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Recruiting opiate users to a randomized controlled trial in primary care: a descriptive study of GP attitudes

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Historically, few randomized controlled trials (RCTs) have been conducted in primary care and problems have been experienced applying this methodology in these settings. In 2001, The Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) was developed. This RCT aimed to compare two detoxification drugs to inform best practice for the treatment of opiate users presenting to primary care requesting detoxification. This paper presents descriptive data from a postal survey of 12 general practitioners (GPs) from 10 primary care practices who were involved in the LEEDS trial. The questionnaire was sent out in November 2004, used open and closed questions and was self-administered. It uncovered factors that affected patient recruitment, GPs' views on the trial and their experience of randomizing opiate using patients. Flexible solutions to overcoming recruitment difficulties are presented alongside idealistic solutions to the problems experienced. The implications of our experiences of conducting this RCT in primary care practices are discussed in the light of conducting RCTs in primary care settings. This will benefit other research teams and clinicians who may be planning to use a similar research methodology.

Key words: general practitioners; opiate detoxification; primary care; randomized controlled trial

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Introduction

The UK has an extensive market for the sale of illicit opiates, particularly heroin, although actual prevalence figures are difficult to establish (National Treatment Agency for Substance Misuse, 2002). The severe physical and psychological symptoms associated with heroin withdrawal often leads people who are addicted to opiates to present to primary care services requesting detoxification. Drugs are prescribed to help people dependent on opiates become abstinent. Historically, primary care has been reluctant to engage with this patient group and only a minority of practices have provided drug treatment for people abusing opiates (Glanz and Taylor, 1986). However, the introduction of the Royal College of General Practitioner's (RCGP) Certificate in the Management of Substance Misuse in 2002 has led to increasing numbers of primary care professionals becoming involved in this aspect of care.

There are few randomized controlled trials (RCTs) evaluating the effects of different drugs for opiate detoxification and, understandably, current UK drugs policy for rapid opiate detoxification does not recommend a 'drug of choice' (National Treatment Agency for Substance Misuse, 2002). Traditionally, methadone has been most commonly used (Seivewright, 2000) yet patients often report distressing symptoms in the latter stages of methadone withdrawal (Wolff *et al.*, 1997). This has

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led to the use of alternative detoxification drugs such as clonidine, lofexidine, dihydrocodeine and buprenorphine. Dihydrocodeine has less distressing withdrawal symptoms than methadone (Strang *et al.*, 1999) but has rarely been studied for the purposes of opiate detoxification (Banberry *et al.*, 2000). Buprenorphine – dissolved under the tongue – is thought to have a lower withdrawal severity when compared with methadone (Bickel *et al.*, 1988). Although buprenorphine and dihydrocodeine have been compared for postoperative pain (Masson, 1981) they have never been directly compared in a randomized trial for opiate detoxification.

Recent information, *targeted at drug users who wish to detoxify*, recommends a move away from dihydrocodeine towards buprenorphine (Preston and Malinowski, 2003). However, this recommendation is not based on evidence from randomized trials. The authors developed a protocol for the Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) (Oldham *et al.*, 2004). This RCT sought to assess the efficacy of buprenorphine and dihydrocodeine for withdrawal from illicit opiates before the use of buprenorphine became ubiquitous within primary care. Between August 2002 and October 2004, 60 people were randomized and followed up within this small but highly successful study. It introduced randomization where little had been undertaken before and demonstrated that evaluative high-grade research can be undertaken in the context of everyday care. However, conducting RCTs amongst general practice populations in primary care has been noted to be problematic (Hetherton *et al.*, 2004; Tognoni *et al.*, 1991; Ward *et al.*, 1999; van der Windt *et al.*, 2000; Wilson *et al.*, 2000). Reasons for this may be clinical equipoise and patient preference (Ward *et al.*, 1999) along with practical problems and over optimism regarding recruitment (van der Windt *et al.*, 2000).

This paper presents descriptive data from a postal survey of general practitioners (GPs) involved in the LEEDS trial regarding factors that affected patient recruitment, GPs' views on the trial and their experience of randomizing. Flexible solutions to overcoming recruitment difficulties are presented alongside idealistic solutions to the problems experienced. The implications of our experiences of conducting this trial will be discussed in the light of conducting RCTs in primary care. This will benefit other research teams and clinicians who may be planning to use a similar research methodology.

Method

Practice recruitment

We recruited general practices through the Leeds Shared Care scheme, a network of 50 practices with particular involvement or interest in substance use. We presented the trial protocol at a network teaching event where GPs had the opportunity to sign an expression of interest form. During the 'first wave' of recruitment in May 2002, 17 practices indicated interest in the trial and estimated the number of people using illicit opiates who presented for detoxification over a six-month period. Practices with less than two detoxifications in six months had to be excluded for reasons of feasibility. Seven practices became involved in the LEEDS trial representing a total of nine doctors. In September 2003, three further practices were recruited to the trial, bringing the total to 10 practices and 12 GPs.

The GP practices involved in the trial were geographically dispersed throughout the city and opiate users were recruited from differing socioeconomic environments. A city centre practice serves the homeless population whilst other practices were in suburban areas with a largely housed population. Practices were not involved in the trial if they did not see enough drug users or had not expressed an interest. We believe that the practices which were involved in the trial were those with higher numbers of opiate using patients presenting for detoxification.

Trial methodology

The Local NHS Research Ethics Committee (LREC) approved the study in April 2002. Drug using patients presenting to primary care services for opiate detoxification were verbally informed about the study by their GP or drugs therapist. If patients met the inclusion criteria (Oldham *et al.*, 2004), they were given information leaflets and decided if they wanted to be involved in the trial. Willing patients gave written, informed consent and were subsequently randomized. The randomization process involved the GP opening the next consecutive envelope in a 'pre-randomized' set which was held in the consultation room. The opaque envelope contained the name of either *dihydrocodeine* or *buprenorphine*, and the patient was then prescribed either of these drugs. An on-site urine sample was requested from each person entered into the trial and the outside of the

randomization envelope was used to record the patient's practice reference number, date of birth, contact telephone number and date of first prescription. This brief information was completed by the GP for each randomized patient. The GP also completed two questions which served to rate the severity of the participant's addiction. Normal clinical care resumed and the patient saw the GP and/or drugs therapist as usual. When participants visited the practice to collect their final prescription, they were asked to provide an on-site urine sample which was tested for opiate metabolites. Any adverse effects were noted. Secondary outcome data was obtained from participants' medical records at three and six months post-detoxification and have been described elsewhere (Oldham *et al.*, 2004).

Questionnaire design

We devised a postal questionnaire in order to gain an understanding of how the GPs viewed the practicalities of recruiting patients and being involved in the LEEDS trial. This was sent out in November 2004 to all GPs ($n = 12$) who had been formally involved in the trial and had received randomization materials. This included GPs who had randomized people and also GPs who had not. Therefore, the whole population of GPs involved in the trial were sent the questionnaire in order to ascertain the views of all GPs. The questionnaire addressed:

- How more participants could have been randomized.
- What (if anything) the research team could have done differently.
- Positive aspects of the trial for either the GP or the drug user.
- Views regarding the possible impact of incentive payments to the GPs or participants.

The project team devised the topic areas of the questionnaire in consultation with a GP who had randomized people into the trial (Appendix). The postal questionnaire was self-administered by GPs. A stamped addressed envelope was included for ease of return. The research team were mindful of the difficulties encountered by Hetherton *et al.* (2004) who experienced problems in gaining feedback on their RCT. Consequently, the questionnaires were deliberately short, asking a total of 10 questions. We used closed questions with a limited number of tick box answers to facilitate the collection of basic data and ideas. Discussion with GPs led to the development of categories for closed questions. Space was provided for the GPs to make further comments or provide explanations after each closed question. One open-ended question was included in the questionnaire which allowed GPs to elaborate regarding any aspect of the trial. We made many attempts to maximize response rates (Barclay *et al.*, 2002) which included telephoning any GPs who had not returned the questionnaire within three weeks and leaving messages with practice staff to remind the GP to complete the questionnaire. One GP completed it via email. The response rate was 91.6% ($n = 11$).

Questionnaire analysis

The small sample size of participating GPs precluded statistical analysis of the survey. Answers to closed questions were accumulated to identify what was most and least important to the GPs. Any comments provided as free text were categorized into topics. Where applicable, attention was paid to distinguishing between more than one topic in a single response. A summary of each topic was then written up.

Results

Analysis of the LEEDS trial is currently being undertaken. This paper reports reflections on conducting the trial and factors affecting recruitment as identified through a small questionnaire survey of the GPs involved in the trial. Any other issues communicated informally throughout the running of the trial were noted as 'field notes' and are also discussed. How we sought to overcome the factors affecting recruitment of opiate users into the trial by the GPs are then examined. Issues which the GPs did not consider a problem when randomizing patients are also discussed.

The LEEDS trial had 60 participants. Six months after the 'first wave' of recruitment, four practices had only randomized a total of six patients. Two practices had not randomized anyone. Over the whole period during which randomization took place one practice randomized 19 patients and one other a total of 35 patients. Three further practices became involved during the 'second wave' of

recruitment with one appearing very enthusiastic. However, only one participant was randomized from these newly recruited practices.

Problem 1: patient preference

Patient preference was a major factor which hindered randomization in this trial. Five out of six GPs who randomized at least one patient into the trial stated in their questionnaire that treatment preference was a main reason why they did not randomize more patients. One GP stated: 'they [patients] commonly had a preference!' (GP 9). There are many anecdotal reasons for patient preference.

Using buprenorphine entails daily 'pickup' from a specified pharmacist which often conflicts with the chaotic lifestyles of many drug users (Preston and Malinowski, 2003). A few patients also told their GP that this would be problematic due to work commitments. Taking dihydrocodeine entails less engagement with pharmacists but involves taking more tablets, more frequently than buprenorphine. A dihydrocodeine detoxification regime could therefore be regarded as more difficult to adhere to.

Previously failed detoxification regimes also played a part in patient preference. Indeed, patients were often reluctant to be prescribed a detoxification drug which had not led to them successfully achieving abstinence in the past. The influence and experience of other drug users also contributed to their preference, with patients stating that others had experienced unpleasant adverse effects from a certain drug. In a few cases, patients wanted to do their detoxification with a partner or friend and so wanted to be sure they received the same detoxification drug.

Potential solutions

To work with patient preference, one GP gave patients their choice of detoxification drug, but discussed being randomized into the trial at a future date should detoxification fail. Many patients were amenable to this suggestion. Some patients, however, had made this 'commitment' yet returned a second time with a strong preference for a particular intervention, which of course was always respected, and they were not randomized.

RCTs are viewed as the 'gold standard' of medical research (Sheikh *et al.*, 2002) but, as we have seen, patient preference is a large obstacle to recruiting participants (Ward *et al.*, 1999). One solution may have been to use cluster randomization (Donner and Klar, 2000). Then the unit of randomization could have been the general practice rather than the individual patient. This decreases patient choice as everyone wanting a detoxification from opiates within one practice would receive the same treatment regimen to which *the practice* had been allocated. A positive aspect of cluster randomized trials is the reduction in time burden on clinicians as they only have to explain one treatment. However, various ethical considerations must be taken into account when designing cluster randomized trials and concerns may arise if treatment options are artificially withheld from patients in some clusters (Medical Research Council (MRC), 2002).

Problem 2: the decline of detoxification

Seven of the eleven GPs reported that people misusing opiates were presenting to primary care less for detoxification and more for maintenance treatments. Some patients require the support of prescribed drugs for several months (Strang *et al.*, 1999) rather than achieving abstinence rapidly as is the case with detoxification. As detoxification regimes can have high relapse rates there has been a recent policy move towards opiate maintenance prescribing (RCGP Certificate in the Management of Drug Misuse Handbook). One GP stated on the questionnaire: 'I'm afraid most patients are requesting stabilisation treatment – [I have] had no-one requesting detox for ages!' (GP 8). Inevitably, this meant a reduction in the number of patients being randomized into the detoxification trial as some GPs changed their prescribing attitudes and moved more towards maintaining patients. One doctor commented 'I have moved towards a more substitute prescribing approach' (GP 3) and another wrote 'I have reduced the number of detox's prescribed and have been putting patients on maintenance' (GP 5).

Potential solutions

The researchers could do very little to change the general decline in detoxification prescribing. As clinicians and researchers, we have recognized that issues of detoxification and maintenance are subject to trends and that we are now currently in a phase where, in the north of England, detoxification is losing ground to maintenance regimes. However,

issues about detoxification will remain pertinent for a substantial number of people. With more resources we could have captured a wider group of GPs and increased recruitment.

Problem 3: drugs therapists' time and work-load

In some primary care practices, drugs therapists meet patients to prepare them for detoxification prior to their GP appointment. If a patient was eligible for the trial, this meant the therapists needed to explain the protocol and effects of *both* detoxification drugs, increasing their work-load. The therapists were concerned that information on two detoxification drugs in one appointment confused patients.

Potential solutions

Once this problem was realized, drugs therapists in some practices started randomizing suitable patients and then referred them to the GP. This was only done if they believed that both buprenorphine and dihydrocodeine were equally suitable for the patient. This resulted in some success at practices where the therapists felt comfortable to randomize. However, some therapists did not want to randomize patients as explaining the project, obtaining informed consent and randomizing was seen as extra work-load and so the same problem continued in some practices. One GP commented that 'better prep of patients by AT [addiction therapist]' (GP 5) would have encouraged them to randomize more patients.

Problem 4: GPs' time and work-load

Insufficient clinical time was *not* viewed as a problem which significantly affected GPs randomizing into the trial as only three GPs stated that time pressure affected randomization. This was possibly because the trial was pragmatically designed to have a minimum impact on clinical practice, both in time and effort in busy primary care settings. The LEEDS trial is an example of how RCTs can be designed to fit into everyday care, even the busy primary care practice.

Problem 5: equipoise

Drug therapists often anecdotally viewed buprenorphine as the 'better' detoxification regime. Dihydrocodeine has been used for many years in the field of substance misuse whereas buprenorphine is a relatively new drug for the purposes of opiate detoxification. Any new treatment could be seen as carrying new hope of improvement in this difficult group of patients and for some time this will facilitate its use, no matter what the evidence of the effects of the new treatment. Certainly, buprenorphine may be seen as easier to manage because it only requires one tablet to be dissolved under the patient's tongue, once a day. In comparison, dihydrocodeine involves taking multiple tablets several times a day. Lack of equipoise often made it hard for drug therapists to advocate buprenorphine for their patients.

Two out of the six GPs who did randomize patients stated they did not have genuine equipoise between buprenorphine and dihydrocodeine, when answering a closed question. Neither GP expanded on this although one stated that 'before the patient came to into the consultation a decision had already been made, usually in discussion with their [patients] drugs worker' (GP 2). Another GP said 'patients generally came in with a preconceived idea of the type of detox, often influenced by the therapist' (GP 7).

Potential solutions

We held a meeting with drug therapists when the problem regarding equipoise of the two treatments was realized. Explaining that the purpose of the trial was to provide an evidence base for the efficacy of the two treatments did not change the minds of the therapists. It did however, help the research team understand why equipoise was a problem, yet this issue was beyond their control. More preparation of all people involved in the care of patients before the study started may have gone some way to dispelling this problem.

Problem 6: incentivization

The issue of incentives is problematic and opinions remain divided. Neither randomized patients nor GPs received any economic incentive for taking part in the trial. The trial was only funded for a part-time research assistant for one year and no monies were provided for incentivization. Sponsorship was not sought from pharmaceutical companies as the team sought to maximize the independence of research activity. Asking GPs to

take part in a clinical trial for no fee whatsoever was daunting. As such, the project relied on the goodwill and interest of GPs for its continuation. Inevitably, this meant that everyday practice demands conflicted with the trial and it became a low priority on the agenda of some practices.

Three questions were asked regarding the use of economic incentives in the questionnaire. Only two GPs stated that incentives for the doctors would have encouraged them to randomize more people into the trial. One GP thought the practice should have received extra funding whilst the other wanted a cash incentive for GPs to randomize. None of the GPs thought that incentives for patients would have encouraged them to randomize more people. Therefore, eight GPs thought that incentives would not have made any difference to their participation in the trial.

Potential solutions

It is common practice to pay research participants for their involvement in research (Ritter *et al.*, 2003). Ideally, the solution would have been to incentivize participation in the trial (both to patients and clinicians) on a per patient basis though this has significant resource implications.

Positive aspects of the trial

In this paper we have highlighted several problematic areas of this study but the survey also illustrated the strengths of the design. All GPs who randomized patients believed that the trial was simple in design and felt that involving drug users in research was important. Most GPs felt they were contributing to important research and that the trial was easy to implement in everyday practice. Some GPs remained enthusiastic about randomizing patients throughout the trial.

One practice randomized 35 patients into the trial whilst another randomized 19, as compared with less than five from all the other practices involved. It is particularly notable that these two practices contained GPs with a special interest in substance use. This comprises both the problem and the solution. Although having a special interest clearly facilitates the study, centralization of interest and skills may not help dissemination of research skills. However, for those simply wishing to ensure that the research is undertaken quickly and efficiently specialist centres certainly have advantages. GPs with a special interest are a recent development in the primary care field (Gerada *et al.*, 2002). Our experience has shown it is possible that their commitment, enhanced knowledge and expertise in a specific area can be harnessed to develop research capacity and activity in the primary care setting.

Discussion

It is acknowledged that many clinical decisions are made in the general practice setting without the support of a robust evidence base for them (Horton, 1999). Consequently, there have been calls to increase the quantity and quality of evaluation activity in primary care. This is particularly pressing in the treatment of drug users as there has been a significant increase in the number of GPs becoming involved in the care of drug users over recent years (Davies and Huxley, 1997).

The LEEDS trial was successful in developing a research capacity within the primary care environment which is typically unused to participating in RCTs. Busy practitioners randomized 60 people misusing opiates, which is a significant achievement given the problems often encountered (van der Windt, 2000; Ward *et al.*, 1999; Wilson *et al.*, 2000). Recruitment gradually decreased over time and the decision was made to close recruitment at 60 participants. The trial was never 'abandoned' as has been noted in previous RCTs conducted in the primary care setting (Fairhurst and Dowrick, 1996).

The complexities of randomizing in primary care were exaggerated in our study due to the characteristics of people misusing illicit drugs, who often lead time pressured, chaotic lifestyles. These characteristics may mean that the issues faced in conducting this trial were different to conducting trials in other areas of primary care research and with other patient groups.

The authors recognize that the trial sample size was small, but we believe that this trial highlights the importance of careful and sensitive setting of the research question and the high levels of commitment and energy needed. It shows how, even with small funding, trials of important questions for people who are difficult to manage are possible in primary care and that such research can be informative.

Randomizing illicit drug users in primary care is a challenging concept. We have shown that multiple

problems endangered the smooth running of the trial, rather than one overarching barrier. The project team believe that dissemination of the practicalities of running the LEEDS trial is an important part of sharing our experience with the research, clinical and wider communities.

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Appendix

The LEEDS trial

Practice identifier _____

GP identifier _____

This short questionnaire will provide the LEEDS project team with valuable feedback concerning the trial. Please answer all questions as fully as possible.

1. The following are statements about your awareness of the trial. Please tick the one you feel is most appropriate

A) I personally randomised patients into the LEEDS trial ☐ **Go to Question 2**

B) I remember the LEEDS trial randomisation materials being sent to me but I didn't randomise any patients ☐ **Go to Question 4**

C) I remember the LEEDS trial being discussed at Shared Care meetings but I had no further involvement ☐ **Go to Question 6**

D) I don't remember the LEEDS trial at all ☐ **Go to Question 8**

2. What would have made you randomise **more** patients into the trial? (Tick as many that apply)

Less busy/more clinical time ☐
More support from the project team ☐
More progress reports from project team ☐
Better communication from project team ☐
More drug users requesting a detox ☐
If my patients didn't already have a treatment preference ☐
If my patients were equally suited to both treatments ☐

Other _____
_____
_____

Go to Question

3. What did you feel were the main positive qualities of the trial? (Tick as many as apply)

Felt I was contributing to important research ☐
Felt involving drug users in research was important ☐
The trial was simple in design ☐
The trial was easy to implement in everyday clinical practice ☐

Other _____
_____
_____

Go to Question 6A

4. What were the main reasons why you didn't randomise any patients into the trial? (Tick as many that apply)

Lost interest	☐	Too busy	☐
Forgot about trial	☐	Didn't know trial was still running	☐
Randomisation seemed too time consuming	☐	Didn't understand the LEEDS trial randomisation process	☐
Not seeing enough patients requesting detox	☐	Didn't feel project had been explained properly	☐
Wasn't sure of the aim of the project	☐	Poor communication with the project team	☐
Didn't feel the project team had involved me enough	☐	Decided that research question wasn't important	☐

Other ______________________________

____

____

Go to Question 5

5. What could the project team have done differently to have encouraged you to randomise patients into the trial? (Tick all that apply)

Explained the randomisation process more clearly	☐	Explained the overall project more clearly	☐
Communicated with you more frequently	☐	Provided you with more support or assistance	☐
Provided regular updates on the project	☐	Nothing – the project team could not have done anything differently to encourage me	☐

Other ______________________________

____

____

Go to Question 6A

6A. Would offering an incentive encouraged you to randomise (more) patients into the trial?

Yes ☐ **Go to Question 6B**

No ☐ **Go to Question 7**

6B. Who should this incentive been payable to?

Drug users ☐ The practice ☐ GPs ☐

Other ______________________________

6C. In what form would the incentive be?

Cash ☐ Vouchers ☐

Other ______________________________

7. If you have any comments you would like to make regarding any aspect of the trial then please do so below

____

____

____

____

____

____

Go to Question 8

8. Have you been personally involved in any other **clinical trials research** within your practice during the last five years?
Yes ☐ No ☐

9. Have you been personally involved in any other research within your practice during the last five years?
Yes ☐ No ☐

10. On average, how many drug users did you see in clinical practice in the last year?
None ☐ 1–10 ☐ 11–20 ☐ 21–30 ☐ 30+ ☐

Thank you! Please send this questionnaire back to Laura Sheard in the pre paid envelope provided by 19th November 2004