary care professionals' to facilitate recruitment. Foy states that 'the key message from reviewing this evidence concerns how little is known about the most effective characteristics of trial organization.'

Others suggest that reducing the work-load of GPs seems to be a key determinant of successful research in primary care. Hunt *et al*. (2001) attempted to set up an RCT comparing problem solving versus SSRIs (selective serotonin receptor uptake inhibitors) for patients with mild to moderate depression. After six months they had failed to recruit a single patient so attempted to find out what went wrong. After reviewing their recruitment strategies (which had been vigorous and followed usual conventions) they state, 'in practical terms, the trial should not have failed as mild to moderate depression is a common presentation in primary care and the research protocol addressed many of the problems identified in previous primary care research failures.' Hunt described how even though the additional tasks the GPs had been asked to do were minimal (such as completing clinical ratings or self-report questionnaires), she speculates 'it is likely that the necessary role change from practitioner to scientist practitioner was too great to facilitate a shift in treating behaviour.' Hunt concludes that there is an inherent contradiction between research and delivery of care in the minds of many clinicians and that this is a basic problem for clinical research.

This paper describes a trial in one Primary Care Trust (PCT) in the North West where target recruitment was achieved, and where qualitative methods within the study were used to define and explain the reasons for successful recruitment.

PRIDE trial

This trial, funded by the Department of Health, was carried out in one PCT in North West England. The aim of this study was to test the feasibility and effectiveness of a new model of care for the management of late-life depression. GPs, practice nurses (PNs) and community nurses (district nurse (DN) and active case managers (ACM)) were invited to refer patients into the study. Recruitment was over eighteen months and 50 patients were needed in both the intervention and treatment as usual groups. There was no payment to the primary care professional for participating. Referral of patients into the study was by the completion by the health professional of a one-side A4 form with demographic details of the patients and a note that the patient had agreed to the referral.

The results of the main trial are reported elsewhere (Chew-Graham *et al*., in press).

Methods

Local Research Ethics approval and PCT Research Governance approval were gained for the study.

All practices received at least one letter giving information about the study (by post and often also by fax) which was then followed up by phone calls from the researchers. Offers of visits to practices from the research associate (RA), principal investigator (PI) and research nurse (RN) were made to further explain the study. The PI (a local GP academic) and RA contacted GPs by telephone and Email to encourage participation. Individual GPs could agree to participate in the study and refer patients: total practice agreement was not required. Practice nurses were contacted via the local practice nurse forum. In addition, presentations were made by the research team at local multidisciplinary meetings and educational events.

Community nurses (initially DNs but later in the study, as ACMs were appointed within the

PCT, these new community nurses were invited to refer patients to the study) were contacted by telephone and letter, and then the RA personally met with staff at meetings, to gain support and agreement to participate in the study.

Throughout the study, phone calls were made and faxes were sent at least two-monthly to all practices and nursing staff to remind them of the study. In addition, the RN provided prompt feedback about *all* patients referred to study to the referring clinician, as well as liaison (according to the trial protocol) with the GP about patients in the intervention group.

To study the recruitment process in more detail, the RA, RN and PI documented verbatim the reasons given by practice staff, GPs, PNs and community nurses during conversations (face-to-face and telephone) for non-participation. In addition, there was a nested qualitative study (reported elsewhere, Burroughs *et al*., 2006) which included 15 interviews with a sample of health professionals who had agreed to participate and refer patients into the study (9 GPs, 3 PNs, 2 DNs and 1 ACM) to explore their attitudes to depression in older people, as well as to participating in research, and to the PRIDE trial in particular. Interviews were taped, with consent, transcribed verbatim and the transcripts read and discussed by researchers from different professional backgrounds (primary care, nursing and psychology). Constant comparison (Strauss, 1986) was used to identify thematic categories which were then tested and explored in subsequent interviews. The themes relating to engagement with and referral to the PRIDE trial are presented in this paper.

Results

This trial achieved on-target recruitment (see Figure 1) with referrals being made by GPs, PNs, DNs and ACMs.

In total 180 referrals were received from 64 health professionals – the majority being from GPs (54). These 54 GPs were based in 25 out of the 42 practices within the PCT.

Interestingly, two practices who actively replied to the initial letter to say that they were definitely not interested in participating (one citing GP shortage and the other not specifying a reason) did refer patients once the trial was underway. Similarly, two practices agreed to a face-to-face meeting with the researchers and did agree at this meeting to participate in the study, but sent no referrals to the study.

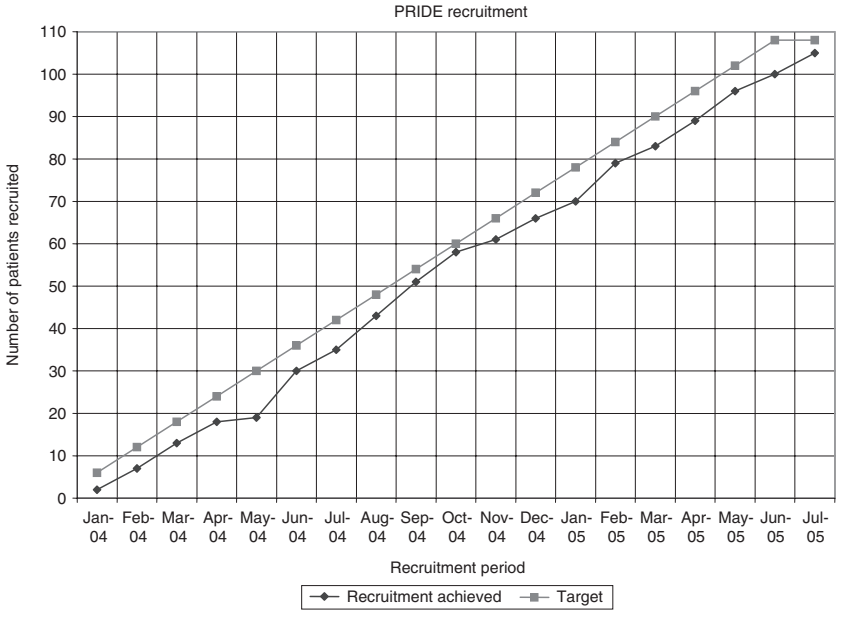

Figure 1 Numbers of patients recruited (NB the original target of 100 was raised to 108 to take account of dropout)

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Meeting community staff was important and this was achieved by discussion with local Managers. All community staff (groups of DNs (4 groups) and individual ACMs (5)) who met with the researchers agreed to participate and refer to the study but referrals were only received from 5 PNs, 4 DNs and 1 ACM.

Reasons for non-participation

Table 1 summarizes the main reasons given by practices at the start of the trial for not wishing to participate.

In 17 practices no direct contact was achieved with the GP or practice nurse, despite letters and faxes sent directly to the GPs. In some cases it appeared that practice support and administration staffs were refusing the request to participate in the study citing heavy work-load or the practice 'not participating in research.' It is difficult to know whether the decision was being made by the support staff or whether they were implementing long-standing practice policy. Single-handed GP practices made up the bulk of those who refused to participate (12 out of the 17), although only 4 practices actually gave that as a reason for not wishing to participate. Two practices cited the new GP contract and the increased work-load that this was perceived to bring (Department of Health, 2003). As the study was carried out at the time the contract was being introduced, with frequent references to increased work-load in the GP press, it is perhaps surprising that this was not cited by many more GPs.

Interestingly lack of remuneration was not given as a reason by any GPs for not agreeing to participate in the study, which suggests that payment is not a prime motivator for GPs to participate in research. This contradicts the findings of Richards *et al*. (2001) who report that lack of remuneration was a problem in recruiting GPs to being involved in research.

Some GPs initially voiced concern over the perceived risk of their patient being randomized to the usual care arm of the study, but following discussion with the research team this did not seem to be a barrier to recruitment, as the GPs who expressed such initial concerns subsequently referred patients to the study.

Table 1 Reasons for non-participation (practices)

Reason given	Number of practices
Practice population (city centre practice – no elderly)	1
'No-one interested' – a response from practice managers	2
'We don't do research'	1
'Already involved in research'	2
nGMS Contract	2
Being single handed	4
Staff shortage (including GP vacancy)	2
Heavy work-load	2
Building work	1

Reasons given for participation

Table 2 outlines the reasons given by health professionals within the semi-structured interviews, for agreeing to participate in the study when first approached. It seemed that the information about the study given to health professionals led health professionals (particularly GPs) to feel that the study would offer them support in the management of patients in an area either in which they had limited expertise or where there was little other resource available. GPs particularly suggested that the availability of the Trial Nurse offered some sort of service for patients with whom they were having difficulties in terms of diagnosis, even if the patient was subsequently randomized to the Control arm of the study, and an intervention for patients randomized to the Intervention group, again emphasized because there was no other service for elderly people with mild/moderate depression in their PCT. All health professionals who had referred to the study mentioned the simple referral process was helpful, although many admitted forgetting about the study in their day-to-day work.

Reasons for continuing to refer to the study

Themes from the qualitative study about continued engagement in the study are presented in Table 3. All participants referred to the responsiveness of the Trial Nurse who usually made contact with the patient within two working days of the referral being made. Health professionals who had referred a patient to the study described satisfaction with the response and a sense that their patients (and themselves) were gaining benefit from the referral.

All health professionals valued the feedback from the initial assessment by the Trial Nurse,

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Table 2 Themes relating to decision to agree to participate in PRIDE trial (all health professionals)

Reason	Data
Trial perceived to offer a service to primary care:	
Support in management of patient in an area that HP has limited expertise (GPs, PNs, DNs and ACMs)	'We were trying to do a little bit of what you were doing on our own 'cos we were being quite holistic and we were doing mini mental states and we were doing depression screening and we were sending it to the GP and nothing really ever happened, it would be unusual if a patient was referred. 'DN 2
Potential service for patient if randomized to intervention group (GPs and DNs)	'Well, we have nothing else to do with this group of patients, at least it was something.' PN 1 'I don't ever refer these people (*older people with depression*) on anywhere, there is nowhere, so this is great, even if they ended up in the Control group, I felt they had received something extra.' GP 7
Assessment of patients in whom they were experiencing diagnostic difficulty (GPs)	'It's always interesting to get somebody else's view about a patient.' GP 5 'There was another one which was very helpful for me in that I referred somebody who I thought had a, probably a mild to moderate kind of reactive depression… and it was helpful to me in that it supported, actually the CPNs view supported my view of what was hap pening and gave me a bit more confidence in pressing on with it… and that actually was helpful for me because it triangulated my view.' GP 7
Simple referral process with minimal extra work-load	'Fine, a straight forwards process, sometimes hard to remember to do it, things happened, I got feedback on what was happening.' GP 3 'The (*referral*) form was so simple, it was no hassle to refer on.' PN 3

Table 3 Themes relating to reasons for continuing to refer (all Health Professionals)

Reason	Data
Responsive Trial Nurse	'There was a real sense, particularly with her, that if she was going to (*accept help*) you needed to seize the initiative and do it fairly quickly. Because if it was going to be – someone will send you an appointment in three or four months – then I think it would be very likely that she'd ignore it. So it's brilliant and the CPN visited her.' GP 5
Feedback from initial assessment	'I would say that PRIDE and (*names a scheme*) are the best referrals that we can do. That might only be because you're the only agencies that we get feedback from because we don't know with (*names a different scheme*) and social services and the rest of it 'cos we don't get anything back.' DN 2
Trial perceived to offer a service	Q: 'What's your experience been (*of the trial*)?' A: 'Brilliant. Overwhelmingly brilliant… and just that one visit (*initial assessment*) was therapeutic for her.' GP 5 Q: Have you found it (*the PRIDE Trial*) alright? A: Mm yeah, it's good. Yeah they (*the patients*) like it, they all like it….they all seem to have done well really. GP 8 'Well there's nowhere else to send these patients, so they get something out of it, as do us GPs who are doing the extra work.' GP 9

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whether or not the patient was eligible for the study or randomized to the Intervention arm of the study. This feedback was felt to offer support to the responsible clinician in the future management of the patient. If a patient was randomized to the Intervention group, this was described as an 'excellent service' by some of the respondents whose patients had been part of it.

Conclusions

This paper describes the results from an RCT located within primary care where target recruitment was achieved. The qualitative aspect of the study illuminates the reasons for succeeding in recruitment and provides valuable lessons for the embryonic Primary Care Networks (Department of Health, 2006).

Not all practices engaged with the study despite very intensive 'marketing' of the trial within the PCT, and in some cases the decision not to learn more about the study seemed to be made by administration staff (in particular in single-handed practices), but when declined by the GP personally 'heavy work-load' was cited most frequently as a reason not to participate in the research. A limitation of the study is that no in-depth interview work was possible with these non-participating GPs, just the telephone discussion with the RA or PI.

Those health professionals who did agree to participate initially, continued referring patients to the study and helped achieve on-target recruitment because the trial was perceived to be local, relevant and offered an additional service to them in the day-to-day management of a particularly underserved patient group. In addition, the swift response of the Trial Nurse in assessing patients and providing feedback helped to remind health professionals about the study and encouraged them to keep referring patients to the study.

There did not seem to be an inherent contradiction between research and delivery of care in the minds of the clinicians, as asserted by Hunt *et al.* (2001). This may have been because the referral form and process was very simple, but was possibly also because the study was perceived to offer a service to the patient by many of the referring clinicians: an initial assessment of the patient with feedback and an intervention which included them and provided information and advice on the continued management of the patients in the intervention arm of the study (Chew-Graham, in press).

The development of Primary Care Networks, a new national policy initiative (Department of Health, 2006) is intended to facilitate recruitment of patients from primary care to research trials. Our study, however, suggests that financial remuneration or developing a research infrastructure is not necessarily the issue, but making trials relevant and responsive to local need, so that health professionals feel that they and their patients *get something out of it*, rather than just referring patients into someone else's study, seems to be a more important factor.

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Competing interests

None declared.

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