Primary Health Care Research and Development 2004; **5**: 5–10

Recruitment by GPs during consultations in a primary care randomized controlled trial comparing computerized psychological therapy with clinical psychology and routine GP care: problems and possible solutions

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A randomized controlled trial was conducted to assess the efficacy of a computerized therapy programme for depression and anxiety, 'Beating the Blues', compared with cognitive-behaviour therapy provided by clinical psychologists and treatment as usual by general practitioners (GPs). The aim of the paper is to describe the study, the problems that were encountered when GPs agreed to recruit participants during consultations and to outline possible solutions to these problems. After three months only five participants had been recruited prompting modification of the study design. After one year only 17 patients had been recruited and the study was discontinued. The GPs indicated that the randomization procedure compromised their traditional role of providing patients with the best possible treatment. This produced role conflict that was resolved by GPs adhering to their care-giving role at the expense of recruiting to the study. GPs also felt that discussion of research took too much time during consultations and was inappropriate given that patients were often somewhat distressed. They also did not see the three treatment arms as equally acceptable, which resulted in GPs failing to recruit patients in case they were randomized to what they considered to be inferior treatments. Competing demands that rendered the study a low priority were also reported. We incorporated suggested solutions to these problems into the study which was rerun and completed after one year with 40 patients having been recruited.

Key words: GPs; methodology; RCTs; subject recruitment

Introduction

Primary care has been highlighted as an NHS research priority, a factor that has led to more research being conducted in primary care settings. Carrying out research in a dedicated clinical environment, however, has proved extremely problematic to some investigators. Tognoni *et al*. (1991) found that over 90% of general practitioners (GPs) who agreed to recruit patients for a randomized controlled trial (RCT) failed to enrol any patients. Like Tognoni and his colleagues, Fairhurst and Dowrick (1996) had to discontinue their RCT when only one patient was recruited by one of 25 participating GPs in a five-month period. Our experience of using GPs to recruit for a randomized controlled trial in a primary care setting is presented below.

Our study sought to investigate the efficacy of a computerized therapy programme for anxiety and depression, 'Beating the Blues', compared with therapy provided by clinical psychologists or treatment as usual by GPs. Traditionally, treatment of

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10.1191/1463423604pc168oa

patients with anxiety and depression involves GP support plus medication and/or onwards referral to a mental health professional such as a clinical psychologist or a counsellor (Gray *et al*., 2001). Both of these interventions are problematic, however. First, many patients refuse medication or stop taking it prematurely (Gray *et al*., 2001). Secondly, mental health professionals are a scarce resource that cannot meet the demands from the community. This dilemma has led to consideration of self-help as an alternative means of meeting the needs of this population. Most recently, this has taken the form of computerized psychotherapy with a proliferation of programmes for different disorders being developed (Burgess *et al*., 1994; Ghosh and Marks, 1987). Contrary to initial concerns about the dehumanizing effects of having patients interact with machines, studies to date have not reported any opposition from patients to using computers and drop-out rates are comparable to those found in face-to-face therapy (Gray *et al*., 2001).

Whilst initial studies are encouraging, it is important to find out the extent to which computer treatment packages are as effective as existing treatments available in the surgery, specifically, GP support and therapy by a mental health professional; that is, to establish whether computerized therapy is comparable in respect of patients overall improvement.

We conducted a RCT comparing three options for treatment for anxiety and depression:

- 'Beating the Blues' – eight once-weekly sessions supplemented by summary sheets and homework tasks for completion between sessions. A research assistant was available to assist with any technical problems.
- Clinical Psychologist – up to eight sessions of cognitive-behaviour therapy within a three-month period.
- GP – appointments as regularly as patients wished.

Method

Preliminary meetings were held at which the rationale for the research and an outline of the research proposal were presented to GPs in five practices. Seven GPs from two large general practices in inner London agreed to participate. These practices served a wide and varied population and had space to accommodate a psychologist and a computer assistant. The primary care teams used were interested in research and mental health issues and all GPs were experienced. One in each practice had a particular interest in mental health: one as a primary care group mental health representative and the other as a local research group member. The remaining GPs said they frequently recognized depression and anxiety in the course of their work. In meetings with the GPs and practice managers, the researchers presented the research proposal (including the nature of the study, its administration procedures and time implications), copies of the ethics committee approval letter and all the materials. The GPs agreed to recruit patients by administering a 12-item General Health Questionnaire (GHQ-12) to any patients who presented with anxiety and depression and who might be suitable participants (aged 18–65 and not currently receiving treatment). The GHQ has been used extensively as a reliable screening questionnaire in primary care and takes only 2–3 minutes to complete and score. Interested patients whose scores exceeded four on the GHQ-12, having been informed about the study, gave consent to participate. They were then given the top envelope in a pre-randomized set of envelopes held at reception. The envelopes were stratified to ensure equal distribution of treatment groups in each surgery. The content of the envelope informed patients of the treatment group to which they had been allocated and outlined procedures regarding making appointments. Participants were also requested to complete the standardized questionnaires in the envelopes: the Beck Depression Inventory (BDI) and the Beck Anxiety Inventory (BAI), which provided baseline measures of severity of symptoms. Additional questionnaires established treatment preference and the patient's attitude to technology. No patients dropped out of the study between the GP's consultation and being given an envelope by the receptionist.

All patients completed weekly self-assessments of severity and distress caused by their presenting problem. They also completed the BDI and the BAI again at three and six months. Participants allocated to 'Beating the Blues' were sent a follow-up questionnaire to elicit qualitative information about their experience of using the programme.

https://doi.org/10.1191/1463423604pc168oa Published online by Cambridge University Press

Number and length of appointments were recorded, as well as the number of visits all patients made to their GPs. All patients had access to their GPs throughout the study.

After three months, only five participants had been recruited by the GPs. The researchers attended practice meetings where a new methodology was negotiated and agreed with the GPs. The revised design relieved GPs of some of the recruitment procedures and specifically of administration of the GHQ-12 which was proving time-consuming; GPs had also found it difficult to introduce the questionnaire to the patients. Instead, the GPs agreed to give patients who presented as depressed or anxious a brief information sheet describing the study. Patients then contacted the research team if they were interested in taking part and a research assistant administered the GHQ-12 and completed the recruitment procedure for suitable patients. Despite these changes, only 17 participants were recruited over a one year period, due to GPs not distributing the information sheet, rendering meaningful statistical analysis untenable. Consequently, the study was abandoned.

In order to identify the problems that undermined the study, a questionnaire was devised by the lead researcher. This sought to explore the issues that had been identified as problematic by the GPs. It also drew on a questionnaire which was developed by Fairhurst and Dowrick (1996) when their randomized controlled trial had to be abandoned due to GPs failing to recruit sufficient numbers of patients after initially agreeing to do so. The questionnaire addressed what had motivated the GPs to participate in the study, their expectations of taking part, and the difficulties they actually encountered once the study was under way (Fairhurst and Dowrick, 1996). The questionnaire was sent to all participating GPs inviting them to share their experience of involvement in the research. In spite of their early enthusiasm and cooperation, GPs failed to maintain interest and time in the study; only two of the seven questionnaires were returned despite follow-up requests. A third GP found the questionnaire too lengthy to complete and requested an interview in which he could represent the views of the other GPs in his practice as discussed in practice meetings and earlier meetings with the research team. This interview was structured around the questionnaire. The views of six of the seven GPs were therefore eventually represented. Advice was also taken from an independent research GP. Their responses were collated and the themes that emerged are presented below.

Results

Issues that compromised the study

The randomization procedure

RCTs are the only means of obtaining the evidence needed to recommend new treatments (Friedli *et al*., 1997). Although the GPs recognized the value of randomization and agreed to participate in the process, the majority of them found the procedure difficult in practice. The traditional responsibility of GPs is the well-being of individual patients which is promoted by directing them to the best possible treatment for their presenting problems. The randomization and recruitment procedures presented GPs with a competing responsibility, specifically, to prioritize scientific advancement from which future patients would benefit (Fairhurst and Dowrick, 1996). GPs were thus presented with an ethical dilemma between care of their patients and research interests, which was ultimately resolved, in the majority of cases, by adherence to their traditional role. The corollary of this was that patients were not entered into the randomization process. As one GP summed up '[The randomization process] is the reason why they didn't get into the study in the first place. It stopped it'.

The randomization process was also viewed as potentially raising hopes in patients that could lead to disappointment if they were not allocated to their preferred treatment. One GP reported that it was difficult to explain the usefulness/efficacy of the treatment options if there was only a one in three chance that the patient would get a particular one. Given that patients were already at least somewhat depressed or stressed, GPs were loathe to risk intensifying this and so 'did not refer patients unless [one] felt they could cope with randomization'.

Failure to meet needs of patients

Whilst GPs were motivated to participate in the study by the prospect of improved services for

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patients, when it came to randomizing patients, concerns about the treatment options emerged and ultimately hindered the recruitment process. Some GPs, although fascinated by the idea of computerized therapy, felt that the computer option was 'too impersonal' and would not meet the needs of the patients. This concern increased with the severity of the patient's distress, as indicated by a GP who reported 'The more depressed the patient, the more I'd be concerned about the computer not being human'. Conversely, other GPs viewed treatment as usual by GPs as inferior and believed that patients would be disappointed if they were randomized to the GP arm of the study as it did not represent a formal psychological treatment. This was particularly so if patients had explicitly requested psychological help. This highlights equipoise as a fundamental requirement of successful RCTs: all treatment arms being perceived as equally effective or ineffective by both the health professional and the prospective participant (Fairhurst and Dowrick, 1996).

Discussing research perceived as detrimental to the consultation

As the trial was concerned with patients who presented with depression or anxiety, recruitment involved raising the issue of the research with patients who possibly presented as emotionally vulnerable or distressed. It seems that this context undermined GPs' ability to introduce the issue of research at all. One GP lacked the desire to be involved in the recruitment process because 'to raise the research seemed alien to the atmosphere of the consultation'. Other GPs also found listening empathically to the patient's problems and then introducing the research, awkward and ultimately aversive. GP consultations are also extremely time-pressured and there were concerns that discussion of the research and administering a screening questionnaire took up too much time. To raise the research detracted from focusing on presenting problems and was felt to be detrimental to patients. This in turn led to a sense of discomfort in GPs. Consequently, in the interest of patient care and GP satisfaction, the research was often not mentioned.

Competing demands

GPs have a multitude of demands on their time. For recruitment to have been successful required the research to take precedence over other demands. This rarely occurred. When asked whether it was difficult to prioritize the study in the face of competing demands, one GP summed up their position as '[It was] Easy – it didn't get prioritized'. Another GP, not surprisingly, identified time spent with patients as his main priority and stated that the study was secondary to this.

Discussion

Research is essential for providing the evidence on which clinical practice should be based. However, clinical research presents very real challenges to GPs which may ultimately undermine research endeavours, as occurred in the present study. Our RCT proved problematic for a number of reasons. GPs lacked confidence in the treatment options such that they were viewed as unequal in terms of effectiveness. GPs also viewed raising the issue of research to distressed patients inappropriate and aversive. These problems may have been averted if the GPs had been more familiar with the available treatments. For example, in the present study if the computerized programme had been used by the GPs rather than simply demonstrated to them, their preconception that it was inappropriate for many patients may have been challenged. Confidence could also have been increased by the provision of published evidence demonstrating the equal efficacy of treatment options (Catalan *et al*., 1984a; 1984b). Research showing no differences in the efficacy of psychological interventions and GP care would have been relevant to the present study (King, 1994).

Most problematic was that involvement of GPs in the randomization process resulted in role conflict which led, in turn, to low levels of recruitment. A similar situation has been observed by other researchers (Fairhurst and Dowrick, 1996; King *et al*., 1994; Tognoni *et al*., 1991) and highlights a fundamental conflict when research and clinical care occur simultaneously (King *et al*., 1994). In their RCT of counselling versus treatment as usual by GPs, King *et al*. (1994) found that many GPs ignored the randomization process and directed patients instead towards the most helpful option. Subsequently, the GPs reported a preference for a third party to randomize participants. In the present study, however, despite the randomization process being devolved to a research assistant, recruitment

https://doi.org/10.1191/1463423604pc168oa Published online by Cambridge University Press

was still poor. This was due to other factors: difficulty in prioritizing the research in the face of competing demands and discussion of research detracting from responding to the patients' needs.

In retrospect, the present study may have been more successful if the study had been designed with GPs and service users involved from the outset. This may have increased GPs sense of ownership of the project which may have helped maintain their interest (Thomas, 2000; personal communication). More importantly, service users and GPs could have discussed and agreed the most acceptable means of introducing the research during consultations which may have increased GPs confidence in carrying out the recruitment procedure. Piloting of the study would also have been beneficial so that any problems with the recruitment and randomization process that emerged could have been resolved immediately. In the current study, the research team should also have considered mechanisms to recruit which did not rely on the GPs doing so. For example, recruitment could have been carried out by third parties, for example, members of the research team itself. Alternatively, reception staff may have been involved. Although reception staff in general practices are typically under considerable pressure, this latter strategy worked in another large RCT in a primary care setting in which reception staff gave out screening questionnaires which they were trained to score and then invited suitable patients to take part in the study. Recruitment, however, was successful only when surgeries were paid for their staff's involvement (Davidson, 2001; personal communication). This approach, however, does raise issues regarding patient confidentiality, and ways of responding to patients who presented as severely depressed or suicidal would have to be devised. An alternative option, which would fulfil the equipoise requirement of RCTs, would have been to use patient preference trial methodology in which only patients who expressed no preference for different treatments entered the randomization process. In the present study, although patient preference was recorded, a preference trial was not set up as much larger samples would have been needed.

Possible solutions

1) Studies are likely to benefit from the involvement of GPs and service users in their design. This could have the effect of increasing GPs sense of ownership of the research and their confidence in recruiting patients during consultations.
2) Previous research suggests that researchers should emphasize to GPs the benefits that can be expected from participation in the trial, and discuss in detail with GPs the implications of participating in the trial (Fairhurst and Dowrick, 1996) and how difficulties might be resolved. Piloting of recruitment procedures is likely to be of great benefit.
3) GPs confidence regarding randomization may be enhanced if they feel confident that the treatment options are equally effective. This may involve familiarizing the GPs with the treatment options for treatment, both theoretically and practically (for example, in the case of a novel approach such as computerized therapy), and, where possible, providing them with published evidence indicating equal efficacy.
4) Regular contact with GPs by the researchers may help to maintain the profile of the research in the face of competing demands.
5) Where GPs do not wish to be involved with the recruitment and randomization procedures as was the case in the present study, researchers could devise other means of recruitment that do not involve GPs directly. These could include posters and information sheets for patients in the surgery inviting people to participate in the research. Researchers or members of the practice staff, such as receptionists, could also introduce the research. Research suggests, however, that the latter will be successful only if staff are paid for their involvement. Any screening of patients by reception staff does raise issues regarding confidentiality however, and how severely depressed or suicidal patients would be managed.

Drawing on these possible solutions, we again modified our methods in the following ways and the study was rerun: 1) patients self-referred to the study from posters and leaflets in the waiting room; 2) a research assistant conducted the screening and randomization procedure; 3) patients were seen by clinical psychologists in the surgeries, thus maintaining the profile of the research; 4) the clinical

https://doi.org/10.1191/1463423604pc168oa Published online by Cambridge University Press

psychologists offered a consultation and therapy service in the practice for patients other than those in the study, as a way of paying the surgery for their involvement. Following these changes, whilst the study remained limited to two new practices of seven GPs in total, the study is now completed and 40 patients were recruited. Comparing patient's test results with published norms for the GHQ-12, BDI and BAI indicated that the patients were a representative sample of patients with a diagnosis of anxiety or depression.

Acknowledgements

We are grateful for the contribution made by Maleha Khan and Tejinder Kondel. We wish to acknowledge the work of Dr Judy Proudfoot in creating 'Beating the Blues' and supporting us with this research. Thanks also to Professor Jeffrey Gray and Professor Sir David Goldberg at the Institute of Psychiatry, and Dr Paul Thomas of Welren.

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