Controlled trials in the evaluation of counselling in general practice

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SUMMARY. In this paper the difficulties of conducting a controlled evaluation of counselling (brief psychotherapy) in general practice are discussed. Results of a pilot study indicate that patients referred by family doctors to counsellors are often seriously emotionally distressed and recovery is slow. Counsellors come from different backgrounds and use a variety of therapies. Although the results show that controlled research is feasible, in a definitive trial patients should be randomized in a stratified manner, according to severity, by the researcher after initial assessments have been made. Counsellors should have a recognized accreditation and preferably be employed for the trial to ensure uniformity of approach and avoid long waiting lists. Blind assessments of outcome are desirable but are not always feasible and reliance on patient self-report is important. Within the limitations of current knowledge, only controlled evaluations will provide a greater understanding of the efficacy of counselling in general practice.

Keywords: counselling; outcome measures; clinical trials.

Introduction

OUTCOME research in counselling (brief psychotherapy) is not merely an interesting scientific question, it is a necessary step to ensure ethical practice.[1] In recent years counsellors have emerged as a profession with their own associations, codes of ethics and methods of working.[2,3] The 1987 government white paper, *Promoting better health*,[4] led to an extension of part reimbursement of salaries of professionals other than general practitioners working in general practice. More recent contractual changes in the National Health Service, whereby family doctors act as purchasers, have also widened the range of professionals working in primary care. This eases the problem of payment for counsellors[5,6] but does not clarify respective roles and areas of expertise.[2] It may also add greatly to the costs of primary health care. Before scarce resources are committed it is essential that methodologically sound studies are undertaken to examine the efficacy of counselling.[7,8]

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Many previous evaluations of counselling in primary care have been limited in their findings or have failed to demonstrate whether or not patients benefit.[9] The multifarious nature of counselling is partly responsible for the confusion. A further obstacle has been a failure to use random allocation of patients to counselling and control groups.[10,11] Even when random allocation has been applied, studies have been hindered by restrictive selection criteria for patients allocated to the therapy, small numbers, ill-defined therapies and inadequate evaluation of outcome.[12-18] Some have even questioned whether controlling for the content of therapy or the training of the counsellor is necessary, suggesting that the relationship between counsellor and client is the most effective element in therapy.[12]

Tognoni and colleagues have highlighted the pitfalls in conducting randomized clinical trials of drug treatments in general practice.[19] Many doctors may agree to participate but few actually start to recruit patients. Much can go wrong in the recruitment, selection, equipping, training, motivation and quality control of participating primary care staff. Data coming from many sources may be mishandled or lost.[20] Many additional and complex problems may arise in controlled trials of psychological therapies in general practice. Experience of a pilot study is presented here in order to extend the debate about clinical trials in general practice.

Pilot study

This pilot study of the efficacy of counselling in general practice had three conditions:

- All patients presenting with psychological problems should be included in the trial. Restricting recruitment to patients with one diagnosis, such as depression, might more easily reveal treatment effects, but the results would be less relevant to the diversity of problems seen in general practice.
- A clear definition of counselling is required. The non-directive approach defined by the British Association for Counselling[21] can be reliably quantified for the purposes of research and is increasingly accepted as the bench mark for the provision of counselling in general practice.
- Outcome criteria must be valid and reliable. Although simple improvement ratings may mislead when the initial severity of the problem is not uniform, severity ratings (symptom scores on questionnaires or interviews) used repeatedly are nonetheless the best measurement of outcome at present.[22] Cost effectiveness in terms of prescribing or surgery visits is helpful, but not all patients referred are high consumers of services or drugs.[22]

The aim of the pilot study was to test the feasibility of a controlled comparison of counselling with standard treatment by the general practitioner. Subsidiary aims were to describe the patients whom general practitioners refer to counsellors and the types of counselling offered in primary care.

Two large, group general practices with five part-time counsellors took part. Patients regarded by the general practitioner as suffering an acute episode of emotional disorder or suffering from a long term problem but with a recent increase in symptoms were recruited. After ensuring informed consent, the doctor established whether the patient had a strong preference to see a

counsellor or to remain with the general practitioner. If strong preferences were expressed patients were given their choice; if not the patients were randomly allocated to either professional (patients were referred to the next available counsellor). This method, which has been used in other trials of therapy,[23,24] was tested in an attempt to modify strict randomization which has proved so difficult to implement in general practice in the past. Subjects randomized to the counsellor were taken on for six to eight sessions over 12 weeks, the time in which people are most likely to respond to counselling.[12] The remainder received routine treatment by the doctor.

Each subject was approached within two weeks of recruitment and before treatment by a research doctor (G B) for an assessment using a standardized interview (clinical interview schedule[25]) and three self-report questionnaires: the 28-item general health questionnaire,[26] the Beck depression inventory[27] and the social problems questionnaire.[28] Subjects in both groups were assessed again at 12 weeks and at six months. At the 12 week point a random half of subjects were interviewed and the remainder contacted by post. At this point general practitioners and counsellors completed a standard form for each patient detailing the number of consultations or counselling sessions and type of treatment or therapy given. At six months all subjects were re-interviewed; they also completed a questionnaire on their perceptions of counselling. Rates of general practice attendance and prescribing patterns for the six months after entry to the trial were collected from the practice records.

Summary of results

Twenty four patients (21 women and three men) were recruited to the pilot study (mean age 35 years, range 22–60 years). Of the 24 patients, 19 were referred to a counsellor and five remained with the general practitioner. Twenty two were followed up at 12 weeks and 20 at six months. The mean scores for the interview and questionnaires at each trial point are shown in Table 1. Of the 24 patients at entry, 20 (83%) scored 18 or above on the clinical interview schedule indicating psychiatric disorder requiring intervention. The mean number of sessions for patients seeing a counsellor was 10 (range one to 20). The mean time spent with the counsellor was 6.6 hours and for those randomized to the general practitioner 2.4 hours. Overall, the mean time spent with either the counsellor or general practitioner was 5.7 hours (range 30 minutes to 20 hours).

In pilot studies only trends can be observed. The mean duration of psychiatric symptoms at entry to the study for the 24 subjects was 15 months (range one to 60 months). Duration of disorder, however, was not associated with interview or questionnaire scores and only one subject reported previous psychiatric treatment. Problems were varied but mainly involved mixed anxiety and depression over relationship or marital problems. A smaller number suffered psychosomatic symptoms or difficulties related to childbirth or child care.

There was no significant correlation between time spent with the counsellor or general practitioner and change in psychiatric scores at six months. Duration of psychiatric symptoms at entry to the study also had no effect on outcome. There was a trend for patients who remained with the general practitioner to show greater improvements in their scores than those who were randomized to the counsellor, despite higher baseline scores in the latter group (Table 1). There was also a trend for patients who scored below the threshold of 18 on the clinical interview schedule at final follow up (nine patients) to have consulted the general practitioner less often and to have received fewer psychotropic prescriptions over the six months than those who scored above the threshold (11 patients) — mean of 5.0 general consultations versus 6.6; mean of 1.3 prescriptions versus 2.1.

Although most subjects found the intervention helpful, counselling was not without its side effects. Two patients said that they wished they had never started. A third, who revealed to the counsellor that she was being physically assaulted by her husband and son, felt abandoned when only four therapy sessions were considered necessary by the counsellor.

Comment

Patients

The patients were more seriously disturbed than had been envisaged. This has changed our view of expected recovery rates and alters our estimation of numbers required for a definitive trial. When this was discussed with the participating doctors, it appeared that limited access to local psychiatric services was an important consideration in their referrals. The counsellor was sometimes the only person to whom a prompt referral could be made. The appropriateness of such referrals is questionable,[29] however, and the slow recovery that occurred over the follow-up period may have reflected the difficult therapeutic challenge these patients presented to the general practitioner or counsellor.

If subjects with this level of distress are to be entered into a substantive trial it would be necessary to stratify the randomization on the basis of severity of psychiatric distress. Stratification reduces chance differences between random groups and ensures that the interaction between severity and outcome can be examined. An upper limit to psychiatric scoring, above which patients

Table 1. Mean scores for the interview and questionnaires at each trial point.

	Mean score								
	Entry			12 weeks			6 months		
	GP patients (*n* = 5)	Counsellor patients (*n* = 19)	All (*n* = 24)	GP patients (*n* = 5)	Counsellor patients (*n* = 17)	All (*n* = 22)	GP patients (*n* = 5)	Counsellor patients (*n* = 15)	All (*n* = 20)
Clinical interview schedule	28.2	32.4	31.5	19.0[a]	21.6[b]	20.9[c]	10.2	21.9	18.8
Beck depression inventory	18.0	22.8	21.9	10.8	15.6	14.5	9.4	16.2	14.5
General health questionnaire	10.4	13.7	13.0	4.8	9.2	8.2	3.0	9.8	8.1
Social problem questionnaire	1.2	2.1	1.9	1.6	1.4	1.4	1.4	1.5	1.5

n = number of subjects in group. [a]4 subjects interviewed. [b]11 subjects interviewed. [c]15 subjects interviewed.

would not enter the trial but would be referred to the psychiatric services, might also be appropriate.

The principal assumption in many controlled trials is that all participants have a common diagnosis and that a uniform measure of outcome is possible. However, this has been criticized on the basis that individuals have their own unique patterns of pathology and restitution.[30] One result has been the popularity of randomized trials in individual patients, but these too are not without drawbacks.[31] Controlled trials remain the most powerful method of establishing efficacy but they can be employed pragmatically with more emphasis on subjective symptoms, daily functioning and quality of life.[32]

General practitioners and randomization

Unlike the experience of Tognoni and colleagues,[19] the doctors in this pilot study were enthusiastic and maintained their interest. They indicated, however, that reminders of the study protocol as well as a regular update on numbers of patients recruited would have been helpful. Some failed to understand that they were intended to provide routine care to patients randomized to them and attempted to counsel patients in a way that was too time consuming.

The doctors disliked carrying out the randomization and directed most patients to the counsellor. They commented that, in their role as doctors, it was difficult to be directly involved in the allocation of the patient. This resulted in 19 patients being referred to counsellors, while five remained with the general practitioners. The tendency for those referred to the counsellor to have higher psychiatric scores at recruitment than those who remained with the general practitioner implied that the doctors may also have been influenced by the severity of the patient's distress.

The method of randomization chosen was not successful. Although the virtue of randomization is that it reduces systematic error, where patients are required to undergo a demanding intervention or where they have strong preferences, it may not be feasible. It has been argued that to optimize motivation it is necessary to take account of patient preference in randomization.[24] Unfortunately, we found that doctors can direct patients in their choice with the result that randomization rarely takes place. The doctors remarked that they could easily suggest to patients that consulting the counsellor might be helpful and thus, patient 'choice' was not always unbiased. Although we believed that general practitioners might feel more in control if they were given the task of randomization, it was clear that they felt uncomfortable in this role. Randomized clinical trials, in which research and clinical care occur simultaneously, challenge the traditional identification of physicians as clinicians or as researchers and may lead to tensions in the doctor–patient relationship.[33] Although the doctors agreed that randomization was essential in a definitive study, their preference was for a third party to randomize subjects.

Randomization process

The researcher cannot remain blind to the allocation if he or she carries out the randomization. It was for this reason also that the feasibility of general practitioners randomizing their patients was examined. Ideally, someone other than the general practitioner or researcher should randomize patients. Involving a third party, however, increases the cost and complexity of the study. Patients may also be more likely to participate if, during the initial assessment, the researcher makes the randomized choice and advises them into which group they have been allocated. If this is done by a third person, the process will be more complicated and subject to error. In any case, our experience demonstrated that it is difficult for the researcher to remain completely unaware of group allocation. Some mention of the type of treatment received readily comes out in interviews, even with careful instructions to patients to conceal which treatment they received. It is crucial to avoid any false assumption that the study is blind; the greatest danger is to assume that it is blind when in fact it is only partially so.[34] Thus, we relied on an extensive battery of self-report schedules which are less likely to be affected by the researcher's knowledge of the treatment group allocation.

Counsellors and their work

The counsellors taking part were those already working in the practices. Their skills were varied and study of their notes revealed that although Rogerian,[35] non-directive, patient-centred counselling usually took place, occasionally cognitive behavioural strategies were also used. Two were working solely as counsellors, one was a social worker and two were community psychiatry nurses. Thus, their varied backgrounds and experience of counselling mitigated against uniformity in treatment. Not all used methods recommended by the British Association for Counselling, and none were accredited by the association. Several had long waiting lists which hindered quick referral.

Concern has recently been expressed about the heterogeneous background and lack of qualifications of counsellors employed not only in general practice[29] but also in the oncology services[36] in the United Kingdom. We suggest that counsellors with an accredited training should be funded for the purposes of a trial. Although increasing the costs, the expertise and practice of counsellors would be standardized and problems of access would be reduced. Doctors and counsellors who took part in this study welcomed this idea and did not believe that it would interfere with normal practice routine. Where a participating practice already has an attached counsellor, provision of a research counsellor as part of the trial would help to reduce the waiting list of the practice's counsellor. Providing a research counsellor is also an incentive for those practices without counsellors to take part in the trial.

Conclusion

Patients referred by family doctors to counsellors working in their practices are often seriously emotionally distressed and recovery is slow. Counsellors come from a variety of backgrounds and tend to use a variety of methods of therapy. However, we would not concur with those who suggest that pursuing a quantitative mode of research should be abandoned in favour of investigating ways of providing a standardized counselling service in primary care.[37] Our results have demonstrated that a controlled trial is feasible and thus we have embarked on a definitive trial with the following caveats. Patients should be randomized in a stratified manner, according to severity, by the researcher after initial assessments have been made. Counsellors should be accredited by the British Association for counselling and preferably employed for the project to avoid non-uniformity of approach and long waiting lists. Blind assessments are desirable but are not always feasible and reliance on patient self report is important. Short periods of follow up are likely to give misleading results; patients should be reassessed a minimum of six months after entry to the study.

Although the results of previous studies give tentative support to the value of counselling in general practice,[9] it is essential that a greater understanding of the efficacy of counselling in this setting is gained. Well conducted, controlled trials have a long history in general practice[38] and the improved health and the sav-

ings that follow from abandoning ineffective or hazardous treatments and introducing useful new treatments far outweigh the costs and difficulties.[20] Within the limitations of our current knowledge, only controlled evaluations will provide the unbiased assessment needed for the evaluation of counselling.

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