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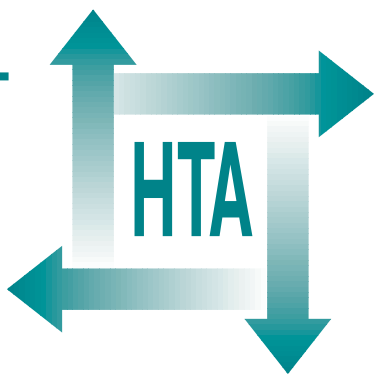

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A randomised controlled trial to evaluate the effectiveness and cost-effectiveness of counselling patients with chronic depression

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NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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Contents

List of abbreviations

BAC	British Association for Counselling
BDI	Beck Depression Inventory
BSI	Brief Symptom Inventory
CBT	cognitive behavioural therapy
CI	confidence interval
CMHT	community mental health team
CPN	community psychiatric nurse
CSRI	Client Service Receipt Inventory
df	degrees of freedom
DSSS	Duke Social Support Scale
GSI	Global Severity Index
HA	Health Authority
IIP	Inventory of Interpersonal Problems
PSDI	Positive Symptom Distress Index
PST	Positive Symptom Total
RCT	randomised controlled trial
SAS	Social Adjustment Scale
SD	standard deviation
UKCP	UK Council for Psychotherapy

Executive summary

Objectives

To examine the effectiveness and cost-effectiveness of short-term counselling in general practice for patients with chronic depression or combined depression and anxiety, compared with general practitioner (GP) care alone.

Design

A randomised controlled trial and economic evaluation with an initial assessment at randomisation and follow-ups at 6 and 12 months.

Setting

Nine general practices that were well-established participants of the Derbyshire counselling in general practice scheme, and already had a counsellor in the practice team.

Subjects

Patients were screened at GP practices, and asked to participate if they scored ≥ 14 on the Beck Depression Inventory (BDI), had suffered depression or depression/anxiety for 6 months or more, were aged 18–70 and had no history of drug or alcohol abuse, psychoses or suicidal tendencies.

Interventions

The experimental group received usual GP treatment and were also referred to an experienced, well-qualified counsellor attached to their general practice. Of the eight counsellors, two practiced cognitive behavioural therapy (CBT) and six had a psychodynamic approach. The controls were referred back to their GP for routine treatment. There were no restrictions regarding the treatment that could be used, except that GPs could not refer controls to practice counsellors.

Outcome measures

The main outcome measure was the BDI. Others included the Brief Symptom Inventory, the Inventory of Interpersonal Problems and the Social Adjustment Scale. All tests were given at initial, 6- and 12-month assessments. Comprehensive costs were also estimated, and combined with changes in outcomes to examine between-group differences and whether counselling was more cost-effective than standard GP care.

Results

The trial recruited 181 patients. There was an overall significant improvement in the actual scores over time but no difference between groups or between CBT and psychodynamic counselling approaches at either 6 or 12 months. However, fewer experimental group patients were still 'cases' on the BDI than controls. This difference was statistically significant at 12 months and neared significance at 6 months (using logistic regression with the initial score as a covariate). In addition, most patients were very positive about the counselling and considered it helpful. Visual inspection of the outcomes suggested that more patients with mild or moderate depression at study entry had improved and ceased to be cases, and that more of these patients had become 'non-cases' in the experimental than the control group. However, a multiple regression analysis indicated no significant interactions between group and initial severity of depression. This could be partly due to there being no difference in outcome between the experimental and control group patients who were initially severely depressed and few of these patients ceasing to be cases at follow-up.

There were no significant differences in the mean total costs, aggregate costs of services, or any of the service-group costs, except for primary care, between the experimental and control groups over time. The cost-burden to GP practices was significantly higher in the experimental than the control group at 6 months.

Conclusions

Although patients were generally appreciative of the counselling received, there was only limited evidence of improved outcomes in those referred to counselling. Stricter referral criteria to exclude the severely depressed may have yielded more conclusive results. It is also difficult to estimate the effect of recruitment by screening rather than GP referral, which may limit the applicability of the results to routine clinical practice, and may have interfered with the normal working alliance established between the GP, patient and counsellor. A patient preference trial may, therefore, have been more appropriate.

The results indicated that there were similar improvements for both CBT and psychodynamic counselling, but a larger population may have shown different results. The same results between experimental and control groups were found when analyses were conducted on those referred to the psychodynamic counsellors only. The lack of improvement in the initially severely depressed patients may have been due to the chronicity of their problems, and investigation into treatment for these patients remains important. The therapy in this study tended to be short term, which is typical of most general practice counselling, but longer-term and more intensive therapy might possibly result in added benefits above GP care for the more severely depressed. It might be advisable to conduct a further trial of counselling in mildly depressed patients to investigate whether the findings of this study are confirmed. In the meantime, patients in this study are being followed up for 3 years to examine the long-term outcomes and between-group differences.

The primary care costs during the intervention period were significantly higher in the experimental than the control group and this was directly due to the costs of the counselling. This additional cost was not offset by subsequent reduced service use and costs, and did not appear to result in cost-savings at 12 months.

Chapter 1
Introduction

Prevalence of depression

The term depression describes a broad spectrum including the syndrome of major depressive disorders, lifelong fluctuating depression and less severe subclinical states, which are often of short duration.[1] Depression is also very common; studies have found a point prevalence of 15–30% in the adult UK population, the variation being due, in part, to the threshold used to define a 'case'.[2] In 1992, Mann estimated that about 60–70% of adults experience depression or worry of sufficient intensity to interfere with their daily functioning and activities at sometime during their lives.[3]

The majority of depressed patients (90%) are managed entirely in primary care and their main point of contact is the general practitioner (GP).[3,4] GPs are the 'gatekeepers' to other psychiatric services and counselling. More than 50% of patients who attend their general practices may present with symptoms of depression, although much remains undetected.[5] Depression is of considerable financial cost to the NHS[6] and the costs of treating depression have been shown to outweigh those of treating psychoses.[7] In fact, the costs of medical treatment are small in comparison with the costs of sickness absence (both certificated and non-certificated) and early retirement. Kind and Sorensen[6] estimated the annual NHS costs to be £417 million (at 1991 prices) and indirect costs of missed days of work and premature mortality to be almost £3 billion.

Depression is also a major problem worldwide. In 1990, unipolar depression ranked fourth in the world as causing the most disease burden and it has been predicted that it will be the second most important cause in 2020, superseded only by ischaemic heart disease.[8]

Psychological treatment for depression

There has been a shift in public attitude towards the value of psychotherapy and counselling as an acceptable intervention for psychological problems. The Defeat Depression Campaign conducted a survey of the general public's attitudes towards depression and found that 91% of respondents thought that people with depression should be offered counselling.[1] Antidepressants have also been found to have low adherence rates and some patients fail to respond to medication or tolerate the side-effects.[1,9] There have also been concerns about drug dependency and a reluctance to use medication to resolve emotional and psychological problems.[10]

The relevance of psychological treatments can also be seen from evidence regarding prognosis. Psychosocial factors play a major part in the prognosis of psychological disorders, and chronicity is associated with long-term social and psychological difficulties. For example, in GP studies, the patient's social circumstances have been found to be the strongest predictor of illness outcome.[11,12] Mann and colleagues[12] found that initial severity of symptoms, perceived poor quality of social life and marriage and being prescribed a psychotropic drug were the most important predictors of outcome after 1 year. Social supports may also play a key role in determining outcome, those with poor relationships improving less often and less quickly.[13,14]

Counselling in primary care settings

The growth in the provision of counselling in primary care has been remarkable and has, in part, been facilitated by the changes brought about by the new GP contract and fundholding.[15] Recent studies suggest that between one-third and half of general practices have a counsellor employed by or attached to their practice.[15,16] The use of counsellors and counselling in tandem with, or instead of, other treatments has now become commonplace in many practices.

GPs have employed counsellors to work in their practices with very little evidence of their efficacy, other than anecdotal accounts. Counselling is a labour-intensive form of treatment and counsellors can only see a small number of patients each week because of the nature of the work. With so many counsellors now employed in primary care, it is imperative that their effectiveness with one of their

major client groups is evaluated, including long-term outcome and cost-effectiveness. While the cost of counselling may be higher than for some forms of psychotropic drug treatment, it may be less than for other types of treatment, such as repeated GP attendance, psychiatric interventions or unnecessary referral for medical or surgical treatment. In addition, the effects of counselling may be longer lasting than drug treatment, because counselling may provide patients with resources that enable them to cope more effectively in the future.

There is much confusion over what 'counselling' actually means and in recent years it has been used to describe a variety of services from financial to beauty counselling. It is difficult to outline a definition accepted by everyone, however the British Association for Counselling (BAC) has produced the most widely accepted definition:[17]

> "Counselling is the skilled and principled use of relationships which develop self-knowledge, emotional acceptance and growth, and personal resources. The overall aim is to live more fully and satisfyingly. Counselling may be concerned with addressing and resolving specific problems, making decisions, coping with crises, working through feelings and inner conflict, or improving relationships with others. The counsellor's role is to facilitate the client's work in ways that respect the client's values, personal resources and capacity for self-determination."

The aim of counselling is generally perceived to be increasing the client's capacity and inner resources to enable them to take control of their life. Counsellors restrain from giving advice because it is intended that the client will take control personally rather then depend on another person. Counselling has been used with a range of people with different problems, including bereavement, recovering from trauma, coping with terminal illness, relationship problems, sexual problems and infertility.[18] People considered unsuitable for counselling include those who have negative views of counselling, those who externalise their problems, those who are suicidal and those suffering from severe psychiatric problems and personality disorders.[18]

Difficulties involved in evaluating counselling

Despite the rapid growth of counselling, there have been few studies that have tried to evaluate it effectively. This is probably due to the great difficulty in carrying out appropriate studies.

Randomised controlled trials (RCTs) have become increasingly utilised for examining the treatment effects of counselling and psychotherapy. RCTs are regarded as the 'gold standard' design in scientific medical research because the effects of bias are minimised through accepted methodological and design features.

In general, there is a broad range of difficulties encountered when conducting an RCT. These difficulties are sometimes termed 'threats to validity'.[19] The internal validity of a study refers to the extent to which the researcher has controlled for the existence of alternative or competing hypotheses that could account for the data. A study high in internal validity would be one that was conducted under laboratory conditions with all variables closely monitored and controlled for. However, this type of study can be criticised as being artificial and not related to real-life situations. The external validity of a study, on the other hand, refers to the degree to which its findings can be reliably and meaningfully generalised to other situations. Thus, a study high in external validity would take place in circumstances as close as possible to naturalistic conditions. Studies high in internal validity are usually low in external validity and vice versa. Researchers must make decisions according to whether their trial should be high in internal or external validity and some compromise is usually necessary. Most studies in psychotherapy are focused on the actual therapy rather than a service in its naturalistic setting[20] and, therefore, try to achieve high internal validity. However, a study with high internal validity uses therapies, settings and clients that are rarely found in everyday practice.

One of the major difficulties in conducting clinical trials is that of achieving a reasonable sample size. In general practice, there is the additional difficulty that high proportions of patients with depression improve over time, regardless of treatment received, although many will become ill again at a later date.[4] This makes the issue of sample size even more important and many studies conducted have insufficient statistical power to show any effect. Relying on GP referral may also lead to an unrepresentative sample. GPs may not readily refer patients to a clinical trial if they believe that counselling would be beneficial, as they may not wish to deny this treatment to their patients. Therefore, GPs with concerns of this nature may only refer those with very minor problems to a clinical trial.

Client motivation can also be a problem. In most trials, subjects must agree to randomisation and accept the treatment to which they have been allocated. The motivation of patients to receive counselling is, therefore, often variable. Some patients may either refuse counselling (even when allocated) or refuse to take part in the follow-up assessments. Alternatively, clients referred to the control group may seek and obtain alternative help from outside the study. Thus, subject motivation and attrition is a considerable problem.

In many trials, it is often difficult to decide what constitutes improvement. The outcome measures used in a number of trials have been criticised and judged to be inappropriate or to lack sensitivity. Most trials now include multiple assessments, including symptoms and measures of social and interpersonal adjustment, and are likely to lead to fairer trials of counselling than those with assessments focusing predominantly on mental health measures. There are also potential difficulties regarding the difference between clinical and statistical significance.[21] It may be possible to detect a statistically significant difference between two groups even though the finding is not worthy of clinical attention, as the change may not indicate an appropriate improvement. For this reason, it is important to measure the extent of change and the number of patients who have made a substantial improvement. In addition, the timing of follow-up assessments can pose problems because some patients may improve rapidly but then relapse, others may take longer but remain well. Some clinical trials have been criticised because follow-up assessments have been undertaken too soon or too long after intervention. The best solution is to follow-up clients more than once; once after cessation of counselling and again at least once at a later time.

Treatment given is often poorly defined and it is, therefore, difficult to assess what is actually causing any improvement. Although some trials employ trained, regularly supervised therapists who use treatment manuals,[22] these are in the minority, and there are also concerns regarding the external validity of these trials. In practice, most clinicians carefully adapt and select the most appropriate interventions for each patient and find it hard to adhere to a theory-driven manual that may not always be appropriate for every client.

There are also a number of other potential problems, including variance in ability between counsellors, the quality of patient–therapist interactions as well as variance among patients. These are documented in more detail elsewhere.[21,23]

Studies evaluating counselling

The first clinical trial that studied counselling in general practice by Ashurst and Ward[24] included 726 patients aged between 16 and 65 years, referred to the study by their GP if they had consulted their GP for what was termed a neurotic disorder. High proportions had also been prescribed psychotropic drugs. Patients who agreed were randomly assigned to counselling or routine GP treatment; although not all those assigned to counselling took up the offer.[24] The two counsellors generally favoured a non-directive approach, and made use of progressive relaxation, supportive counselling, interpretative psychotherapy, transactional analysis, behavioural techniques, gestalt and dream work. While a high proportion of the patients valued the help they received, no significant differences in outcomes between groups 1 year later were elicited, although it was felt by the authors that some individuals benefited considerably.

Another study, carried out in Sydney, Australia, compared the outcomes of three groups to which patients had been randomly assigned.[25] Patients were aged between 18 and 65 and had had persistent psychological symptoms for at least 6 months. In one group, 18 patients received eight weekly half-hour sessions of brief problem-orientated psychodynamic psychotherapy from a trained psychotherapist. Another group of 18 individuals received eight weekly half-hour appointments with their GP (who had no specific training), and the third group of 20 patients received no additional therapy. No differences were found between the three treatment groups in outcome scores measuring symptom severity, social dysfunction, physical disability and medication. However, high refusal and drop-out rate problems were encountered in this study.

In a third study by Boot and colleagues,[26] patients referred to a counsellor had improved much more than those receiving GP treatment and this difference was statistically significant. Those referred to the counsellor also felt more satisfied with the service and fewer were taking psychotropic drugs or were referred elsewhere. However, outcome was assessed using a questionnaire (the General Health Questionnaire) that is best used for screening, and was measured

only 6 weeks after initial referral to the study. There were also problems with the randomisation procedure and subject attrition. While 192 patients were recruited into the study, only 108 (56%) returned the follow-up questionnaires. In addition, although randomisation should make the two treatment groups reasonably equal, 124 were referred to the counselled group and only 68 to the GP group.

In a pilot study conducted by King and colleagues,[27] patients could select whether to receive non-directive counselling or routine care from their GP. Although patients could choose, the 19 patients receiving counselling did not make any more improvement than the five receiving GP care alone. King and colleagues are now undertaking a further two-centre patient-preference trial in which patients can choose counselling, cognitive behavioural therapy (CBT) or GP treatment or alternatively agree to randomisation (King M and colleagues, Royal Free Hospital School of Medicine, London: personal communication, 1997).

GPs were asked to refer patients to the study by Friedli and colleagues if they were suffering from an emotional problem.[28] A total of 136 patients entered the study. Overall, no statistically significant differences were found in outcome between the group referred to counsellors and those referred back to their GP for routine treatment. However, in a post hoc analysis, the researchers included only those initially defined as cases on the Beck Depression Inventory (BDI) (using a score of 14 or over). Under these conditions, those referred to the counsellor improved more than those who were not ($p = 0.035$). The counsellors all used Rogerian non-directive counselling methods and undertook between one and 12 sessions over a 12-week period. Depression, anxiety, other mental health disorder symptoms and social adjustment were measured by self-reporting at baseline, 3 and 9 months.

Hemmings conducted a study that included 188 patients and did not find any statistical difference in outcome between the group referred to a counsellor and those receiving routine GP advice.[29] Patients were included in the study with a variety of different problems and symptoms. The three counsellors were trained using different models but all exceeded the minimum requirement for the BAC accreditation. Outcomes were measured at 4 and 8 months and included assessments of interpersonal problems, clinical symptoms and self-esteem. A study by Harvey and colleagues[30] conducted in nine practices also found no difference in mental health or functional outcome at 4 months in 162 patients with diverse mental health problems referred to generic brief counselling or usual GP care.

The evidence from clinical trials to date has indicated that counselling has, at best, only a weak effect on outcome. This differs considerably from anecdotal evidence or from the views of patients. Even within these clinical trials, clients receiving counselling are very positive about its effects.[24]

Economic evaluation

Recent changes in the NHS have meant that effectiveness and value for money in the provision of services has become paramount. It is important, therefore, to have thorough reviews of research examining effectiveness and cost-effectiveness of treatments to enable purchasers to make informed decisions. This is particularly relevant to counselling in primary care, as it is necessary to establish the effectiveness of counselling in general practice before embarking on its large-scale adoption, and economic analysis is one way of evaluating this. A cost-effectiveness study is not necessarily about choosing the cheapest option, but assessing costs while considering the most effective option.

Investigators have suggested that the costs of counselling can be offset by reductions in other medical costs. A number of studies have investigated utilisation of medical services and have shown a reduction in visits made to GPs after cessation of counselling compared to before counselling was received.[24,31,32] Several studies have also found a reduction in the number of psychotropic and other drugs prescribed,[32–36] or a reduction in referrals to psychiatrists after a counselling attachment had been instigated.[35] These results should be interpreted with caution, as it is likely that the client will be referred at a time of crisis in their lives when attendance is also likely to be high. Visits to the GP may have reduced without the intervention of a counsellor as the crisis abated. In addition, a GP may feel under less pressure to prescribe a psychotropic drug when a counsellor is involved.

Some studies have found that practices with counsellors refer fewer patients to community mental health teams (CMHTs) than practices without,[37] thus reducing the costs of outside

referrals. However, while involvement of a counsellor may reduce referrals to mental health professionals outside the practice, it is likely that approximately half of the referrals to counsellors would be managed by the GP themselves and not referred elsewhere.[15,38,39] Indeed, increasing the number of mental health professionals attached or employed in the primary care team may increase the number of patients referred to them with fewer patients being managed solely by the GP or other primary care team members.[40]

Clinical trials involving a range of mental health professionals have yielded mixed evidence of the cost-effectiveness of psychological treatments. Robson and colleagues[41] evaluated a clinical psychology service based in a health centre. They collected data on the number of GP attendances, all drug prescriptions and hospital referrals 34 weeks before and after entry into the study, and found that treatment by a clinical psychologist significantly reduced drug costs. They estimated that over one-quarter of the salary of a senior psychologist working in a general practice could be found from savings in the drugs bill alone.[41] Gournay and Brooking[42] evaluated counselling using community psychiatric nurses (CPNs). They collected extensive data on number of GP attendances in the 6 months prior to and after trial entry, use of CPNs, psychiatric and social services, absences from work, drugs dispensed, use of hospital resources, patients' and relatives' costs for travel and work loss and any other associated expenses. There was a net economic benefit associated with counselling, however, the only significant difference was attributable to the single measure of workdays lost.[42]

Harvey and colleagues[30] compared generic counselling with usual GP care by assessing prescribed medication, practice staff costs, counsellor time and referrals to other agencies. They found that mean staff costs were higher for the counselled group but that medication costs, referrals and total resource use were less than in the control group. There was no clear cost advantage associated with either the routine GP group or those receiving counselling, which suggested that there were no increased costs attached to seeing a counsellor. The mean total costs (including all referrals) per subject were £71.21–£81.23 for the counselled group and £89.67–£109.51 for the GP care group. Hemmings collected economic data on use of medical services and prescribing patterns and found no differences between subjects referred to the counsellor and those referred to the GP.[29] However, the group treated by the counsellor were less likely to be referred to other mental health services. The evidence of whether counselling was cost-effective in Friedli and colleagues' study was mixed.[28] At the 3-month follow-up, the number of GP visits had increased in the controls, but this difference had disappeared at 9 months.

Studies in the US have yielded evidence of the cost-effectiveness of counselling. The use of psychotherapy and behavioural medicine services has been shown to reduce medical utilisation and this is why some health insurance companies have added psychotherapy to the list of services covered by their schemes.[43] The 6-year Hawaii Medicaid Project,[44] which included patients with heart disease, hypertension, diabetes and even substance abuse, found that targeted focused psychological treatment produced a dramatic and significant reduction in subsequent medical needs and medical resource consumption of a group of patients. However, it may be more difficult to show a reduction in resource use in Great Britain because health expenditure per capita is generally much lower than in the US.

Rationale for the study

GPs tend to support the value of counselling[45] without any real evidence of effectiveness. A proper evaluation of counselling is vital if it is to maintain credibility. In addition, since NHS funds are finite and the number of counsellors employed by GPs is increasing, it is important to establish whether counselling is more or less cost-effective than routine GP care. This study was a clinical trial of patients with chronic depression that had had symptoms for 6 months or more. Patients who were assessed as depressed and appropriate were randomly allocated to the experimental group where they were referred to a counsellor or to the control group where they were referred back to their GP for routine care.

The present study concentrated on those with chronic/persistent illness (i.e. symptoms for 6 months or more) because this group makes up a constant load for the GP in terms of time spent in consultation[4] and are high consumers of psychotropic drugs. The chronically ill make

up a large subgroup of those who are anxious and depressed. In 1981, Mann and colleagues conducted a 1-year follow-up study of 100 patients selected by their GP as suffering from non-psychotic illness. They found that only one-quarter of the group had shown a rapid recovery in the early months of follow-up without relapse, about half had an intermittent course and one-quarter had a chronic course with regular GP consultations throughout the year.[12] This cohort was also followed up 11 years later, and 32% of the cohort were well; 21% had experienced one acute episode of non-psychotic illness lasting less than 1 year and 47% had chronic or relapsing illness.[46] This chronic subgroup has also been recognised in the US.[47]

The effect of psychosocial factors on prognosis indicates the relevance of psychological treatment for those with chronic depression. The chronically ill are less likely to improve over time without treatment than those with symptoms of recent onset, making it easier to assess the effects of any treatment given. It is also possible that those with chronic illness will be more motivated to accept help from a counsellor. Indeed, studies of the effectiveness of social work on those who are chronically depressed or anxious suggest that this group of patients may be particularly helped by psychological therapies and will be more motivated to receive such help.[13,48] In addition, no clinical trials of counselling in general practice have been specifically conducted on this group.

This study also evaluated whether counselling is more beneficial for certain subgroups of patients, including the initial severity of symptoms, the amount of social support available and whether a psychotropic medication had been prescribed. Previous work has suggested that patients with poor social support from others may benefit more from psychological and psychosocial therapies.[13,14] The lack of confidants (or someone to talk to) may mean that patients benefit from the close relationship with a counsellor and the opportunity to discuss problems or difficulties in greater depth. Findings from the National Institute of Mental Health project,[49] which evaluated two brief psychotherapies for the treatment of outpatient depression, indicate that severity of depression may be an important factor. There were four different treatment groups: CBT, interpersonal psychotherapy, antidepressant plus clinical management and placebo plus clinical management. The results were complex, but revealed that there were no differences among treatments for the less severe groups, although there were consistent significant differences among treatments in the more severe subgroups.

Some commentators have suggested that the combination of medication and psychological therapy is more effective than either treatment alone.[50] Klerman[50] found interpersonal therapy was more effective for endogenous depression in combination with medication than either treatment alone. However, Robinson and colleagues, in their review,[51] found no evidence of an advantage of combined treatment. Klerman and colleagues reviewed the data in 1994[52] and concluded that the data on the possible additive or synergistic effects of combined therapy for depression were inconsistent. Given this mixed set of results, it was considered relevant to examine the issue of the effects of combined therapy on outcome, although drug treatment was not randomised.

The present study was undertaken in Derbyshire and had the major advantage of studying counsellors in one of the most funded and well-organised schemes of counselling in general practice in the UK. The scheme was set up in 1991 and currently funds counsellors in 65% of practices. The salaries of the counsellors are met, in part, by the Health Authority (HA). All the counsellors employed in general practices in Derbyshire fulfil essential criteria, including eligibility for BAC membership. Practices are allocated 6 or 12 hours of counselling per week depending on their list size, and many practices supplement their counselling service by paying for extra hours out of their own funds. In addition, all counsellors receive 1 hour of supervision weekly from the psychotherapy department of the District HA.

The study was designed to be high in external validity and to mimic as far as possible normal working practices. For example, it involved practices that already had a counsellor working in the team that was well established within that team. It also involved counsellors and GPs working as normal in their practices. The counsellors were asked to counsel the patients in the same way as they did with other patients and to use the range of interventions that they considered most appropriate for the patient's needs. The GPs were also asked not to change their normal working patterns with the patients referred, and their treatment options were not limited, apart from not being able to refer patients in the control group to the practice counsellor. While this

may have lost some of the internal validity, it did mean that the treatments received by patients in the study were very similar to those referred outside the trial.

Aims and hypotheses of the study

The main aims of the study were to compare:

- the effectiveness of counselling plus routine GP care (experimental group) with routine GP care alone (control group) on the clinical and social outcomes of chronically depressed patients at both 6 and 12 months following initial assessment
- the costs of both medical and other services used by patients in the two treatment groups as well as the total costs of patients during the study period.

The null hypotheses of the study were that there would be no differences in:

- outcomes (either clinical or social) between the experimental and control groups
- the costs of treatment between the experimental and control groups.

Chapter 2
Methods

Original design

The number of patients required for the study was based on using the BDI as the main outcome variable. In order to detect a difference in outcome between the groups of 3.5 (standard deviation (SD) = 8) in BDI score at 90% power and a 5% significance level, approximately 70–80 patients were required in each group. These estimates were derived from previous RCTs with which comparisons will be possible.[53,54] It was proposed that the study would recruit 200 patients into the trial to allow for those lost during follow-up.

General practices in north and south Derbyshire were approached; initially by a letter explaining the aims of the study and then by a follow-up telephone call. The nine practices that expressed an interest were contacted and meetings were arranged with the research staff to explain the study further. Counsellors and GPs were invited to participate in a meeting to discuss the referral protocol and the type of depression/anxiety appropriate for referral into the study. The referral protocol and a patient information leaflet were then drawn up and sent out to GPs and counsellors for comment and any suggestions were incorporated into the final versions.

The forms to be completed by counsellors were taken to a meeting of counsellors and discussed, and any suggestions were incorporated into the final versions. Research packs were sent to the GPs, which included patient referral forms, patient consent forms, the referral protocol, a letter to GPs explaining the study, GP information leaflets, patient information leaflets and post-treatment forms for completion by the GPs. In addition, referral protocols, initial assessment forms, diary forms, final assessment forms and patient consent forms for taping were sent to the eight counsellors taking part to ensure that their work with patients was recorded in detail. Ethical permission for the study was obtained from both north and south Derbyshire Ethics Committees.

The nine practices ranged from a small single-handed practice to larger health centres and covered a range of different socio-economic areas. GPs were asked to refer patients into the study who had suffered depression or depression/anxiety as their main symptom for over 6 months. Other inclusion criteria included that they must have no history of suicidal intent, no psychotic symptoms and no history of drug or alcohol problems. 'Heartsink' patients or those who had been chronically depressed over a considerable number of years were also excluded. It was not considered appropriate to include patients in the trial who had consistently not responded to all treatments offered. The inclusion and exclusion criteria are detailed in *Box 1*.

BOX 1 Criteria for inclusion and exclusion

Criteria for inclusion

Aged 18–70

Had mild to moderate symptoms of depression for 6 months or more

Depression or depression/anxiety as their main symptom

Score of 14+ on the BDI

Criteria for exclusion

Severe depression or anxiety

Symptoms of anxiety only

Significant history of alcohol- or drug-related problems

Psychotic features or current or past history of suicidal attempts

Chronic depression over a number of years (5 years or over)

'Hard to treat', 'difficult' or heartsink patients (i.e. frequent attenders with unexplainable physical symptoms)

Receipt of counselling in the last 6 months

It was planned that all referred patients should be given an initial assessment by the research fellow using a series of questionnaires that assessed symptoms, social functioning and other relevant details. If patients fulfilled the entry criteria of the study, scored 14 or above on the BDI and were willing to take part, they were randomly allocated by a member of the HA to the experimental or control group using random number tables. Those in the experimental group were

referred to a counsellor and the controls were referred back to their GP. It was then planned for patients to be followed up using the same questionnaires 6 and 12 months after the initial referral. Follow-up interviews were carried out by the research fellow, who was unaware of the outcome of the randomisation process.

Pilot study

The pilot study was conducted from December 1995 to March 1996. Three practices were selected to take part and GPs from those practices were asked to refer patients into the pilot study, and five patients were eventually recruited. All procedures, questionnaires, forms and other instruments were tested and evaluated. As a result of the pilot study, some minor changes were made to the patient information leaflets to make them clearer to patients.

The biggest problem encountered in the pilot study was the rate of referral. Referral was very slow and a number of reasons for this were given by the GPs. Many found it difficult to ask their depressed patients if they would take part in a research project. Some felt uncomfortable with the fact that patients would be randomised to receive counselling or GP treatment, because they believed that certain patients would benefit from counselling and did not want them to be allocated to the control group. Others indicated that they found it difficult to remember to ask patients to take part in the trial.

The results and problems of the pilot study were discussed with the GPs, and, in response to the problems, a flow diagram of the process, guidelines on how to explain the study to patients and desktop reminders were developed to try to encourage GPs to refer patients to the study.

The patients participating in the pilot study were followed up at 6 and 12 months after initial assessment using the same questionnaires. In addition, at the 6-month follow-up, patients were given a questionnaire asking for their views on the treatment they had received and their suggestions of any possible improvements. A few amendments were made to this questionnaire before its use in the main study. Information on referrals, medication and GP visits were collected from patients' notes and computer records, and these data were checked against each other.

The main study: changes in research design

GPs reassured the researchers that they would refer patients into the main study and recruitment began in April 1996. However, after 2 months only five more referrals had been made despite attempts to encourage referral by repeated meetings, telephone calls, desktop reminders and letters. It was not possible to continue with the study using the original design because the pace of recruitment was far too slow. In addition, it was possible that patients that were appropriate for the trial were being referred directly to the counsellors or other mental health professionals and thereby bypassing the trial. This might also mean that those being referred to the trial were in some way atypical.

It was concluded that the study should continue using another method of recruitment that would mean that the pace of the study was not determined by GP referral of patients. Although the recruitment method was altered, the rest of the study remained the same, namely randomisation and follow-up of patients. The new recruitment method, resulting from a change in the referral process, was suggested by a clinical trial undertaken by Lewis, Sharp and Mann comparing high- and low-dose tricyclics, placebo and practice nurse intervention (Lewis G, University of Wales College of Medicine, Cardiff: personal communication, 1996). Patients were now recruited by screening GP attendees using the BDI.[55] Patients who scored 14 or above and met the inclusion criteria were asked if they would take part in the study. This score was chosen as it had been used in other studies of counselling in general practice to indicate 'caseness'[28] (King M, Royal Free Hospital School of Medicine, London: personal communication, 1995), and the higher cut-off meant that patients with borderline mild depression were excluded. The study process then continued as previously proposed, including initial assessment, randomisation and follow-up of patients taking part in the study.

The new process of referral

Researchers attended a number of morning, afternoon and evening surgeries in nine practices. Screening sessions were at different times in the practices each week to enable a range of patients to be screened in each practice. All patients attending these surgeries were given an initial one-page information sheet as they entered the practice. If patients were willing to help, they were asked by researchers to fill in the

questionnaire consisting of general demographic information and the BDI. The questionnaire also asked patients if they were depressed and for how long, and to detail any previous treatment. After completing the questionnaire, patients were given an information leaflet about the study. All patients who completed the questionnaire also received a letter explaining the results of the questionnaire. GPs were also informed of all patients' scores and asked to notify researchers if patients were unsuitable for the trial according to the original referral protocol. Any patients whose answers on the BDI suggested that they were a suicide risk or scored above 40 were referred to the GPs by an immediate telephone call and a follow-up letter.

Patients who scored above 14 on the BDI and met the previously determined inclusion criteria were approached by telephone and asked if they would be willing to take part in the study. An appointment, normally within 1 week of initial contact, was made for an initial assessment interview.

The initial assessment

Firstly, patients were thanked for agreeing to take part in the trial and were informed that all information they gave would be confidential to the researcher and their GP. The assessment consisted of a number of questionnaires for which the research fellow was available for help with their completion if the patient requested. After the questionnaires had been completed, the research fellow explained why the study was being conducted and how the randomisation worked. Patients were told that they would receive a letter informing them of the group to which they had been assigned. If they had been referred for counselling, the counsellor would contact them to make an appointment. If they were referred back to their GP, they should arrange an appointment with the GP if appropriate. They were also informed that their GP could withdraw them from the trial at any time if they wished. The researcher then asked the patients if they had any questions and gave them an information leaflet that reiterated the above.

The assessment measures adopted had been fully validated and standardised in other studies and were relatively short to complete. Measures were also chosen that had been used in other studies of counselling so that results would be comparable. Participants were asked to complete another BDI,[55] which was used to measure symptoms of depression and was the main outcome measure. In addition, the Brief Symptom Inventory (BSI)[56] was used to measure mental health symptoms and the Inventory of Interpersonal Problems (IIP) used to measure functioning in interpersonal relationships.[57] These two measures were recommended by Parry[20] and have been utilised in a number of other studies of counselling. Other measures utilised were the Social Adjustment Scale (SAS) to measure social functioning[58] and the Duke Social Support Scale (DSSS).[59,60] The latter was used to measure the level of social support available, and was included to assess whether counselling would be more beneficial to those with poor support networks.[13]

Details of patients who were appropriate and had agreed to take part in the study were given by hand to the HA who undertook the randomisation using random number tables, to ensure that the assessor would be blind to treatment. The experimental group was referred directly to the counsellor working in the practice. Those referred to the control group were referred back to their GP for routine treatment. GPs were informed by letter of the result of randomisation for all the patients in the trial. Letters were also sent out to patients explaining which group they had been assigned to.

Measures of treatment received

Eight counsellors (six females and two males) took part in the trial (one worked at two practices) and all were BAC accredited or eligible for BAC accreditation; they were highly trained and had considerable experience of counselling in a general practice setting (*Box 2*). Six of the counsellors took a broadly psychodynamic approach to their work and two took a mainly cognitive approach (see appendix 1 for further details of the counselling interventions given to study patients). The counsellors were asked to try to keep the number of sessions to the HA guidelines of six to 12 sessions.

Counsellors were given forms to complete and diaries to record the process of treatment. To ensure that counsellors were actually using the mode of therapy that they specified as adhering to (either psychodynamic or CBT), a number of sessions were audio taped and kept for later analysis. The decision not to use treatment manuals to standardise treatment was made because the counsellors wanted flexibility to

BOX 2 Age, qualifications and work experience of counsellors in the study

Counsellor	Age	Qualifications
1	43	Certificate in Counselling; Advanced Diploma in Psychodynamic Counselling; BAC accredited; 10 years of experience in primary care and private practice; 6 years as training mentor with South Derbyshire HA scheme; 3 years as Counselling Coordinator for South Derbyshire HA; 1.5 years as Director of Counselling in primary care.
2	40	Foundation course in Counselling; Diploma in Occupational Therapy; registered Psychotherapist UK Council for Psychotherapy (UKCP); Masters in Disability Studies; BAC accredited; 2 years of managing a residential home for psychiatric patients and counselling in a hospital setting; 6 years as a CMHT psychotherapist; 10 years of counselling in primary care.
3	47	Diploma in Counselling; Certificate in Counselling Supervision; BAC accredited; UKCP registered British Association CBT Psychotherapist; 8 years of counselling in a hospital addiction unit; 3.5 years as a college counsellor; 6.5 years of counselling in a general practice setting.
4	60	Post-graduate Diploma in Counselling and Early Human Development; Masters in Counselling; Certificate in Sudden Death and Accident Counselling; Certificate in Counselling Couples, BAC accredited; 7 years of counselling patients with terminal illness and bereavement in Leicestershire Hospice; 2 years of counselling children; 6 years of counselling in a general practice setting.
5	42	Diploma in Counselling; Masters in Counselling; Post-Graduate Certificate of Education in Counselling Supervision; BAC accredited; 2 years of counselling psychiatric outpatients; 3.5 years on a staff counselling service; 10 years in a general practice.
6	48	Diploma in Occupational Therapy; Masters in Counselling Psychology; Diploma in Clinical Hypnosis; Diploma in CBT; 7 years as an Occupational Therapist in a psychiatry department and a day unit; 6 years of counselling in a general practice setting.
7	40	Masters in Counselling Practice; Diploma in Psychodynamic Studies; BAC accredited; UKCP registered Psychodynamic Psychotherapist; 7 years of counselling in a general practice setting.
8	52	Masters in Counselling; Certificate in Bereavement Counselling; Certificate in Systemic Family Systems Therapy; BAC accredited; 5 years as a college counsellor; 5 years in private practice; 7 years of counselling in a general practice setting.

respond to the individual needs of the patients. Only one restriction was placed on the GPs regarding their treatment and involvement of patients within the trial, which was that they were not allowed to refer control patients to the practice counsellor. Otherwise, GPs and counsellors could treat both control and experimental group patients as usual.

In order to obtain details regarding the treatment given, information was obtained from medical notes on the number of times these patients saw their GP and other primary healthcare professionals. Details of psychotropic drug (defined using the BNF) prescribing were obtained, and drugs used for the treatment of anxiety, depression and any other psychological problems were included for later analysis. This covered hypnotics and anxiolytics, antidepressants and drugs used in psychoses and related disorders. Data were also collected on hospital attendances, absences from work, medication, serious illnesses and referrals for the year prior to study entry until 1 year after entry. Details were also obtained on any history of mental health problems, referrals to mental health services and psychotropic medication in the previous 10 years. Medical records were not always found to be accurate, and, in order to combat this, a sticker was placed on the notes of every patient in the trial to remind GPs to add all information relevant to the trial. In addition to the collection of information from the medical notes, data were also collected from computer records so that any information included in one but not the other was obtained.

The follow-up assessments

All patients were followed up at 6 and 12 months after initial assessment. Patients were contacted by telephone to arrange follow-up assessments at their general practice. Most were completed within 1 week of the 6-month follow-up date. At the assessment, patients were thanked for attending and given the same set of questionnaires

as in the initial assessment. In addition, patients were asked to complete a questionnaire that elicited their views on treatment, and, again, assistance was available from the researcher on the completion of these forms if requested. The researcher was unaware of the group to which patients were allocated and was, therefore, blind to treatment status at first follow-up. However, in some cases, patients would indicate the treatment received and it was thus not always possible to stay blind, especially for the 12-month follow-up.

Economic evaluation

The economic evaluation was fully integrated with the outcomes study. Four principles guided this part of the study:

- costs data should be comprehensive
- cost-variations should be explored
- cost-comparisons should be made carefully
- costs data should be combined with outcomes.

The estimation of comprehensive costs requires completion of the three tasks described below. This approach also ensures that disaggregated costs data are available, which describe the costs associated with the service and support components of each person's care package.

Data on service use form the basis of the cost-estimations and were recorded on a specially adapted version of the Client Service Receipt Inventory (CSRI), administered alongside the other assessments.[61] This schedule allowed detailed information to be recorded on the patients' accommodation and living situation, their employment status and the frequency and duration of contact with a range of social and healthcare services provided by primary care groups, health trusts, social services departments and independent sector organisations. Collection of such data and the identification of support packages were the first of the three costing tasks required to estimate comprehensive costs.[62]

The second task undertaken was an estimate of the unit cost for each service used by study members. Some costs were taken from an annual compendium of nationally applicable unit costs[63] and others were estimated specifically for this research. Particular attention was paid in ensuring accuracy in estimating unit costs for contact with practice-based counsellors by using data made available by each of the nine participating practices. All unit costs were valued as the long-run marginal opportunity costs and appendix 2 shows the detailed calculations.

The third task was an estimate of comprehensive client-level care package costs. The unit costs (per minute, per appointment, etc.) were adjusted for the frequency and duration of use of each service by each patient as recorded on the CSRI. This allowed calculation of the total cost of service packages as well as subtotals associated with various groups of component services. In turn, these individual level data facilitated implementation of the second and third principles, explorations of cost-variations and more accurate estimation of group costs for between-group comparisons.

The final costs rule is that cost information should be combined with evidence on outcomes. In this context, outcomes refer to changes in patient welfare, such as improvements in mental health. The interpretation of the analyses presented here rests on the 'decision rules' commonly employed in economic analyses.[64] Thus, for the counselling service to be found to be more cost-effective than the standard GP service, the costs should be equivalent between the groups and the outcomes generated by the counselling service better, the outcomes should be equivalent and the costs for the counselling group lower, or both the outcomes should be better and the costs lower in the counselling group.

Comparison of study patients with those referred by GPs and audit data

It was recognised that changing the referral process would change the population of patients in the trial. It was, therefore, important to ascertain whether the patients recruited into the trial were different from those depressed patients normally referred by the GPs to the counsellors. In order to obtain this information, patients referred by the GP directly to the counsellor who were depressed or had a combination of depression and anxiety were asked by the counsellor to complete a questionnaire. This was done for a 12-month period. The questionnaire included the BDI, and asked patients for various demographic details (age, sex, marital status), details of any previous history of depression or prior treatment and their views on counselling and medication. This enabled a comparison of trial patients with GP-referred patients.

The details of trial patients were also compared with GP referrals to counsellors using the data from the audit forms that are routinely completed by counsellors as part of South Derbyshire HA's counselling in general practice scheme. Audit data were collected over the 3 years (1996–1998) for all patients seen in the previous year. The audit forms collect data on age and sex of patients, waiting times, whether patients have had previous psychological therapies, whether patients were on psychotropic medication, number of sessions, whether they were referred to other mental health agencies, presenting problems and outcome on discharge from counselling.

Data analysis

Data from the assessments were coded and analysed using SPSS for Windows. To examine differences between the time periods, *t*-tests for paired samples were used. Univariate analysis of covariance was used to analyse follow-up data, with the initial score as the covariate. In order to evaluate clinical significance, recovery was also assessed by analysing the number of cases of depression in both groups at onset and subsequently. Cut-off points were employed to ascertain the proportion of patients who recovered and logistic regression was used to analyse these cases. Multiple regression techniques were used to investigate the effects on outcome of other variables and their interactions with counselling intervention. Confidence intervals (CIs) are listed for the main outcome measures and for any major differences found between the two groups and any significant or near-significant values are given.

The procedure recommended by Altman[65] to analyse the effect of drop-outs on the data was applied, which involved:

- assigning the most optimistic outcome to all patients who dropped out and analysing the data
- assigning the most pessimistic outcome to all patients who dropped out and analysing the data
- analysing the data excluding all drop-outs.

To compare the costs data, a number of statistical procedures were undertaken. Simple *t*-tests are applicable for the sample size and investigation of the mean costs is recommended in economic analyses because the ability to make inferences about the arithmetic mean are most useful to healthcare decision-makers.[66] Due to the skewness of the data, however, results were checked using simple non-parametric tests (Mann–Whitney *U*) and bootstrap re-sampling techniques.[67]

Chapter 3
Results

Recruitment to the study

Patients were recruited by screening those who volunteered to complete the BDI when attending the surgeries at GP practices. Approximately nine visits to practice surgeries were conducted each week and all practices were visited at least once in every 2 weeks. Over 2 years, a total of 1550 patients were screened at the practices and 432 (28%) scored 14 or over on the BDI. Of these, 77 patients refused to take part and a further 171 were unsuitable because of one of the following reasons: recent onset of depression; too old or too young; past history or currently seeing a counsellor or mental health worker. In addition, GPs asked for three patients not to be included. After 2 years of screening, 181 patients were recruited into the trial (see *Figure 1*).

Patients were asked for their reasons for attending the surgery on the day they filled in the questionnaire (*Table 1*). They attended for many different reasons, which were split into 16 categories according to the chapters in the BNF. One-fifth attended for a psychological problem.

Initial characteristics and differences between groups

Of the 181 patients recruited, 92 were allocated to the experimental group and 89 to the control group (see *Figure 1*). There were some data missing for one patient in the experimental group, but any information that was available was included. A number of factors, namely age and gender, type of job, marital status, history of previous depression, whether taking psychotropic medication, initial assessment scores, initial costs and service use, and patient's views of counselling and use of psychotropic medication, were compared between the experimental and control groups to ascertain any differences at the baseline assessment.

The mean ages were 42 and 44 in the experimental and control groups, respectively. An independent *t*-test was conducted to test for age differences between the two groups but this was not statistically significant ($t = 0.74$; degrees of freedom (df) = 178; $p = 0.46$). Many more women than men took part in the study, which is probably a reflection of differences in GP attendance rates between men and women as well as the greater proportion of women attendees who have mental health problems. Although there were slightly more men in the control group than the experimental group, this difference was not statistically significant ($\chi^2 = 2.45$; df = 1; $p = 0.11$) (*Table 2*).

The majority of participants were married (65%), 16% were separated or divorced, 11% were single and 8% widowed (*Table 3*). Although there were slightly more separated and divorced participants in the experimental group and slightly more married people in the control group, this difference was not statistically significant. Over half of the participants were living in households without children (*Table 3*), and this was probably a reflection of the age and marital status of participants, and there was no statistically significant difference in the number of children between the two groups.

High proportions of the patients were owner-occupiers and the majority were also working (55%). However, 26% were unemployed and 19% were retired (*Table 3*). More participants worked in non-manual than manual occupations, however, there were no statistically significant differences between groups for either the employment category or housing status.

Medical information

Medical records were examined to ascertain whether patients had been prescribed psychotropic medication at the time of the first assessment and patients were also asked at this assessment whether they were taking this medication. The medical records indicated that 50% of the experimental group and 34% of the control group were prescribed psychotropic medication at the time of the first assessment (*Table 4*). This was statistically significant (mean difference 16%; 95% CI, 3% to 29%; $\chi^2 = 4.88$; df = 1; $p = 0.027$). However, only 29% of the patients in the experimental group indicated that they were taking this medication compared with 22% of the control group (*Table 4*). There is, therefore, a large

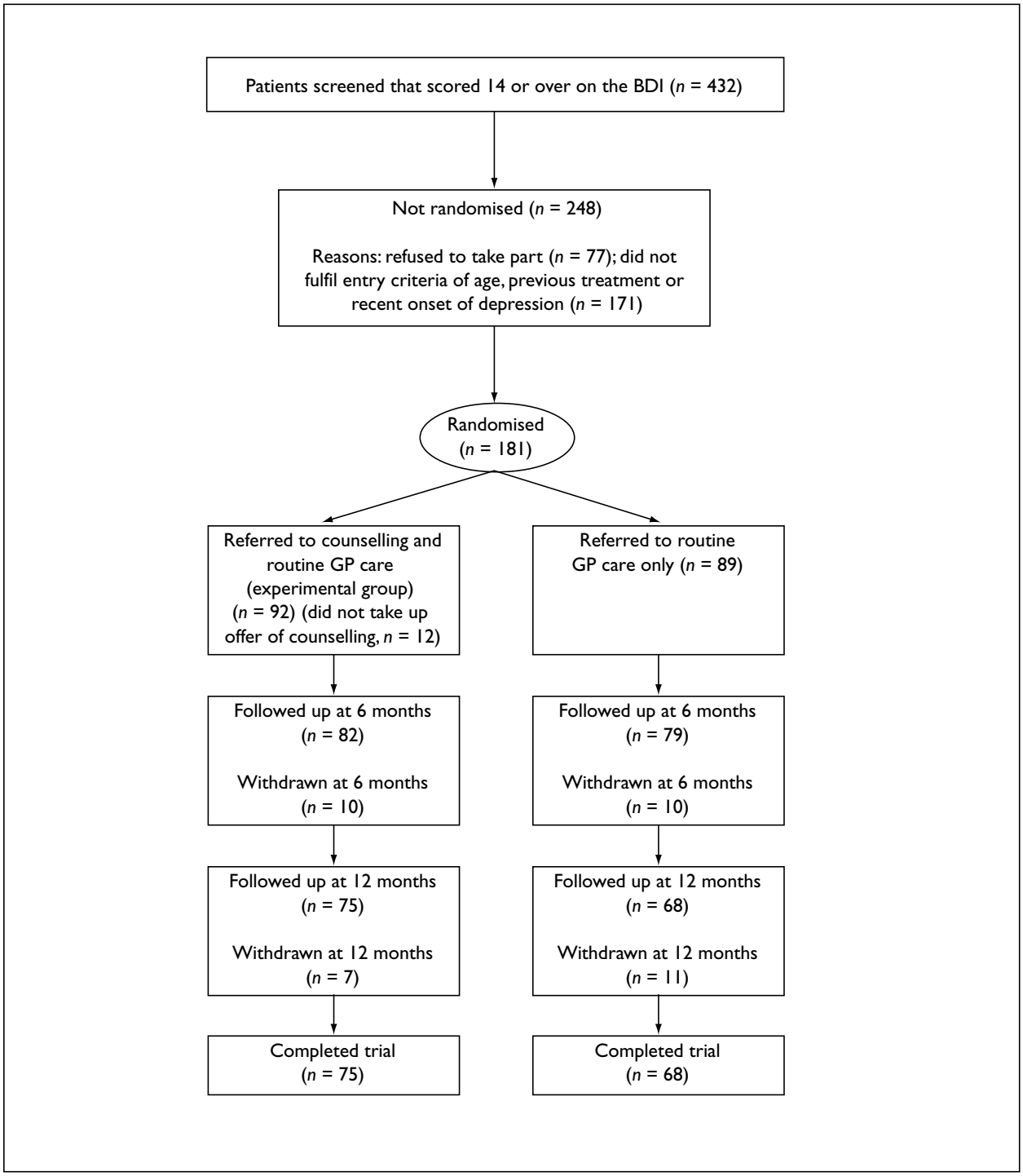

FIGURE 1 *Participant flow and follow-up*

discrepancy between patients' accounts of taking medication and the drugs prescribed according to medical records.

Two-thirds of participants had had previous treatment for depression/anxiety and this was similar in both groups. The majority had received medication before, but few had received counselling (*Table 5*).

In the previous 10 years, 21 (23%) patients in the experimental group and 23 (26%) controls had been referred to a psychiatrist. This included two experimental and four control group patients in the last year.

Initial assessment scores

The overall mean score on the BDI was 21; the experimental group had a slightly higher mean

TABLE 1 *Reasons for attendance of all patients filling in the initial questionnaire*

Reason for attendance	Study group		All patients filling in questionnaire	
	Number	%	Number	%
Obstetrics and gynaecology	20	11	149	10
Cardiovascular	17	9	141	9
Psychological	37	21	148	10
Musculoskeletal and eye	13	7	105	7
Skin	9	5	83	5
Infections	6	3	75	5
Other	79	44	849	54
Total	181	100	1550	100

TABLE 2 *Age and gender of patients in each group*

Age	Experimental group		Control group	
	Number	%	Number	%
Male				
18–29	0	0	2	2
30–45	7	8	6	7
46–70	7	8	14	16
Female				
18–29	18	19	12	13
30–45	29	32	25	28
46–70	31	33	30	34
Total	92	100	89	100

TABLE 3 *Summary of demographic characteristics*

Patient characteristics	Experimental group		Control group		*p*
	Number	%	Number	%	
Marital status					
Married	58	63	60	67	
Single	9	10	10	11	0.36
Widowed	8	9	7	8	
Separated/divorced	17	18	12	14	
With/without children					
With children	37	40	43	48	0.30
Without children	55	60	46	52	
Housing situation					
Privately rented	9	10	5	6	
Council rented	23	25	19	21	0.55
Owner occupied	60	65	65	73	
Employment category					
Manual	19	20	17	19	
Non-manual	31	34	32	36	0.98
Retired	18	20	17	19	
Unemployed	24	26	23	26	

TABLE 4 *The prescription and consumption of psychotropic medication – medical records and patients' accounts*

Whether taking psychotropic medication	Experimental group		Control group		*p*
	Number	%	Number	%	
Medical records					
Yes	45	50	30	34	0.03
No	45	50	59	66	
Patients' self-report					
Yes	26	29	20	22	0.35
No	65	71	69	78	

TABLE 5 *Previous history and treatment of depression and anxiety*

Prior history and treatment	Experimental group		Control group		*p*
	Number	%	Number	%	
Previous history of depression					
Yes	61	67	56	63	
No	30	33	33	37	0.56
Previous treatment					
Counselling	7	12	9	17	0.76
Medication	41	70	30	57	
Counselling plus medication	6	10	7	13	
Other	5	8	7	13	

TABLE 6 *Mean scores and SDs of the measures at first assessment*

Scores on assessment	Experimental group		Control group		*p*
	Mean	SD	Mean	SD	
BDI	21.5	6.0	19.8	5.7	0.07
IIP	48.5	20.6	43.9	15.9	0.12
BSI (GSI)	70.1	6.6	69.5	7.0	0.60
BSI (PST)	67.5	6.6	66.9	7.0	0.56
BSI (PSDI)	66.7	7.6	65.8	6.6	0.41
SAS	2.6	0.4	2.5	0.4	0.09
DSSS	0.3	0.1	0.3	0.1	0.74

score (22) than the control group (20), and this difference nearly reached statistical significance (mean difference = 1.6; 95% CI, –0.11 to 3.34; $t = 1.85$; df = 178; $p = 0.07$); making it very important to use the initial scores in any data analysis involving the BDI (*Table 6*).

According to Salkind,[68] who conducted studies in general practice using the BDI, scores of 0–10, 11–17, 18–23 or 24 and over indicate no depression, mild depression, moderate depression or severe depression, respectively. Using this system, there were 66 patients who were mildly depressed at first assessment, 57 who were moderately depressed and 57 who were severely depressed (*Table 7*).

The BSI has nine subscales: somatisation, obsessive–compulsive, interpersonal sensitivity, phobic anxiety, paranoid ideation, psychoticism, depression, anxiety and hostility. There are three summary scores. First, the Global Severity Index (GSI), considered to be the most sensitive indicator of a person's distress, is a score combining information about the number of symptoms a person is experiencing as well as the distress level.

TABLE 7 *Initial severity of depression*

Severity of depression	Experimental group		Control group		*p*
	Number	%	Number	%	
Mild depression	27	30	39	44	0.13
Moderate depression	31	34	26	29	
Severe depression	33	36	24	27	

Second is the Positive Symptom Distress Index (PSDI), which measures the average level of distress, and third is the Positive Symptom Total (PST), which measures the number of symptoms reported regardless of intensity. Possible scores range from 0 to 80, and a case is indicated by a score of over 63. The means and SDs of the three summary measures are included in *Table 6*. There were no statistically significant differences between the two groups on any of the scores.

The IIP only has an overall score. The initial scores of the two groups were compared, and there were no statistically significant differences between them. The overall IIP scores were compared with population means derived by Barkham and colleagues,[57] and the scores of the patients in this study were considerably higher than those of the general population, but similar to the patient population means in the study of Barkham and co-workers. In addition, there were no statistically significant differences in the SAS total score or the DSSS at baseline between the two groups.

Patients' views on treatment

Patients were asked for their views on counselling and psychotropic medication using two 8-point scales. Approximately two-thirds of both groups had positive opinions about counselling (points 6–8 on the scale), a small number of individuals were negative (1–3), and the remainder were mostly neutral (4 or 5), and there were no statistically significant differences in patient views on the value of counselling between the groups (*Table 8*). However, it seems likely that patients with strong feelings against counselling would not have entered into the trial, as they would not wish to receive this type of treatment. Patients were also asked for their views on psychotropic medication, and these were generally more negative with only 28% having a positive opinion.

Comparison of study patients with those referred by GPs directly to the counsellors

Since the original method of recruitment via the GP had to be abandoned, there was concern that the patients recruited into the trial would differ from those routinely referred to counselling by the GP. Therefore, trial participants were compared with those patients routinely referred by the GPs, and there were no statistically significant differences in gender or marital status between the trial group and the GP-referred group (*Table 9*). The mean BDI score at baseline was 21 for the trial group and 23 for the referred group, but this difference did not reach statistical significance ($t = 1.59$; df = 228; $p = 0.114$).

Patients referred from the GP to the counsellor directly were asked if they were taking psychotropic medication, and 56% indicated that they were compared with 26% in the trial group (*Table 9*). This difference was statistically significant (mean

TABLE 8 *Patients' initial views regarding counselling and psychotropic medication*

Patients' views	Experimental group		Control group		*p*
	Number	%	Number	%	
Views of counselling					
Negative	4	5	10	11	0.17
Neutral	23	25	25	28	
Positive	64	70	54	61	
Views of psychotropic medication					
Negative	42	46	35	40	0.64
Neutral	25	28	27	30	
Positive	24	26	27	30	

TABLE 9 *Demographic characteristics of patients referred by the GP directly compared with trial patients*

Demographic characteristics	Trial group		Patients referred to by GPs		*p*
	Number	%	Number	%	
Sex					
Female	144	80	38	76	0.53
Male	36	20	12	24	
Marital status					
Single	18	10	10	20	0.35
Married	118	66	31	62	
Widowed	15	8	2	4	
Divorced/separated	29	16	7	14	
Previous history of depression					
Yes	63	35	18	36	0.89
No	117	65	32	64	
Previous history of treatment (where applicable)					
Medication	71	63	21	66	
Counselling	16	14	2	6	
Medication plus counselling	13	12	9	28	
Other	12	11	0	0	
Patients taking psychotropic medication (patients' self-reports)					
Yes	46	26	28	56	0.001
No	134	74	22	44	

difference 30%; 95% CI, 14% to 46%; $\chi^2 = 20.98$; df = 1; $p < 0.001$). This difference could have been due to the majority of the direct referral patients having discussed their psychological problem with their GP (this leading to the referral and possibly a prescription) while this was not necessarily so for all the trial group.

There were no statistically significant differences between trial and GP-referred patients according to patients' views about treatment. Slightly more patients in the trial group were negative about drug treatment than those in the GP-referred group, and similar percentages were positive regarding counselling.

Comparison of study patients with audit data

Audit data are routinely collected by counsellors working in general practices across Derbyshire. The results are shown in *Table 10* and include all cases and not just trial patients who are anxious or depressed. Percentages rather than actual numbers were available to the researchers. There were more patients in the trial from the 46–65 age range, which could have been due to the fact that recruitment of patients was often during the day when many of the younger patients might have been at work. This may have also accounted for the lower percentage of men included in the trial.

Audit data is obtained from patients' medical records and not their own accounts. It is, therefore, only possible to compare psychotropic drug prescriptions rather than medication taken. The results suggest that the percentage of GP-referred patients who were prescribed psychotropic medication was roughly similar to the percentage of the trial subjects with this type of prescription. More of the GP-referred patients had been treated before and more were referred to further mental health services, tentatively suggesting some differences between groups. However, this is to be expected because the audit data relates to all referrals.

The number of counselling sessions given and the non-attendance rates of trial subjects were also compared with the audit data to estimate whether patients in the trial were less motivated than referred patients. The non-attendance rates within the study were 14%, and in Derbyshire, as a whole, non-attendance rates were 13% in 1996, 17% in 1997 and 19% in 1998, indicating that the non-attendance rates were slightly lower among the trial subjects. The trial subjects also had a slightly higher number of counselling

TABLE 10 *Comparison of trial patients with audit data (in percentages only)*

Demographics and treatment history	1996 audit (%)	1997 audit (%)	1998 audit (%)	Trial subjects (%)
Age group				
16–18	2	3	4	2
19–30	27	26	30	18
31–45	44	43	41	35
46–65	24	25	23	41
65+	3	3	2	4
Sex				
Male	34	33	30	20
Female	66	67	70	80
Patients on psychotropic medication (%)	n/a	n/a	41	42
Patients with previous psychological therapy (%)	n/a	n/a	21	14
Number of sessions				
0–3	39	43	36	26
4–6	35	36	41	44
7–12	21	18	18	27
12+	5	3	5	3
Patients referred to other mental health services (%)	24	12	8	2

n/a, not applicable

sessions overall than the patients included in the audit. These findings suggest that the trial patients were as motivated to receive counselling as the patients referred directly by the GPs.

Professionals seen between first assessment and 6-month follow-up

Most patients (87%) allocated to the experimental group saw the counsellor at least once. In the experimental group, 52% saw only the counsellor, 30% saw both the counsellor and the GP and 11% saw only the GP (*Table 11*). Five (5%) patients in the experimental group saw another therapist after the initial assessment with the counsellor, and the counsellors in question felt that these patients were inappropriate for short-term counselling and thus referred them to other services. Three were referred to a member of the CMHT, one was referred for occupational therapy and one to a psychologist and for group therapy. Only 2% of patients did not see the GP, counsellor or any other therapist. In the control group, 93% saw the GP and 7% of patients did not see anyone (*Table 11*). Nine (10%) patients who saw their GP were referred to another therapist for treatment. Two were referred to the CMHT, one was referred to a self-help group, three to psychotherapy, one to a mother and baby psychiatric unit, one was referred to a counsellor specialist in domestic violence and one to a psychiatrist and then a psychologist.

Experimental group: treatment from counsellor

Only minimal information regarding the counselling intervention is given here; further details are given in appendix 1. With regard to the type of counselling patients received, 19 patients were referred to a counsellor with a mainly cognitive approach and 73 to a counsellor with a mainly psychodynamic approach. However, only 59 of the 73 referred to a psychodynamic counsellor actually saw the counsellor, and 16 out of the 19 patients who were referred to the CBT counsellors attended. Patients' views of counselling and medication were examined to see if it was those patients with negative views of counselling that did not attend after being referred, but only one of the four patients who had initially expressed negative views failed to attend.

TABLE 11 *Professionals seen in the 6-month period after the first assessment*

Professionals seen[a]	Experimental group		Control group	
	Number	%	Number	%
Saw counsellor only	48	52	0	0
Saw GP only	10	11	74	83
Saw counsellor and GP	27	30	0	0
Saw other therapist after being seen and referred by either GP or counsellor[b]	5	5	9	10
Saw no-one	2	2	6	7

[a] *Using a combination of data from the CSRI, patient records and patient's views questionnaires*

[b] *Experimental subjects were first seen by the counsellor and referred on; controls were first seen by the GP and referred on*

The mean number of sessions was six and the range was from one to 16 sessions. About three-quarters had four sessions or more (*Table 12*). Only two patients had more than the maximum number of 12 sessions recommended by the HA. There was no significant difference in the number of sessions between those receiving psychodynamic therapy (mean = 6.6) and those receiving CBT (mean = 6.3).

TABLE 12 *Number of counselling sessions*

Number of sessions	Experimental group	
	Number	%
1–3	19	27
4–6	14	20
7–9	25	35
10–12	11	15
13–16	2	3

Counsellors were asked to tape at least one session with each patient. However, only six counsellors submitted tapes on 25 different sessions with 20 patients. At the present time, a detailed analysis of the tapes has not been conducted, although experienced counsellors have confirmed from the recordings that the therapy used was appropriate according to the model specified by the study counsellors.

Experimental and control groups: contacts with GP

Table 13 illustrates the number of visits that patients made to their GP during the 6 months after entry into the trial. Using Mann–Whitney *U* tests, there were no significant differences between groups in the number of visits made or in the number of visits made due to the change in scores between the two time periods (0–6 and 6–12 months) (see *Table 14*).

Experimental and control groups: psychotropic medication

Table 15 illustrates the number of patients that took psychotropic medication according to patients' self-reports and their medical records. These two different sources were included because patients may not have had the prescription dispensed or taken the medication prescribed. As can be seen, there was quite a large discrepancy between these two sources of information. The patients' accounts suggested that slightly more

TABLE 13 *Number of GP visits for all patients in the 6 months after study entry*

Number of GP consultations	Experimental group		Control group	
	Number	%	Number	%
0	6	7	1	1
1–3	27	33	30	38
4–6	31	38	34	43
7–9	17	21	8	10
10–12	1	1	6	8
Total	82	100	79	100

TABLE 14 *Medians and quartiles for the number of visits to the GP (according to medical records) and change in scores between the two time periods*

Number of visits	Experimental group		Control group		*p*
	Median	Quartiles 25/75	Median	Quartiles 25/75	
Mean no. of visits for 6 months prior to first assessment (period 1)	4	2/7	4	2/8	0.83
Mean no. of visits between first and 6-month assessments (period 2)	4	2/6	4	2/6	0.76
Change in score between period 2 and period 1	0	–2/2	0	–3/1	0.13

TABLE 15 *Psychotropic medication taken between the initial and 6-month assessments: data obtained from patients' medical records and patients' self-reports*

Whether taking psychotrophic medication	Experimental group		Control group		*p*
	Number	%	Number	%	
Medical records					
Yes	35	43	36	46	
No	47	57	43	54	0.71
Patients' self-reports					
Yes	24	29	29	37	
No	58	71	50	63	0.32

control group patients took psychotropic drugs between assessments than experimental group patients, however this difference was not apparent from the medical note information. The medical records also gave some suggestion that the control group patients were prescribed psychotropic drugs over a longer time period than experimental group patients (*Table 16*), but this difference between groups was not statistically significant.

Drugs were more likely to be prescribed for those with more severe depression. According to medical records, 60% of those classified as severely depressed were prescribed a psychotropic drug compared with 43% of those classified as moderately depressed and 32% classified as mildly depressed. The severely depressed were also more likely to be prescribed medication for 4–6 months. Indeed, 40% of those classified as severely depressed were prescribed psychotropic medication for 4–6 months compared with 16% of the moderately depressed and 15% of the mildly depressed.

Experimental and control groups: private treatment

Patients also arranged a variety of private treatments for their depression. In the experimental group, one patient saw a reflexologist, one had private counselling, one saw a

TABLE 16 *Length of time patients had been prescribed psychotropic drugs according to medical records*

Length of time	Experimental group		Control group		*p*
	Number	%	Number	%	
No time	47	57	43	54	
0–1 month	11	13	3	4	0.10
2–3 months	8	10	12	15	
4–6 months	16	20	21	27	
Total	82	100	79	100	

hypnotherapist, one saw a homeopath and one patient went to see Relate. Two control group patients paid for private psychotherapy, one saw a chiropractor, one saw a homeopath and the fifth patient had Reiki as a treatment.

Data analyses at 6-month follow-up

The main outcome measure in this study was the BDI. Other outcome measures included the BSI, the SAS and the IIP. Statistical analyses were conducted to compare differences in outcome between the experimental and control group subjects.

Improvement over time

Six-month follow-up data was not obtained for 20 participants (10 from each group) for a variety of reasons: three participants in the experimental group and three controls asked to be withdrawn from the trial, three patients in the experimental and six in the control group did not attend assessments even after two appointments had been made and three patients in the experimental group and two controls moved house or proved impossible to contact. Therefore, 6-month follow-up data was available for 82 and 79 patients in the experimental and control groups, respectively.

The patients who withdrew from the trial were compared using data collected at first assessment with those remaining to see if there were any differences between these two groups. There were no differences between those who withdrew and those who remained according to their initial score on the BDI, their gender or age, or their marital or employment status. In addition, there were no differences according to whether they were being prescribed psychotropic drugs at the first assessment, their previous treatment for depression, whether they had had a previous history of depression or their views on counselling or medication.

Prior to statistical analyses, an initial exploratory analysis of the data was completed to see whether it was normally distributed. This revealed that most of the variables were normally or almost normally distributed, and parametric tests were, therefore, possible on relevant variables. Initial analysis of the main measures (the BDI, the BSI, the IIP and the SAS) revealed that both the experimental and control groups improved significantly between first assessment and 6-month follow-up. An improvement is indicated by a reduction in score on all measures (*Table 17*).

Differences between experimental and control groups in outcome scores

The main analysis conducted was 'intention-to-treat' analysis, that is, all randomised patients have been kept in the analysis. This includes all non-compliers with counselling and the few patients who sought psychological help outside the study. As there were some differences in the initial mean scores between the experimental and control groups, univariate analyses of covariance were also conducted on all outcome measures (the BDI, the BSI, the SAS and the IIP), and the initial score used as the covariate. However, these analyses found no statistically significant differences between groups on any of the outcome variables (*Table 18*), but the covariate (the initial score) was significant at the 1% level or below in each case indicating the importance of the initial score on follow-up outcome.

Differences between experimental and control groups in the number of cases

In addition to investigating the mean scores, clinical outcome was investigated by examining the proportion of participants who were considered to still be cases at 6 months. Patients

TABLE 17 *Initial and 6-month follow-up mean scores on main measures*

Scores on questionnaires	Experimental group				Control group				*p*
	Initial		6 months		Initial		6 months		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
BDI	21.5	6.0	16.0	9.3	19.9	5.7	16.0	8.1	0.001
IIP	48.2	20.6	41.3	20.8	43.9	15.9	37.8	17.1	0.001
SAS	2.6	0.4	2.4	0.6	2.5	0.4	2.4	0.5	0.001
BSI (GSI)	70.1	6.6	65.4	9.7	69.6	7.0	64.1	9.3	0.001

TABLE 18 *Analyses of covariance showing baseline and main group effects for the main measures at 6 months*

Source of variation	Sum of squares	df	Mean square	95% CIs for main effect	F	Significance of F
BDI						
Baseline effect[a]	3,081.2	1	3,081.2		53.9	$p < 0.01$
Main effect	36.1	1	36.1	Mean 0.95; CI, –3.3 to 1.42	0.6	$p = 0.43$
BSI (GSI)						
Baseline effect	4,864.8	1	4,864.8		81.2	$p < 0.01$
Main effect	19.2	1	19.2	Mean 0.69; CI, –1.72 to 3.11	0.3	$p = 0.57$
SAS						
Baseline effect	15.3	1	15.3		76.6	$p < 0.01$
Main effect	0.2	1	0.2	Mean 0.08; CI, –0.06 to 0.22	1.2	$p = 0.28$
IIP						
Baseline effect	29,943.7	1	29,943.7		168.5	$p < 0.01$
Main effect	27.2	1	27.2	Mean 0.82; CI, –3.3 to 5.0	0.2	$p = 0.70$

[a] *The baseline effects (time from baseline and using the score from the first assessment as the covariate) were all statistically significant. The main effects (difference between the two treatments and using the baseline scores as a covariate) were not statistically significant*

were considered to still be cases if they scored 14 or over on the BDI, 63 or over on any of the total score measures of the BSI, or 2 or more on any one of the subcategories (work, housework, social and leisure activities, extended family, marital relationship, parental relationships and the family unit) of the SAS.[69] At 6 months, nearly 60% of the patients were still cases on the BDI but this included fewer people in the experimental group than the control group (*Table 19*), and this difference between groups almost reached statistical significance ($p = 0.065$) using logistic regression with initial BDI score as the covariate (*Table 20*). More than half the patients were still cases on the BSI at 6 months and there were similar proportions in each group, and the between-group difference was not significant ($p = 0.90$) (*Table 19*). On the SAS, over two-thirds of patients were still cases at 6-month follow-up. There were slightly fewer cases in the experimental group than in the control group but this was not significant ($p = 0.09$) (*Table 19*).

In order to check that the results were not due to the non-inclusion in the analysis of patients who withdrew from the 6-month assessment, the results were re-analysed taking these patients into account. This was achieved by following Altman's[65] recommended procedure:

TABLE 19 *Number of cases (and percentages) on the BDI, the SAS and the BSI over time and by group (excluding those who dropped out)*

	Experimental group		Control group		Total sample	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	44/82	54	49/79	62	93/161	58
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	48/82	58	45/79	57	93/161	58
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	58/82	71	61/79	77	119/161	74

TABLE 20 *Results from logistic regression between experimental and control groups on whether they are a case or non-case on the BDI at 6 months, with initial BDI score as the covariate*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.17	0.04	1	< 0.001	1.21	1.12 to 1.30
Experimental/control group	–0.71	0.38	1	0.065	0.51	0.25 to 1.04
Constant	–2.00	0.80	1	< 0.001		

- assigning the most optimistic outcome to all patients who dropped out and analysing the data
- assigning the most pessimistic outcome to all patients who dropped out and analysing the data
- analysing the data excluding all drop-outs.

If all three analyses yield similar results in the same direction, it is possible to be more confident of the findings. The analysis excluding the drop-outs is detailed above and, as *Table 19* illustrates, there were fewer cases based on the BDI and SAS scores at follow-up in the experimental group than the control group, however, there was no difference in the number of cases between groups based on the BSI.

Table 21 shows the results when the most positive outcome is assumed for those patients who dropped out (i.e. all drop-outs improve and cease to be cases). Although there were fewer cases in the experimental group than the control group on the BDI and the SAS, this difference was not statistically significant using logistic regression with the initial score on the BDI ($p = 0.11$), the SAS ($p = 0.19$) or the BSI ($p = 0.90$) as the covariate. *Table 22* assumes the most negative outcome for those patients who dropped out (i.e. all patients who withdrew continue to be cases). Fewer individuals in the experimental group were cases at 6 months on the BDI and the SAS than in the control group. This difference between groups was significant for the BDI ($p = 0.046$; *Table 23*) but not for the SAS ($p = 0.09$) or the BSI ($p = 0.90$).

Additional analyses taking into account treatment received

The previous analysis was performed according to intention-to-treat, and the analyses of covariance were repeated excluding various categories of patients who had not adhered to the treatment allocated to them. In the first of these analyses, patients in the experimental group were excluded who did not attend for counselling and patients in the control group were excluded who did not see the GP. Although there were no significant differences between groups according to the mean follow-up scores, there were significantly fewer cases using logistic regression on the BDI ($p = 0.014$) and the SAS ($p = 0.034$) in the experimental group than in the controls (*Tables 24* and *25*), however, there were no differences according to the BSI ($p = 0.67$).

In the second of these analyses, only patients in the experimental group who did not attend for

TABLE 21 *Number of cases (and percentages) on the three main psychological outcome measures across time and by group, assuming the most positive outcome for drop-outs*

	Experimental group		Control group		Total sample	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	44/92	48	49/89	55	93/181	51
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	48/92	52	45/89	51	93/181	51
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	58/92	63	61/89	69	119/181	66

TABLE 22 *Number of cases (and percentages) on the three main psychological outcome measures across time and by group, assuming the most negative outcome for drop-outs*

	Experimental group		Control group		Total sample	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	54/92	59	59/89	66	113/181	62
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	58/92	63	55/89	62	113/181	62
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	68/92	74	71/89	80	139/181	77

TABLE 23 *Results from logistic regression between experimental and control groups on whether they are a case or non-case on the BDI at 6 months, assuming the most negative outcome for drop-outs*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.18	0.04	1	< 0.001	1.20	1.11 to 1.29
Experimental/control group	–0.69	0.37	1	0.046	0.50	0.25 to 0.98
Constant	–3.05	0.72	1	< 0.001		

TABLE 24 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the BDI at 6 months, excluding patients who did not adhere to the treatment allocated*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.18	0.04	1	< 0.001	1.20	1.11 to 1.30
Experimental/control group	–0.99	0.41	1	0.014	0.39	0.18 to 0.82
Constant	–3.39	0.80	1	< 0.001		

TABLE 25 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the SAS at 6 months, excluding patients who did not adhere to the treatment allocated*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	2.78	0.61	1	< 0.001	16.19	4.87 to 53.86
Experimental/control group	–0.93	0.44	1	0.034	0.40	0.17 to 0.93
Constant	–5.83	1.45	1	< 0.001		

counselling were excluded. As with the previous analysis, there were no significant differences between groups according to the follow-up mean scores, however, there were significantly fewer cases using logistic regression on the BDI ($p = 0.021$) and the SAS ($p = 0.027$) in the experimental group than in the controls. Again, there were no differences according to the BSI ($p = 0.86$).

Different counselling models

Nineteen patients were referred to a counsellor with a mainly CBT approach and 73 were referred to a counsellor with a mainly psychodynamic approach. The type of counselling that patients received was not determined by random allocation, but by the model of counselling used by the counsellor attached to a patient's practice. The initial and 6-month follow-up scores on the

BDI for these two groups are detailed below. One-way analyses of covariance indicated that there were no significant differences in outcome scores at 6 months between those referred to the psychodynamic counsellors and those referred to the CBT counsellors (*Table 26*). Logistic regression on whether patients were cases or not at 6 months also yielded no significant differences between counselling approaches. However, it must be remembered that the number of patients referred to the CBT counsellors was low, and it would thus be highly unlikely for significant differences to be found.

TABLE 26 *Mean BDI score at 6 months for the two counsellor approaches (change in score in brackets)*

Counsellor approach	First assessment	6-month follow-up
Psychodynamic	22.0	16.1 (5.9)
CBT	19.5	15.5 (4.0)

Psychodynamic counselling

One weakness of the trial design was that there were two different counselling approaches. Since the number of patients that saw CBT counsellors was quite small, the main analyses were repeated including only those patients that saw a psychodynamic counsellor compared with the control group. At 6-month follow-up, this did not weaken the power of the study, as there were still 144 patients in the study. The mean BDI score at 6 months was 16.1 for patients referred to the psychodynamic counsellors and 16.0 for the control group. Analysis of covariance indicated that there were no statistically significant differences between groups on any of the main measures at 6 months (*Table 27*). The numbers of cases on the BDI, the SAS and the BSI at 6 months were also compared between the experimental and control groups. The percentages of patients who were cases at follow-up (*Table 28*) were very similar to those found for the experimental group as a whole including those referred to CBT counsellors. The difference between groups was not significant for the BDI ($p = 0.095$), the BSI ($p = 0.83$) or the SAS ($p = 0.14$).

The Altman procedures were also undertaken excluding the 19 patients referred to CBT counsellors. No significant difference in the BDI score was found between groups when the most positive outcome was assumed ($p = 0.15$), but a significant difference in the BDI score was found when the most negative outcome was assumed ($p = 0.054$).

In conclusion, there appears to be no major differences between these results and the 6-month analyses, which included those referred to a counsellor using CBT.

Inconsistency between findings

There were no statistically significant differences between the experimental and control groups when the actual 6-month scores on the BDI

TABLE 27 *Analyses of covariance showing baseline and main group effects for the main measures at 6 months: including only those referred to psychodynamic counsellors*

Source of variation	Sum of squares	df	Mean square	F	Significance of F
BDI					
Baseline effect[a]	2,861.79	1	2,861.79	48.59	$p < 0.01$
Main effect	42.51	1	42.51	0.72	$p = 0.40$
BSI (GSI)					
Baseline effect	4,201.12	1	4,201.12	67.04	$p < 0.01$
Main effect	30.13	1	30.13	0.48	$p = 0.49$
SAS					
Baseline effect	12.78	1	12.78	60.51	$p < 0.01$
Main effect	0.15	1	0.15	0.69	$p = 0.41$
IIP					
Baseline effect	22,926.76	1	22,926.76	127.37	$p < 0.01$
Main effect	8.02	1	8.02	0.05	$p = 0.83$

[a] *The baseline effects (time from baseline and using the score from the first assessment as the covariate) were all statistically significant. The main effects (difference between the two treatments and using the baseline scores as a covariate) were not statistically significant*

TABLE 28 *Number of cases (and percentages) on the BDI, the SAS and the BSI over time and by group, including only those referred to the psychodynamic counsellors*

	Experimental group		Control group		Total sample	
	Number	%	Number	%	Number	%
BDI						
Baseline	73/73	100	89/89	100	162/162	100
6 months	36/65	55	49/79	62	85/144	59
BSI (GSI)						
Baseline	63/72	88	71/89	80	134/161	83
6 months	38/65	59	45/79	57	83/144	58
SAS						
Baseline	66/72	92	80/89	90	146/161	91
6 months	47/65	72	61/79	77	108/144	75

were analysed, but there were a smaller number of patients who were still cases in the experimental group than the controls at 6 months. This latter difference almost reached statistical significance. This inconsistency in results could be due to the case/'non-case' dichotomy providing more limited information, as it does not yield any information on changes between levels of severity of depression (apart from case/non-case) including deterioration over time. In order to investigate a possible reason why the results were inconsistent, the patients were divided into three groups according to the severity of their initial symptoms and the outcome of patients in both the experimental and control groups were compared by visual inspection.

Table 29 shows that the higher number of 'not depressed' or non-case patients in the experimental group than in the controls at 6 months was due to the improvement of patients with initially mild or moderate depression. Of the initially mildly depressed patients in the experimental group, 72% were classified as not depressed at 6 months compared with 54% of the controls. Similarly, 55% of the initially moderately depressed patients in the experimental group were classified as not depressed at 6 months compared with 32% in the control group. However, a different picture emerges for patients who were severely depressed initially. Only a small proportion of the severely depressed patients had become not depressed in both groups, and half of the experimental group had remained severely depressed compared with 32% of the controls. This lack of improvement in the severely depressed group who were referred to a counsellor may be one of the main reasons why no significant differences were found between the experimental and control groups according to the actual BDI scores at 6 months.

TABLE 29 *Outcome and 'caseness' according to the initial severity on the BDI score: experimental and control groups*

Initial severity	Follow-up severity of experimental group	Follow-up severity of control group
Mild (BDI score = 14–17)	Non-case (improved) = 18 (72%) Mild at follow-up = 2 (8%) Moderate at follow-up = 4 (16%) Severe at follow-up = 1 (4%)	Non-case (improved) = 19 (54%) Mild at follow-up = 14 (40%) Moderate at follow-up = 2 (6%) Severe at follow-up = 0 (0%)
Moderate (BDI score = 18–23)	Non-case (improved) = 16 (55%) Mild at follow-up = 3 (11%) Moderate at follow-up = 5 (17%) Severe at follow-up = 5 (17%)	Non-case (improved) = 7 (32%) Mild at follow-up = 3 (13%) Moderate at follow-up = 7 (32%) Severe at follow-up = 5 (23%)
Severe (BDI score = 24+)	Non-case (improved) = 4 (14%) Mild at follow-up = 5 (18%) Moderate at follow-up = 5 (18%) Severe at follow-up = 14 (50%)	Non-case (improved) = 4 (18%) Mild at follow-up = 5 (23%) Moderate at follow-up = 6 (27%) Severe at follow-up = 7 (32%)

TABLE 30 *Results from a multiple regression on follow-up BDI score at 6 months. The interactions were not significant so have not been included*

Source of variation	Sum of squares	df	Mean square	F	Significance of F
Experimental/control group	35.50	1	35.50	0.63	$p = 0.43$
Initial social support score	228.53	1	228.53	4.05	$p = 0.05$
Initial BDI score	2299.17	1	2299.17	40.77	$p < 0.001$
Taken psychotropic drugs/or not	0.83	1	0.83	0.02	$p = 0.90$

A similar picture emerges if only the patients referred to the psychodynamic counsellors are included and compared with the controls. A higher proportion of patients in the experimental group with initially mild or moderate depression improved than the controls. However, more of the severely ill patients in the experimental group failed to improve than in the controls.

Multiple and logistic regression analyses

A number of other variables may affect outcome apart from the initial severity of depression, including medication received and taken as well as the social support available. In addition, there may be interactions between these variables and counselling intervention; certain subgroups may benefit more from receiving counselling than others. For example, an interaction between group (experimental/control) and initial severity is suggested by the findings shown in *Table 29*.

A multiple regression analysis was conducted using the 6-month BDI score as the dependent variable. The initial score measuring social support and the initial BDI score were included as covariates. Two binary variables were also included; whether they were in the experimental or control group and whether or not they had taken psychotropic drugs in the period between initial and 6-month assessments (*Table 30*). The interactions between group (experimental/control) and the other three variables were also included in the model. None of the interactions were significant and were thus omitted from the model, including the interaction between group and the initial BDI score ($p = 0.56$). Of the main effects, the initial BDI score was highly significant ($p < 0.001$) and the initial social support score was also significant ($p = 0.046$), but there were no significant differences between the experimental and control groups after adjusting for the other variables ($p = 0.43$) (*Table 30*). Parameter estimates for the initial BDI score were 0.70 (95% CI, 0.49 to 0.92), indicating that the higher the initial score the higher the 6-month BDI score. Parameter estimates for the initial social support score were –8.90 (95% CI, –17.62 to –0.17), indicating that the lower the initial score (low scores mean low levels of social support), the higher the 6-month BDI score.

A similar multiple regression analysis was carried out using the 6-month BSI score as the dependent variable and the initial BSI score as the covariate. Only the initial BSI score was statistically significant. A multiple regression with the 6-month SAS score also showed that only the initial SAS score was significant.

The logistic regression analyses were repeated for whether patients were a case or not on the BDI at 6 months including the initial social support scores, the initial BDI score, whether they were in the experimental or control group and whether or not they had taken psychotropic medication between the first and 6-month assessments. It can be seen from *Table 31* that there

TABLE 31 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the BDI at 6 months*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.19	0.04	1	< 0.001	1.21	1.11 to 1.31
Experimental/control group	–0.75	0.38	1	0.05	0.47	0.23 to 0.98
Initial social support score	–2.55	1.37	1	0.06	0.08	0.01 to 1.14
Whether taking psychotropic drugs or not	–0.50	0.41	1	0.22	0.61	0.27 to 1.36
Constant	–2.45	0.97	1	0.01		

was a significant difference in outcome between the experimental and control groups ($p = 0.045$) and that the initial social support score also almost reached statistical significance ($p = 0.062$). A similar logistic regression was performed for the BSI but none of the variables, apart from the initial BSI, were statistically significant, and the same was true for the SAS.

Patients' views

At the end of the 6-month assessment, the patients were asked about their experience and their views relating to their treatment using a questionnaire that was adapted from one used by Corney and Jenkins.[70] Only the main results are presented here; detailed results including patients' comments are included in appendix 1.

Experimental group: patients' views of counselling treatment

Patients were asked whether they had seen a counsellor and were asked about their experiences of counselling. The majority were very positive about their experiences. Of those who saw a counsellor, 73% found the visits useful, 86% found it easy to talk to the counsellor and 82% felt that the counsellor understood their problems and feelings (*Table 32*). Patients were also asked, 'How much do you think you have changed as a result of counselling?' and were given five categories of response (*Table 33*). More than two-thirds of the patients who received counselling felt that they had changed for the better, one-quarter considered that there had been no change and only one person thought they had changed for the worse.

TABLE 33 *How much did you change as a result of counselling?*

Change because of counselling	Number	%
A great deal of change	11	16
Change for the better	40	56
No change	19	27
Change for the worse	0	0
A great deal of change for the worse	1	1

When patients were asked whether counselling had helped them in any of a series of responses (*Table 34*), a high proportion felt that seeing a counsellor had helped them. Patients were then asked an open-ended question 'Did counselling help you in any other way?' The written responses of the patients suggested that they perceived counselling to be helpful in a number of ways, including helping them understand their problems more clearly, discovering the possible cause of their problems, being able to talk to someone independent and non-judgmental, giving them time and space to talk without distractions, providing emotional support and improving their self-confidence. Ten patients made some negative comments, but were generally positive about counselling.

A further seven patients, however, indicated negative feelings overall suggesting that the process had made them feel worse rather than better. These seven patients did not differ from the others in any predictable way, and they had been generally positive about counselling prior to allocation. The counsellors assessed four of them initially as having 'some motivation' to receive counselling help and two out of the seven were

TABLE 32 *Patients' views of the counselling they received*

Patients' views		Number	%
Did you find your visits to the counsellor useful?	Yes	52	73
	Unsure	11	16
	No	8	11
Did you find it easy to talk to the counsellor?	Yes	61	86
	Unsure	4	6
	No	6	8
Did you think you had enough time to explain your problems to the counsellor?	Yes	35	50
	Unsure	16	22
	No	20	28
Do you think the counsellor understood your problems and feelings?	Yes	58	82
	Unsure	8	11
	No	5	7

TABLE 34 *Patients' views of how counselling helped*

	Yes		Unsure		No		Not applicable	
	No.	%	No.	%	No.	%	No.	%
Did counselling make you feel less depressed or anxious?	44	62	14	20	13	18	0	0
Did counselling get you to work out or solve your problems?	46	65	16	22	9	13	0	0
Did counselling give you relief by being able to talk about your problems?	61	86	3	4	7	10	0	0
Did counselling help you cope with your feelings?	41	58	21	30	9	12	0	0
Did counselling help you to change within yourself?	36	51	20	28	15	21	0	0
Did counselling improve communication with your partner or family?	24	34	16	22	17	24	14	20
Did counselling giving you a clearer picture of who you are and the future?	37	52	8	11	15	21	11	16
Did counselling help you with sexual difficulties?	6	8	6	8	18	26	41	58

classified as having 'severe depression'. There were also no differences according to the type of counselling received by these seven patients than for the group as a whole and no one counsellor received more negative comments than the others.

GP treatment: experimental and control groups

Patients in both groups were asked about the treatment that they had received from their GP. Twenty-one (26%) of the experimental group had talked things over with their GP compared with 65 (82%) of the control group. They were also asked to estimate how much they had changed as a result of the help from their GP and patients in the experimental group tended to be more positive about this treatment than the controls. A slightly higher proportion of patients in the experimental group felt that this treatment had resulted in some change for the better (*Table 35*).

Patients were asked a number of questions regarding the helpfulness of talking things over with their GP. Of the 21 patients in the experimental group who received this treatment, two-thirds said that it made them feel better and most said that being able to talk about their problems gave them relief. However, less that one-fifth felt that the treatment helped them actually solve their problems. In the control group, two-thirds felt that it gave them relief to talk about their problems and one-third considered that it made them feel less depressed or anxious. However, less than one-fifth considered that it had helped them to actually solve their problems (*Table 36*). Patients' views on whether talking to their GP had been helpful

TABLE 35 *How much have you changed as a result of talking things over with the GP?*[a]

	Experimental group		Control group	
	Number	%	Number	%
A great deal of change for the better	1	5	3	4
Some change for the better	11	52	27	41
No change	9	43	33	51
Some change for the worse	0	0	1	2
A great deal of change for the worse	0	0	1	2

[a] *This question was not applicable for 61 patients in the experimental group and 14 patients in the control group who indicated that they did not talk things over with the GP*

TABLE 36 *Patients' views of the helpfulness of talking things over with the GP*

	Those answering yes in experimental group		Those answering yes in control group	
	Number	**%**	**Number**	**%**
Did the treatment help you solve your problems?	4	19	12	18
Did the treatment make you feel better?	15	71	28	43
Did the treatment make you feel less depressed or anxious?	6	29	21	32
Did the treatment give you relief by being able to talk about your problems?	18	86	42	65
Did the treatment help you cope with your feelings?	6	29	18	28
Did the treatment improve communication with your partner or family?	2	10	5	8
Did the treatment help you sort out sexual difficulties?	0	0	0	0

varied. Some control group patients considered the doctor to be very helpful, and understanding with the time to listen; others felt that their GP was rushed, unsympathetic or could not really help them with their problems. A small proportion commented that they needed to talk to someone with more time 'like a counsellor'. Some of the experimental group patients felt that talking things over with their GP had given them relief from their symptoms. However, others felt that their GP did not have time to talk or were concerned about 'taking up valuable GP time'.

Medication: control and experimental groups

During the 6-month period between assessments, 39 patients in the control group and 26 in the experimental group had taken psychotropic medication according to the patients' views questionnaire. Over 70% of those taking medication in the control group felt that it had made them feel better and had made them feel less depressed or anxious. Over half felt that the medication helped them to cope with their feelings and 44% felt that it gave them space to work out their problems. In the experimental group, similarly high proportions of those taking psychotropic medication considered that the drugs made them feel less depressed and helped them to cope with their feelings. However, only 15% felt that the medication gave them space to solve their problems (*Table 37*).

Patients were asked, 'How much did you change as a result of taking the medication?' Their responses are shown in *Table 38*. High proportions felt that they had changed for the better. Patients were also asked to give their overall views of the medication, and approximately 50% of both groups were positive about medication, 30% had mixed feelings and 20% were predominantly negative, although controls were generally more positive about medication than experimental group patients.

TABLE 37 *Patients' views of the medication*

	Those answering yes in experimental group		Those answering yes in control group	
	Number	**%**	**Number**	**%**
Did the medication make you feel less depressed or anxious?	16	62	28	72
Did the medication make you feel better?	19	73	30	77
Did the medication get you to work out or solve your problems?	6	23	17	44
Did the medication give you space to let you solve you problems?	4	15	17	44
Did the medication help you cope with your feelings?	14	54	20	51

TABLE 38 *How much did you change as a result of taking the medication?*

Amount of change due to medication	Experimental group		Control group	
	Number	%	Number	%
A great deal of change for the better	2	8	2	5
Change for the better	19	73	26	67
No change	4	15	10	26
Change for the worse	0	0	1	3
A great deal of change for the worse	1	4	0	0

Patients' views on whether they would have liked a different sort of help

Patients were given five categories of response (*Table 39*) to the question 'Would you have liked a different sort of help?'. In the experimental group, small proportions of patients indicated that they would have preferred to see their GP or have been prescribed medication, and even higher proportions indicated that they would have liked more practical help and 24% felt that they wanted more advice on what to do. However, 36% of the experimental group said 'no' to all of the alternatives suggesting that they were satisfied with the treatment received, and only 6% of patients seeing the counsellor wanted a referral to another agency.

Approximately one-quarter of the controls would have preferred help from a counsellor, and slightly higher proportions of patients in the control than the experimental group would have preferred more practical advice on what to do. A small proportion of controls would have liked a referral to another agency, and only 11 (14%) said 'no'

TABLE 39 *Patients' preferences for help*

Patients' views on different types of help	Experimental group (*n* = 71)		Control group (*n* = 78)	
	Number	%	Number	%
Would have preferred to see the doctor (experimental group) or counsellor (control group)?				
Yes	1	2	20	26
Unsure	7	10	24	31
No	63	88	34	43
Would have preferred tablets from the GP?[a]				
Yes	8	11	5	10
Unsure	2	3	14	28
No	61	86	31	62
Would have preferred more practical help?				
Yes	13	18	18	23
Unsure	9	13	19	24
No	49	69	41	53
Wanted more advice on what to do?				
Yes	17	24	27	34
Unsure	14	20	20	26
No	40	56	31	40
Wanted referral to another agency?				
Yes	4	6	5	6
Unsure	2	3	9	12
No	65	91	64	82

[a] *This was not applicable for those on medication*

to all of the alternatives suggesting that they were satisfied with the treatment that they had received.

Additional treatment: experimental and control groups

Both groups were asked to specify their views about any other treatment that they had in addition to the treatment received from the counsellor or GP, including treatment given as a result of GP referral or from the patient arranging it themselves. Some data were missing because some patients did not fill in this section, even though, according to the CSRI questionnaire, they had received treatment from another professional. Data on views of alternative treatment were available for four of 10 experimental group patients and 10 of 14 controls. Patients were asked how much they thought they had changed as a result of their additional treatments, and the majority of patients in both groups felt that there had been a change for the better. Only two of the controls considered that there had been no change.

All patients were also asked if anyone or anything else had helped them, and a range of other help was mentioned, including changes in personal circumstances (*Table 40*). Only eight patients (two in the experimental and six in the control group) felt that nothing had helped them, including GPs, counsellors, other health professionals, medication or other more informal sources of help.

The 12-month follow-up assessment

At 12 months, data was collected from 143 patients (79% of those originally recruited into the study), which was an adequate number for the data analysis based on the original power calculations. Of the 18 patients that withdrew between 6 and 12 months, three patients in the experimental group and six controls did not attend the assessment session after two appointments had been arranged, three patients in the experimental and four in the control group moved house or were impossible to contact and one patient in each group asked to be removed from the trial.

Medical and counselling treatment between 6 and 12 months

Many patients were still in contact with their counsellor between the first and second follow-up assessments and high proportions in both groups saw their GP at least once. In addition, 17% of the experimental group saw a counsellor in this period. Only 10 patients in the trial did not see anyone for treatment during the 6- to 12-month period (*Table 41*).

TABLE 40 *Did anything else help you with your problems (excluding medical professionals or counsellors)?*

Unofficial sources of help	Experimental group		Control group	
	Number	%	Number	%
Family and friends	39	48	34	43
Change in circumstances	7	9	6	8
Self-help and support groups	2	2	3	4
Church	1	1	1	1
Time	0	0	1	1
Time off work	0	0	1	1
No-one else helped (apart from professionals)	47	57	48	61

TABLE 41 *Professionals seen between the 6- and 12-month assessments*

Professionals seen	Experimental group		Control group	
	Number	%	Number	%
Saw GP only	38	51	55	81
Saw counsellor and GP	13	17	1	2
Saw other therapist and GP	17	23	8	12
Saw no-one	7	9	3	5

TABLE 42 *Other therapists seen in the 6- to 12-month period between first and second follow-ups*

Therapy received	Number in experimental group	Number in control group
Psychiatry and CPN	1	1
CMHT	2	0
Psychotherapy	1	0
Group therapy	1	0
Occupational therapy	1	2
Other advice/counselling	2	2
Physiotherapy	4	2
Reflexology	1	1
Chiropractice	2	0
Therapeutic massage	1	0
Acupuncture	1	0

Eight patients in the control group and 17 in the experimental group saw other therapists as well as their GP. Of these, five in the control group and eight in the experimental group saw mental health professionals or therapists that used psychological treatments, and three controls and nine experimental group patients saw a range of other therapists for treatment. However, it was not always straightforward to ascertain how much of this treatment was related to patients' depression, as many patients felt that the relief from pain was helpful in lifting their mood (*Table 42*).

Although slightly fewer patients (91%) in the experimental group attended their GP between the first and second follow-up assessments than control group patients (95%), the actual number of attendances was similar for both groups (*Table 43*). Using Mann–Whitney *U* tests, no significant difference in the change in scores between period 3 and period 2 (see *Table 44*) between groups were detected.

Psychotropic medication

Similar proportions of patients in the experimental and control groups were prescribed psychotropic medication between the 6- and 12-month assessments (*Table 45*), and there was no evidence to suggest that experimental group patients were being prescribed medication for shorter periods of time (*Table 46*).

Improvement over time

Analysis of the measures, using paired *t*-tests, revealed that participants had improved substantially between the first assessment and the 12-month follow-up. This was statistically significant at below the 0.1% level for all measures. However, as *Table 47* illustrates, the majority of this improvement occurred in the first 6 months and there was little additional improvement between 6 and 12 months.

Differences between experimental and control groups in outcome scores

Univariate analyses of covariance were conducted on the 12-month follow-up data for the outcome measures (the BDI, the BSI, the IIP and the SAS) using the initial score on the questionnaire as a covariate. These analyses found no statistically significant differences between the groups on

TABLE 43 *Number of GP attendances for patients between the 6- and 12-month follow-up (according to medical records)*

Number of attendances	Experimental group		Control group	
	Number	%	Number	%
0	7	9	3	4
1–3	30	40	42	62
4–6	31	42	14	21
7–9	7	9	6	9
10–12	0	0	3	4
Total	75	100	68	100

TABLE 44 *Number of GP attendances during the three different time periods (according to medical records)*

Different time periods	Experimental group		Control group		*p* (Mann–Whitney)
	Median	Quartiles 25/75	Median	Quartiles 25/75	
Mean number of attendances in the 6 months before study entry (period 1)	4	2/7	4	2/8	0.83
Mean number of attendances between first and 6-month assessments (period 2)	4	2/6	4	2/6	0.76
Change in scores between period 2 and period 1	0	–2/2	0	–3/1	0.13
Mean number of attendances between 6- and 12-month follow-ups (period 3)	3	2/5	3	2/4	0.37
Change in scores between period 3 and period 2	–1	–2/1	–1	–2/1	0.40

TABLE 45 *Number of patients who had psychotropic drug treatment according to medical records*

Whether taking psychotrophic medication	Experimental group		Control group		*p*
	Number	%	Number	%	
Yes	30	40	26	38	0.83
No	45	60	42	62	

TABLE 46 *Length of time patients had psychotropic drug treatment according to medical records*

Length of time	Experimental group		Control group		*p*
	Number	%	Number	%	
No time	45	60	42	62	0.77
0–1 month	6	8	5	7	
2–3 month	10	13	12	18	
4–6 months	14	19	9	13	
Total	75	100	68	100	

TABLE 47 *Mean scores and SDs on the main outcome measures across time and groups*

	Experimental group		Control group		Total	
	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*
BDI						
Baseline	21.5 (6.0)	92	19.9 (5.7)	89	20.7 (5.9)	181
6 months	16.0 (9.3)	82	16.0 (8.1)	79	16.0 (8.7)	161
12 months	15.0 (9.8)	75	15.3 (8.6)	68	15.1 (9.2)	143
BSI (GSI)						
Baseline	70.1 (6.6)	92	69.6 (7.0)	89	69.9 (7.0)	181
6 months	65.4 (9.7)	82	64.1 (9.3)	79	64.8 (9.5)	161
12 months	64.1 (11.3)	75	64.0 (9.6)	68	64.1 (10.5)	143
IIP						
Baseline	48.2 (20.6)	92	43.9 (15.9)	89	46.1 (18.5)	181
6 months	41.3 (20.8)	82	37.8 (17.1)	79	39.6 (19.1)	161
12 months	40.2 (22.3)	75	38.2 (18.3)	68	39.3 (20.5)	143
SAS						
Baseline	2.6 (0.4)	92	2.5 (0.4)	89	2.5 (0.4)	181
6 months	2.4 (0.6)	82	2.4 (0.5)	79	2.4 (0.6)	161
12 months	2.3 (0.6)	75	2.4 (0.6)	68	2.4 (0.6)	143

treatment outcome for any of the measures, however, the covariate was significant at the 1% level or below in each case (*Table 48*).

Differences between experimental and control groups in the number of cases

The scores on the BDI, the SAS and the BSI questionnaires were re-examined to establish whether patients were considered to still be cases (a score of 14 or over on the BDI, 63 or more on the BSI and at least 2 on the SAS) at 12-month follow-up (*Table 49*). There were fewer cases on the BDI in the experimental than in the control group at 12 months (47% compared with 63%) and this difference was statistically significant using logistic regression with the initial score on the BDI as the covariate ($p = 0.01$) (*Table 50*). A similar difference occurred, but to a lesser extent, using the BSI (GSI) (57% compared with 63%), but did not reach statistical significance ($p = 0.251$). There was no difference between groups on the SAS (77% compared with 73%; $p = 1.00$).

Table 51 shows the results when the most positive outcome is assumed for those patients who dropped out (i.e. all improved and ceased to be cases). There were fewer cases in the experimental than the control group on the BDI, and this difference neared statistical significance using logistic regression with the initial score

TABLE 48 *Analyses of covariance showing baseline and main group effects for the main measures at 12 months*

Source of variation	Sum of squares	df	Mean square	F	95% CIs for main effect	Significance of F
BDI						
Baseline effect	2,591.9	1	2,591.9	38.0		$p < 0.001$
Main effect	49.2	1	49.2	0.7	Mean 1.18; CI, –1.56 to 3.92	$p = 0.4$
BSI (GSI)						
Baseline effect	5,203.2	1	5,203.2	70.1		$p < 0.001$
Main effect	10.5	1	10.5	0.1	Mean 0.54; CI, –2.31 to 3.40	$p = 0.71$
SAS						
Baseline effect	8.7	1	8.7	32.4		$p < 0.001$
Main effect	0.4	1	0.4	1.7	Mean 0.11; CI, –0.06 to 0.28	$p = 0.20$
IIP						
Baseline effect	28,660.5	1	28,660.5	130.8		$p < 0.001$
Main effect	0.2	1	0.2	0.01	Mean –6.96; CI, –4.98 to 4.85	$p = 0.98$

TABLE 49 *Number of cases (percentage) on the BDI, the SAS and the BSI across time and by group (not including those who dropped out)*

	Experimental group		Control group		Total	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	44/82	54	49/79	62	93/161	58
12 months	35/75	47	43/68	63	78/143	55
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	48/82	58	45/79	57	93/161	56
12 months	43/75	57	43/68	63	86/143	60
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	58/82	71	61/79	77	119/161	74
12 months	58/75	77	50/68	73	108/143	75

TABLE 50 *Results from logistic regression between experimental and control groups on whether they are a case or non-case on the BDI at 12 months, with initial BDI score as the covariate*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.16	0.04	1	< 0.001	1.18	1.09 to 1.27
Experimental/control group	0.97	0.38	1	0.010	0.38	0.18 to 0.80
Constant	–3.04	0.76	1	< 0.001		

TABLE 51 *Number of cases (percentage) on the three main psychological outcome measures across time and by group, assuming the most positive outcome for drop-outs*

	Experimental group		Control group		Total	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	44/92	48	49/89	55	93/181	51
12 months	35/92	38	43/89	48	78/181	43
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	48/92	52	45/89	51	93/181	51
12 months	43/92	47	43/89	48	86/181	48
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	58/92	63	61/89	69	119/181	66
12 months	58/92	63	50/89	56	108/181	60

as the covariate ($p = 0.066$), but there were no statistically significant differences on the SAS ($p = 0.55$) or the BSI ($p = 0.75$). *Table 52* assumes the most negative outcome for those patients who dropped out (i.e. all continued to be cases). Fewer individuals in the experimental group were cases at 6 months on the BDI and the SAS than the controls. This difference was significant for the BDI ($p = 0.003$) (*Table 53*), but not the SAS ($p = 0.79$) or BSI ($p = 0.18$).

Additional analyses taking into account treatment received

The previous analysis was performed according to intention-to-treat. However, the analyses of covariance were repeated excluding various categories of patients who had not adhered to the treatment allocated to them. In the first of these analyses, both patients in the experimental group who did not attend for counselling and patients in the control group who did not see the GP were excluded. Although there were no significant differences between groups according to the follow-up mean scores, there were significantly fewer cases in the experimental group than in the controls using logistic regression on the BDI ($p = 0.007$) (*Table 54*). There were no differences using the BSI ($p = 0.17$) or the SAS ($p = 0.72$).

In the second of these analyses, only patients in the experimental group who did not attend for counselling were excluded. As with the previous analysis, there were no significant differences between groups according to the mean follow-up scores, however, there were significantly fewer cases in the experimental group than in the controls using logistic regression on the BDI ($p = 0.005$). There were no differences using the BSI ($p = 0.18$) or the SAS ($p = 0.70$).

Different counselling models

As with the 6-month data analysis, the patients in the experimental group were divided into two groups: those referred to a counsellor with a CBT approach and those referred to a counsellor with a psychodynamic approach. Analysis of covariance on the 12-month outcome measures detected no differences according to the type of counselling received. Logistic regression on whether patients were cases at 12 months also yielded no significant differences between counselling approaches.

TABLE 52 *Number of cases and percentage on the three main psychological outcome measures over time and by group assuming the most negative outcome for drop-outs*

	Experimental group		Control group		Total	
	Number	%	Number	%	Number	%
BDI						
Baseline	92/92	100	89/89	100	181/181	100
6 months	54/92	59	59/89	66	113/181	62
12 months	52/92	57	64/89	72	116/181	64
BSI (GSI)						
Baseline	78/92	85	71/89	80	149/181	82
6 months	58/92	63	55/89	61	113/181	62
12 months	60/92	65	64/89	72	124/181	68
SAS						
Baseline	82/92	89	80/89	90	162/181	89
6 months	68/92	74	71/89	80	139/181	77
12 months	75/92	82	71/89	80	146/181	81

TABLE 53 *Results from logistic regression between experimental and control groups on whether they are a case or non-case on the BDI at 12 months assuming the most negative outcome for drop-outs*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.16	0.04	1	< 0.001	1.17	1.09 to 1.26
Experimental/control group	–1.05	0.35	1	0.003	0.35	0.18 to 0.70
Constant	–2.54	0.70	1	< 0.001		

TABLE 54 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the BDI at 12 months excluding patients who did not adhere to their allocated treatment*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.16	0.04	1	< 0.001	1.17	1.08 to 1.26
Experimental/control group	–1.10	0.40	1	0.007	0.33	0.15 to 0.74
Constant	–3.00	0.80	1	< 0.001		

Psychodynamic counselling

As previously stated, one weakness of the trial design was that two different counselling approaches were used, and, therefore, the main analyses of the 12-month data were repeated with only those patients that saw a psychodynamic counsellor compared with the control group. However, at 12 months, there were only 128 patients in this analysis, which is fewer than the number of subjects anticipated as necessary in the original power calculation (> 140).

Analysis of covariance indicated that there were no statistically significant differences between groups on any of the main measures (*Table 55*). Although the initial mean BDI scores of those referred to the psychodynamic counsellors (mean score 22, SD 6.1) was higher than the score for the controls (mean score 19.9, SD 5.7), the mean 12-month BDI scores for the two groups were almost identical: 15.4 (SD 10.3) versus 15.3 (SD 8.6) for the experimental and control groups, respectively (*Table 56*).

Comparison of the numbers of cases on the BDI, the SAS and the BSI between the experimental and control group at 12 months revealed that the percentages of patients who were considered still cases at 12 months (*Table 57*) were very similar to those found for the experimental group as a whole including those referred to CBT counsellors. There were more cases in the control group than in the experimental group for the BDI (63% compared with 48%), but the opposite was true

TABLE 55 *Analyses of covariance showing baseline and main group effects for the main measures at 6 months*

Source of variation	Sum of squares	df	Mean square	F	Significance of F
BDI					
Baseline effect[a]	2,364.09	1	2,364.09	33.39	$p < 0.01$
Main effect	33.53	1	33.53	0.47	$p = 0.49$
BSI (GSI)					
Baseline effect	4,369.97	1	4,369.97	55.42	$p < 0.01$
Main effect	9.73	1	9.73	0.12	$p = 0.73$
SAS					
Baseline effect	7.31	1	7.31	26.09	$p < 0.01$
Main effect	0.01	1	0.01	0.34	$p = 0.56$
IIP					
Baseline effect	22,727.82	1	22,727.82	100.25	$p < 0.01$
Main effect	12.46	1	12.46	0.06	$p = 0.82$

[a] *The baseline effects (time from baseline and using the score from the first assessment as the covariate) were all statistically significant. The main effects (difference between the two treatments and using the baseline scores as a covariate) were not statistically significant*

TABLE 56 *Mean BDI score at two time points according to counselling received (change in score in brackets)*

Counsellor approach	First assessment	12-month follow-up
Psychodynamic	22.0	15.4 (6.6)
CBT	19.5	13.3 (6.2)

using the SAS, and there was less difference between groups for the BSI. The difference between groups was only found to be significant for the BDI ($p = 0.017$) (*Table 58*), and not for the BSI ($p = 0.43$) or SAS ($p = 0.53$).

The Altman procedures were also undertaken excluding the 19 patients referred to CBT counsellors. No significant difference was found on

TABLE 57 *Number of cases (and percentages) on the BDI, the SAS and the BSI across time and by group, including only those referred to the psychodynamic counsellors*

	Experimental group		Control group		Total	
	Number	%	Number	%	Mean (SD)	*n*
BDI						
Baseline	73/73	100	89/89	100	162/162	100
6 months	36/65	55	49/79	62	85/144	59
12 months	29/60	48	43/68	63	72/128	56
BSI (GSI)						
Baseline	63/72	88	71/89	80	134/161	83
6 months	38/65	59	45/79	57	83/144	58
12 months	36/60	60	43/68	63	79/128	62
SAS						
Baseline	66/72	92	80/89	90	146/161	91
6 months	47/65	72	61/79	77	108/144	75
12 months	49/60	82	50/68	74	99/128	77

TABLE 58 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the BDI at 12 months, including only those referred to the psychodynamic counsellors*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.17	0.04	1	< 0.001	1.19	1.09 to 1.29
Experimental/control group	0.98	0.41	1	0.017	0.38	0.17 to 0.84
Constant	–3.20	0.82	1	< 0.001		

the BDI when the most positive outcome was assumed ($p = 0.10$), but there was a significant difference when the most negative outcome was assumed ($p = 0.003$). No significant differences between groups were found when the most positive outcome was calculated for the BSI ($p = 0.97$) or the SAS ($p = 0.27$), or when the most negative outcomes were considered for either ($p = 0.24$ and $p = 0.87$, respectively). In conclusion, there appears to be no major differences between these results and the 12-month analyses that included those referred to a counsellor using CBT.

Inconsistency between findings

The differences in outcome between groups at 12 months were similar to those obtained at 6 months, and there were no significant differences when the actual 12-month BDI scores were analysed but statistically significant differences were found when the number of cases at 12 months were considered. In order to investigate the reason for this disparity, the patients were divided into three groups according to the severity of their initial symptoms, as in the 6-month data analysis, and the 12-month outcomes of patients in both the experimental and control groups were compared. *Table 59* shows that the higher number of not depressed or non-case patients in the experimental than in the control group at 12 months was due to the improvement of patients with mild or moderate depression initially. Of the initially mildly depressed patients in the experimental group, 75% were classified as not depressed at 12 months compared with 48% of the controls. Similarly, 59% of those with moderate depression initially in the experimental group were classified as not depressed compared with 33% of the controls. At 12 months, only a small proportion of the severely depressed patients had become not depressed in both groups, and over one-third remained severely depressed. This is a very similar picture to that at 6 months and suggests that the relative lack of improvement in the severely depressed patients referred to a counsellor may be one of the main reasons why no significant differences were found between the experimental and control groups according to the actual BDI scores at 12 months.

A similar picture emerges if only the patients referred to psychodynamic counsellors are included and compared with the controls. More experimental group patients with initial mild or moderate depression were not depressed at 12-month follow-up than controls. However, there were a number of initially severely depressed patients in the experimental group that remained severely depressed after 12 months.

TABLE 59 *Outcome and caseness according to the initial severity on the BDI score for both the experimental and control groups*

Initial severity	Follow-up severity in experimental group	Follow-up severity in control group
Mild (BDI score 14–17)	Non-case (improved) = 18 (75%) Mild at follow-up = 3 (13 %) Moderate at follow-up = 2 (8%) Severe at follow-up = 1 (4%)	Non-case (improved) = 15 (48%) Mild at follow-up = 12 (39%) Moderate at follow-up = 2 (7%) Severe at follow-up = 2 (7%)
Moderate (BDI score 18–23)	Non-case (improved) = 16 (59%) Mild at follow-up = 3 (11%) Moderate at follow-up = 5 (19%) Severe at follow-up = 3 (11%)	Non-case (improved) = 6 (33%) Mild at follow-up = 5 (28%) Moderate at follow-up = 3 (17%) Severe at follow-up = 4 (22%)
Severe (BDI score 24+)	Non-case (improved) = 6 (25%) Mild at follow-up = 1 (4%) Moderate at follow-up = 6 (25%) Severe at follow-up = 11 (46%)	Non-case (improved) = 4 (21%) Mild at follow-up = 7 (37%) Moderate at follow-up = 3 (16%) Severe at follow-up = 5 (26%)

Multiple and logistic regression analyses

A similar multiple regression analysis was conducted as with the 6-month data using the initial social support and BDI scores as covariates and the same two binary variables, but using the 12-month BDI score as the dependent variable. The interactions between group (experimental/control) and the other three variables were also included in the model. None of these interactions were significant, including the interaction between group and initial BDI score ($p = 0.26$), and were omitted from the model shown in *Table 60*. Of the main effects, the initial BDI score was highly significant ($p < 0.001$) and the initial social support score was also significant ($p = 0.024$), but there were no significant differences between the experimental and control groups after adjusting for the other variables ($p = 0.45$). As at 6-month follow-up, parameter estimates for the initial BDI score (0.61; 95% CI, 0.36 to 0.86) indicated that the higher the initial score, the higher the 12-month BDI score. Parameter estimates for the initial social support score (–11.25; 95% CI, –21.02 to –1.49) indicated that the lower the initial score, the higher the 12-month BDI score. Similar multiple regression analyses were performed using the 12-month BSI score with the initial BSI score as the covariate and using the 12-month SAS score with the initial SAS score as the covariate, and demonstrated that only the initial BSI and SAS scores were statistically significant.

The logistic regression analyses were repeated for whether or not patients were a case on the BDI at 12 months, including the initial social support scores, the initial BDI score, whether they were in the experimental or control group and whether or not they had taken psychotropic medication between the first and 6-month assessments. It can be seen from *Table 61* that there was a significant difference in outcome between the experimental and control groups ($p = 0.008$) and that the initial social support score was highly statistically significant ($p = 0.0006$). A similar logistic regression was carried out with the BSI but none of the variables, apart from the initial BSI, were statistically significant. However, a logistic regression performed on the SAS indicated that the initial social support score was significant ($p = 0.02$) as well as the initial SAS score.

Costs analyses

For each time period, costs were estimated for services and support used over the 6 months prior to interview. In this report, three sets of results are presented reflecting the aims of the study:

- a description of the service-use data for each study period and for each group
- a description of the cost data as a total and by service groups in each study period and group

TABLE 60 *Results from a multiple regression on follow-up BDI score at 12 months. The interactions were not significant so have not been included*

Source of variation	Sum of squares	df	Mean square	F	Significance of F
Experimental/control group	38.66	1	38.66	0.59	0.45
Initial social support score	342.68	1	342.68	5.19	0.02
Initial BDI score	1503.28	1	1503.28	22.77	< 0.001
Taken psychotropic drugs or not	114.83	1	114.83	1.74	0.19

TABLE 61 *Results from logistic regression between experimental and controls groups on whether they are a case or non-case on the BDI at 12 months*

Variable	B	Standard error	df	*p*	Exp (B)	CIs for Exp (B)
Initial BDI score	0.14	0.04	1	< 0.01	1.15	1.06 to 1.25
Experimental/control group	–1.09	0.41	1	< 0.01	0.33	0.15 to 0.75
Initial social support score	–5.18	1.53	1	< 0.01	0.06	0.01 to 1.11
Whether taking psychotropic drugs or not	–0.11	0.43	1	0.79	0.89	0.38 to 2.09
Constant	–0.92	0.97	1	0.35	–	–

- a comparison of costs in each study period and each group, employing measures of the total costs of care packages, service costs and GP-based costs.

In the main, the analyses focus on the costs of providing specialist and generic health and social care services and other forms of support. The costs associated with informal support or the patients' costs borne as a result of attending treatment have not been estimated because no data were collected for these. Finally, the costs associated with use of employment services (job centres) have not been included; some data on the use of these services were collected but there was not sufficient detail to estimate the associated costs. The services were only used by 11 cases over all three of the time periods and would contribute only a small amount to the total costs of support. All costs data are reported at 1997–1998 prices.

Service use

Table 62 shows the number of people in each group who used each service at least once in the previous 6-month period. The adopted approach is to be as comprehensive as possible when collecting data on use of services and supports. This is particularly important when evaluating mental healthcare because there are complex interactions between psychological and somatic health that are not easy to disentangle. It was difficult to assess, therefore, which services were used to alleviate mental distress and which were used solely for general health. There are also complex interactions between psychological health and other events in a person's life. An impending or recent divorce, for example, may occur within the same time period as an episode of depression, contact with the GP and a visit to the solicitor, and it is not easy to be certain which of these played a part in reducing symptoms. However, cost provides a useful summary measure of all the supports used over a specified period.

The overall picture is one of low levels of service use with the exception of contact with the primary care team members. Specialist mental healthcare, community health or social care and the criminal justice services were rarely used, although there was a fairly high rate of consultations with solicitors or lawyers. About 10% of each group was admitted to hospital during each time period, and one-quarter attended outpatient clinics, although most outpatient appointments were at clinics for general health problems.

Almost everyone in the study remained in contact with their GPs throughout the duration of the study and between half and two-thirds of each group had additional contact with the practice nurse. Between eight and 11 patients used complementary therapies, including homeopathy, hypnotherapy, acupuncture, reflexology and Reiki.

It is notable that the randomisation process at study entry appears to have allocated people with dissimilar personal characteristics but similar service-use patterns to each group. This is an important issue to consider, for, had major service use or cost-differences been found for subsequent time periods, this could have been due to differences in care history. With the expected exception of the practice counsellor, service-use patterns changed very little over time, although there may have been some substitution effect between primary care and hospital inpatient services at 6 months. By the 12-month follow-up interviews, the number of people using in- and outpatient hospital services had reduced considerably.

Closer examination of the data on receipt of counselling services and the associated costs prior to the 6-month assessment reveals some interesting variations. The costs of counselling were estimated using data from the counsellors' notes. Each counsellor was asked to keep ongoing and accurate records of the frequency and duration of face-to-face contacts and time spent on other work undertaken for each patient. These data are likely to be more accurate than either patients' self-reports or GPs' notes. A unit cost for each counsellor was estimated using data provided by each GP practice, and included support and overhead costs. The calculations resulted in unit costs of between £23.40 and £32.70 per hour. Enough data were provided by the counsellor records to estimate the costs of counsellor support for 72 of the 82 patients in the experimental group at the 6-month assessment. The mean number of sessions was six and the median was seven (18 people), with 33 people seeing the counsellor six or fewer times in the preceding 6 months and 21 seeing the counsellor between eight and 16 times. Of the 72 experimental group patients analysed, 38 did not miss any of their scheduled sessions, 17 missed one session and 17 missed between two and five sessions. Each session lasted an average of 55 minutes. Time spent by counsellors on client-related work other than face-to-face contact during the period of treatment was considerable;

TABLE 62 *Use of health and social care services*

Services	Baseline		6 months		12 months	
	Experimental *n* = 91	Control *n* = 89	Experimental *n* = 82	Control *n* = 79	Experimental *n* = 75	Control *n* = 68
Accommodation						
Domestic	91	89	82	79	75	68
Specialised	0	0	0	0	0	0
Primary care[a]						
GP[b]	89 (89)	86 (87)	71 (76)	72 (78)	58 (68)	57 (65)
Practice counsellor[b]	1 (0)	0 (0)	67 (76)	1 (0)	12 (10)	2 (1)
Practice nurse	44	51	35	31	26	24
Medication[c]	45	31	35	36	30	29
Mental health						
Psychiatrist	0	1	0	1	1	1
Psychotherapist	0	0	2	2	1	0
Psychologist	0	0	1	1	1	0
CMHT therapist	1	1	3	1	3	1
CPN	0	0	0	0	0	1
Community health						
General nursing	7	7	2	6	1	2
Occupational therapist	3	2	1	0	1	2
Physiotherapist	7	4	3	5	6	4
Social care						
Social worker	4	2	0	1	0	0
Day activity service	1	1	0	0	0	0
Drop-in/social club	3	4	3	2	3	3
Volunteer/befriender	1	0	0	2	0	0
Complementary therapy	7	4	4	4	6	1
Self-help group	0	1	0	2	1	1
Home help	2	1	3	0	2	0
Other advice	1	3	3	7	2	2
Hospital services						
Inpatient admission	14	11	7	12	5	8
Accident and emergency attendance	9	1	2	4	2	3
Outpatient attendance	29	32	26	26	17	20
Day hospital	3	5	5	9	3	3
Criminal justice services						
Police	5	6	3	4	3	0
Solicitor/lawyer	13	6	10	9	9	3

[a] *Data from GP notes missing for one person*

[b] *Frequency recorded in GP notes given in parenthesis*

[c] *Prescribed at least one type of mental health medication in the 6 months prior to interview. The cost data include the costs of non-mental health medication as well*

across all 72 attendees, the average amount of time was about 105 minutes (SD 71 minutes; range 10 minutes–5 hours). Commonly, the amount of time spent was 1 and 2 hours (18 and 19 people, respectively), which translates into average costs per experimental group patient of £210 (SD £112) over the 6-month period, with a minimum cost of £41 and a maximum of £492.

The costs of the mental health medication prescribed were also explored in detail using data taken from GPs' notes. At baseline, the average cost for the experimental group was £11 (SD £24), but £22 (SD £31) for the 45 people who were actually prescribed mental health medication. The mean cost for the control group was £16 (SD £32), but for the 30 people actually prescribed drugs the mean cost was higher at £45 (SD £40). At 6 months, 35 people in the experimental group had been prescribed medication, compared to 36 in the control group, and the mean costs per person prescribed medication were £41 (SD £38) and £40 (SD £29), respectively. At 12 months, 30 people in the experimental group had been prescribed medication, compared to 26 controls, which equated to mean costs per person prescribed medication of £50 (SD £54) and £66 (SD £77), respectively. No between-group cost differences were seen with *t*-tests for prescribed mental health medication at baseline ($p = 0.28$), 6 months ($p = 0.92$) or 12 months ($p = 0.51$).

Total costs and funding

Across the whole study sample, average total costs per person showed little change over time:

- £4906 for the 6 months prior to initial assessment ($n = 179$)
- £5061 for the 6 months to first follow-up interview ($n = 161$)
- £4995 for the 6–12 month period after study entry ($n = 143$).

These figures include the costs of accommodation and living expenses, which absorb 89–92% of the total costs of care packages at each time period. Accommodation costs are commonly estimated so that, if some study members live in supported or staffed accommodation (perhaps hostels or residential care), it can be ensured that a like-with-like comparison is made in terms of the scope of costs without undertaking a complex disaggregation of costs in the staffed accommodation. In this study, everybody lived in domestic accommodation, predominantly in owner-occupied properties (73% of study members at baseline), and, therefore, to examine more closely the cost impact on provider organisations, analyses were focused on service costs excluding accommodation and living costs.

Table 63 shows the proportion of the total service costs absorbed by each service group. Service costs were aggregated according to the groups presented in *Table 62*, mainly according to the type of provider, for example, hospital care or primary care services. The social care category included services funded by the public sector but provided by either social services departments or independent sector organisations. Costs associated with alternative therapy were also included in this category although it is possible that some of these were self-funded.

The costs data can best be understood in relation to the service-use data in *Table 62*; for example,

TABLE 63 *Percentage contribution of service group costs to total service cost*

Services	Baseline		6 months		12 months	
	Experimental *n* = 90	Control *n* = 89	Experimental *n* = 82	Control *n* = 79	Experimental *n* = 75	Control *n* = 68
Primary care	25%[a]	20%	51%	29%	41%	37%
Mental health	–[b]	1%	2%	7%	4%	6%
Community health	5%	3%	1%	2%	5%	3%
Social care	10%	10%	23%	4%	19%	1%
Hospital services	52%	64%	21%	55%	26%	51%
Criminal justice	8%	1%	3%	2%	5%	2%
Mean total service cost per person for 6 months	£409	£573	£633	£513	£384	£469

[a] *All percentage figures have been rounded to nearest whole number*
[b] *Denotes a contribution of less than 1%*

hospital care absorbed a high proportion of total service costs. About 50% of hospital costs were due to quite common use of outpatient appointments, yet 40% of this service group costs were due to the relatively rarely used – but high-cost – inpatient hospital admissions. At the other end of the spectrum, almost everybody made considerable use of GP services, which accounted for 22–50% of primary care costs, yet the contribution of the GP contacts to total service costs was low (about 11%). On average, study members visited their GPs three times in each of the 6-month periods. As a group, people with depression may place a high cost-burden on any one general practice, but the relatively low unit cost (approximately £10 for a surgery appointment with a GP) ensures that the contribution to the cost of individual care packages is small.

Cost comparisons

Tables 64–66 show the comparison of total, service and primary care costs between groups for each time period. Three statistical procedures were used to test for differences between the groups, and the results of the *t*-tests are reported in these tables. For each average cost, the SD was high reflecting the wide range of individual-level costs found, not least due to the high proportion of zeros (no services received) in the costs dataset. Only one set of costs data for an individual service is normally distributed; the sixth-month costs for GP contacts for the experimental group, and, because most of the cost variables were not normally distributed, the Mann–Whitney *U* test was also applied. The findings on group differences showed the same results as the *t*-tests with the exception of the comparison of service cost at

TABLE 64 *Total costs:[a] comparisons between groups and at each time period*

Time period	Mean cost per person (SD)				*p*	Mean £ difference[b]	95% CI for £ difference[b]
	Experimental	*n*	Control	*n*			
Baseline	£4841 (1578)	90	£4972 (1878)	89	0.62	125	–369 to 637
6 months	£5051 (1920)	82	£5071 (1642)	79	0.94	20	–552 to 659
12 months	£4884 (1485)	75	£5119 (1583)	68	0.36	221	–243 to 745

[a] *Includes costs associated with accommodation and living expenses and all other service use*
[b] *Cost-estimation taken from the bootstrap analysis using 500 re-samples*

TABLE 65 *Service costs:[a] comparisons between groups and at each time period*

Time period	Mean cost per person (SD)				*p*	Mean £ difference[b]	95% CI for £ difference[b]
	Experimental	*n*	Control	*n*			
Baseline	£409 (655)	90	£573 (1277)	89	0.28	164	–10 to 486
6 months	£633 (1152)	82	£513 (867)	79	0.46	121	–428 to 198
12 months	£384 (520)	75	£469 (836)	68	0.47	86	–149 to 352

[a] *Excludes costs associated with accommodation and living expenses*
[b] *Cost-estimations taken from the bootstrap analysis using 500 re-samples*

TABLE 66 *Primary care costs:[a] comparisons between groups and at each time period*

Time period	Mean cost per person (SD)				*p*	Mean £ difference[b]	95% CI for £ difference[b]
	Experimental	*n*	Control	*n*			
Baseline	£101 (87)	90	£113 (104)	89	0.41	11	–17 to 36
6 months	£321 (191)	82	£149 (194)	79	< 0.01	173	–232 to 116
12 months	£157 (186)	75	£174 (215)	68	0.62	20	–54 to 87

[a] *Includes costs associated with contact with GPs, practice nurses, prescribed medication and practice-based counsellors*
[b] *Cost-estimations taken from the bootstrap analysis using 500 re-samples*

6 months where the non-parametric test showed that more people in the experimental group had higher costs.

Table 64 shows that mean total costs were similar for both groups and that there were no significant differences in mean total cost between the groups over time. *Table 65* shows the cost-comparisons excluding accommodation and living costs, and there were no differences between the groups for the aggregate cost of services. Moreover, there were no significant differences between the experimental and control groups on any of the service group costs that make up the total used in *Table 63,* with the exception of primary care costs. When primary care costs were examined separately (*Table 66*), the costs at 6 months were found to be significantly different when the costs of the counselling received by the experimental group were included. If the counselling costs were removed from the service group, the difference disappeared ($p = 0.87$).

At the time the study was designed, there were insufficient data available from other studies to ascertain whether the sample size required for the outcome study would be large enough to detect a difference in costs. Often a study has a sufficient sample size to show significant differences in outcome measures, but is still underpowered for cost-comparisons or an economic evaluation.[71] This is due to the wide variation commonly found in the costs of health and social care support packages and the skewed distribution of the data; it is often the case that a few people use very expensive services causing a long tail in the distribution and that others use no services at all giving a cost of £0. A retrospective analysis was, therefore, undertaken once the costs had been estimated and there was information on the distribution of the cost data. The results showed that, for the most part, this study did not have sufficient power to detect between-group cost-differences at the 5% significance level; at least 150 people would be needed in each arm. Only for the sixth-month primary care cost-comparisons were there sufficient patients in the sample to detect any cost-differences. Bootstrap techniques, however, confirmed the results of the *t*-tests for each set of comparisons in *Tables 64–66,* and mean cost-differences and their CIs that are presented were taken from these analyses.

The results of the cost analyses suggest that there were no differences in the cost implications of each treatment option, except for a cost-burden to the GP practices linked to the use of counselling services in the very short term. This additional cost was not offset by reduced costs within primary care services or other agencies during the treatment period or in the following 6 months.

Chapter 4
Discussion

Problems encountered

Recruitment

This study had to overcome a number of problems. The first and most serious was that of recruitment. Originally, the GPs were asked to refer patients into the trial, but this resulted in a very slow rate of recruitment. GPs expressed a number of reasons for this, including finding it difficult to ask depressed patients if they would take part in a research project, concerns that depressed patients would be allocated to the control group and thus be denied access to counselling and finding it difficult to remember the trial when in the consulting room. While one advantage of this particular study was the use of a well-established counselling scheme, this was also a disadvantage because counselling was not perceived as an untested new treatment. Many of the GPs already valued counselling and had asked for a counselling attachment to be set up some time before. Although the GPs recognised the need for a scientific evaluation of the counselling service, they preferred the trial to be undertaken on patients other than their own. A large number of researchers attempting to undertake clinical trials within general practices have encountered very similar problems to these, and this has led some to abort their trial completely.[72]

The revised recruitment procedure, however, means that the results of the study cannot be generalised to cover GP referrals to counsellors but, instead, relate to 'screened' GP attenders, limiting the external validity of the study. Caution is thus necessary when making any generalisations from the trial to routine clinical care in the NHS. While the trial patients did not differ from the overall patient population in many important aspects, such as demographic characteristics, and severity of or past history of depression, there may have been unmeasured differences that affected clinical outcome; for example, the data analyses suggest that trial patients may have received fewer psychotropic drugs as a result of the recruitment method than those patients with depression referred directly to the counsellor by the GP. This is likely to be partly due to the fact that all of those referred by the GP to the counsellor directly would have discussed their depression or problems with the GP and thus had the opportunity to receive a prescription. However, not all of the trial participants would have had this opportunity before the initial assessment. There are also concerns that the GPs may have been more selective when referring to the trial, screening out those with multiple problems that were not amenable to counselling help.

Client motivation

One concern regarding this method of recruitment is that participants might have been less motivated to receive counselling intervention than GP-referred patients. However, 89% of those referred to the experimental group in the study attended at least one counselling session, which was higher than the attendance rates of GP-referred patients as recorded by audit. Both trial and GP-referred patients were also asked their views on counselling prior to receiving such help, and no differences were found between the two groups, with the majority of patients being positive towards counselling. However, the relatively high motivation levels of trial patients could have been due to the fact that patients could withdraw from the trial before randomisation if they did not wish to take part. Of those who met the inclusion criteria for the trial, 77 were unwilling to take part, and many of these may not have wanted counselling help.

Attrition

Information was not obtained for 20 (11%) of the original 181 patients at the 6-month follow-up assessment and a further 18 (10%) at the 12-month follow-up assessment. However, this was a lower attrition rate than has been found in many other studies,[24–26,30] and comparable numbers in both the control and experimental groups failed to complete, thus resulting in similar totals of remaining patients in each group. In addition, an analysis of the initial characteristics of patients revealed that there were no significant differences in demographic characteristics, initial scores on the first assessment or previous history and treatment between patients who failed to complete and those remaining.

Compliance with randomisation

Non-compliance with randomisation is another problem commonly encountered. In this study, a few patients in the experimental group (11%) did not attend for counselling and a small number of controls (10%) were referred to alternative services. However, the percentages of patients that did not adhere to the treatment allocated or were referred elsewhere were smaller than the numbers indicated in other studies.[24–26,29] It was not possible or ethical to restrict the treatment options of the GPs (including medication) for any of the patients within the trial, and the only restriction, therefore, was referral to the practice counsellor for control group patients. While the main analysis was undertaken according to intention-to-treat, subsequent analyses that excluded patients who did not adhere to treatment found similar results.

Accuracy of records

Records were not always found to be accurate, and there were often discrepancies between patients' accounts and medical and counsellors' records. A decision on which source was most likely to be correct had to be made in many cases, which was particularly important for the economic evaluations. In general, GPs' medical notes were used to ascertain the number of visits made to the GP and the prescriptions written, the counsellors' records for visits to the counsellor, and the patients' accounts for other service use and whether they took the medication prescribed.

Assessment procedures

It is very difficult to make decisions on how and when to make assessments. This study examined clinical and social outcomes as well as patients' views, and there were concerns over whether the assessment interviews were therapeutic, as has been found in other studies.[73] Although all patients in both groups were initially assessed using the same interview, this could have meant that the counsellor's interventions made less of an impact. For this reason, the assessments were kept to a minimum with most information collected by questionnaire rather than by interview. Although it was necessary to achieve some sort of rapport with the patients, discussion of their problems was avoided where possible.

The lack of differences found between groups may have been due to the measures used being insensitive to change. Although the BDI is now commonly used in intervention studies, it might not be the most appropriate measure for the assessment of counselling. Patients referred to counsellors often have many complex problems, and it is arguable that researchers should use more individually tailored measurements of change.

Another difficulty of the trial was that patients often told the researcher about contacts with the counsellor during the 6-month interview, and the researcher was thus not always blind for the 12-month assessment. However, most of the outcome measures were collected using questionnaires in order to reduce any interviewer bias.

Counselling intervention

This study used highly trained and experienced counsellors already employed by the GP practices, and all the counsellors had at least 6 years of experience in general practice and were accredited or eligible for accreditation by the BAC. However, they did not all adhere to the same theoretical model or method of counselling, which could have been a distinct disadvantage. The majority of the counsellors were trained in psychodynamic counselling, but two used mainly CBT techniques. As two distinct therapies were offered, the trial assessed counselling as a service rather than as a therapeutic treatment. Allocation to type of therapy was not random and the number of patients seen by the counsellors using CBT techniques was small. Therefore, the outcome of the two therapies could not be compared. However, it was possible to restrict the analyses to those who were referred to the psychodynamic counsellors and the findings for this group were very similar to the experimental group as a whole.

The counsellors had developed a method of working within the surgery setting, and considered it essential to retain their flexibility to enable them to adapt to the needs of each individual patient. Not adhering to a treatment protocol or manual decreased the internal validity of the study and also meant that it was difficult to classify what interventions took place. However, it did ensure that the counselling received by trial patients was very similar to that normally received by patients within these practices, and the interventions could, therefore, be tailored to the needs of the individual patient rather than those of the study. Another major difficulty faced in the study was the potential variation in the quality and type of counselling given. It is not possible in any study of counselling to control for all the variables that might affect the outcome. Many commentators suggest that it is the individual relationship, the working alliance, which is the most important factor determining

outcome, and , therefore, the gender and age of both the counsellor and the patient (as well as their relationship) might play a role as well as the type of counselling employed.

The effect of medication

It was not possible to investigate the effect of medication on outcome in this study because, unlike counselling intervention, it was not assigned on a random basis; GPs could prescribe when they considered it appropriate. The results suggested that although more experimental group patients had received a psychotropic drug prescription prior to referral, there were no differences between groups during the period between assessments. The results of the multiple regression analyses suggested that taking a psychotropic drug did not have a significant effect on outcome, but no attempt was made in the trial to standardise the medication given, either in terms of the type of drug, the dosage, the length of time prescribed or encouragement of patients to adhere to the drug regime.

Findings from the study

Initial assessment and randomisation

No differences between the experimental and control groups were detected in the randomisation process, which was conducted by an independent HA member of staff, and both groups were similar on most measures studied including demographic characteristics, history of depression and treatment and social functioning. However, the experimental group patients had slightly higher scores on the BDI and significantly more had been prescribed psychotropic medication.

Approximately two-thirds of the trial patients had positive views about counselling, and similar results of patients' views have been recorded elsewhere.[1,39] However, views of drug treatment were more negative with only 28% having a positive view. There were no significant differences between the groups in the views on counselling or medication.

Treatment given and outcome at 6 and 12 months

With regard to the treatment patients received, 87% of the experimental group saw the counsellor and 93% of the control group saw the GP. Only 5% of the experimental group saw another therapist compared with 10% of the control group. In the 6- to 12-month period, some patients in the experimental group were still seeing the counsellor, and small numbers in both groups also saw other therapists during this period.

Although more patients in the experimental group than the controls were being prescribed psychotropic medication prior to entry into the study, this difference disappeared in the 6 months following inclusion. Some studies have found a similar reduction in psychotropic drug prescriptions when patients are referred to a counsellor,[26] but other studies have not.[24] In this study, there were no statistical differences between groups and similar proportions of experimental and control patients were prescribed psychotropic medication.

There were few differences between the two groups with regard to GP attendance; rates were similar between groups both before entry into the study and in the 6- and 12-month periods afterwards. Referral to the counsellor did not, therefore, result in a decrease in the number of visits to the GP. Other studies also vary in this regard; some studies have reported that patients are less likely to visit GPs when they are referred to a counsellor,[28] while other studies have not made this observation.[24,26] In addition, there was only a small reduction in GP attendance rates in the 6 months following study entry, although there was a larger significant reduction in the 6 months after that. The lack of variation in GP attendance rates over time might be due to the method of recruitment, which did not rely on GP referral. GPs may be more likely to refer time-consuming high-attenders to a study than low-attenders, thus studies which recruit by GP referrals may show particularly high attendance rates prior to entry.

The mean scores on all of the outcome measures showed significant improvement between entry into the study and 6 months later. However, 58% of patients were still considered a case on the BDI, suggesting that, although their scores had reduced, many patients had not completely improved. A similar proportion of patients in the study were still cases on the BSI (GSI) and three-quarters were cases on the SAS at 6-month follow-up. Only a little additional improvement was made between 6 and 12 months after study entry. At the 12-month assessment, 55% were still cases on the BDI, 60% on the BSI (GSI) and 75% on the SAS. Initial severity was an important factor in determining whether patients were still cases at follow-up, and, indeed, very high proportions of those initially assessed as being severely depressed were still depressed

at follow-up. The low rates of recovery might have been due to the chronicity of these patients' problems; patients were only included in the trial if they had suffered symptoms for 6 months or more prior to study entry. Thus, patients who improved rapidly after an episode were excluded. In addition, high proportions had social problems at the initial assessment (89% were considered cases on the SAS) and the majority of these problems were still present 6 and 12 months later.

Comparison of these outcome findings with other clinical trials is difficult because the outcome measures used may be different or outcomes may have been measured at different follow-up intervals. In addition, many studies only report changes in the mean scores over time rather than the number of patients who are still cases at follow-up. There is some evidence that, although studies have shown a reduction in mean scores over time, there are still a number of patients who are cases at follow-up. For example, Friedli and co-workers found that 41% were still cases at 3 months (using a cut-off score of 14 on the BDI) and 33% at 9 months even though only 74% of participants were classified as BDI cases prior to study entry.[28]

Although studies of screened primary care attenders suggest that high proportions of these patients improve over time, they also show that many have recurrent problems and frequently relapse.[4] Those who fail to restitute tend to have associated social difficulties, including interpersonal problems, chronic housing and financial difficulties and a higher probability of chronic physical ill-health. In the study by Mann and colleagues, patients were contacted after 1 year and about half had an intermittent course of neurotic illness and a quarter were chronically ill,[12] and many of these patients were still ill 11 years later.[46] Studies of depression in other settings have shown that although high proportions of patients may initially improve over time, they still remain symptomatic and relapse is common.[21] These findings suggest that more longer-term treatments and involvement may be needed;[21] longer periods of initial treatment, maintenance treatments and booster sessions may be more appropriate than short-term therapy.[53] Interventions aimed at improving living and social circumstances[13] may also be beneficial.

Differences in outcome between groups

At the 6-month follow-up, there were no significant differences between the experimental and control groups on any of the outcome measure scores even when adjusted for initial score and other variables. This lack of difference also occurred in the analyses that excluded patients who did not adhere to their allocated treatment and in the analyses that only included patients referred to the psychodynamic counsellors. Although there were no significant differences in the outcome scores, there were slightly fewer cases in the experimental than in the control group on the BDI (54% versus 62%, respectively) and on the SAS (71% versus 77%, respectively) at 6 months, but not on the BSI (58% versus 57%, respectively). The difference almost reached statistical significance for the BDI ($p = 0.07$) and less so for the SAS ($p = 0.09$). There was a significant difference between groups on the BDI when the most negative outcome (i.e. all drop-outs were still cases) was assumed ($p = 0.05$) and in the analyses excluding those patients who did not adhere to their treatment ($p = 0.01$). The difference between groups on the BDI was not significant when the most positive outcome (i.e. all drop-outs were non-cases) was assumed ($p = 0.11$) or when only patients referred to the psychodynamic counsellors were included ($p = 0.10$).

There were also no significant differences between the experimental and control groups on the main outcome measures at the 12-month follow-up when the actual scores were used. However, more patients were still cases in the control than in the experimental group at 12 months on the BDI (72% compared with 60%) and the BSI (63% compared with 57%), but not on the SAS. These differences were statistically significant for the BDI ($p = 0.01$) but not for the BSI or the SAS. This significant difference between groups on the BDI was also found when the most negative outcome was assumed ($p < 0.01$), in the analyses that excluded patients who did not adhere to their treatment ($p < 0.01$) and in the analyses that only included patients referred to the psychodynamic counsellors ($p = 0.02$), and it almost reached statistical significance when the most positive outcome was assumed ($p = 0.07$).

A visual inspection of the outcome of the two groups suggests that the inconsistency between these findings may be due to the higher number of severely depressed patients allocated to the experimental group and the lack of improvement in this severely depressed group. The data suggest that higher proportions of the initially mildly and moderately depressed patients improved and were classified as non-cases in the experimental group than the controls. This would

explain the nearly significant differences found at 6 months and the significant differences found at 12 months. There was, however, less improvement in the patients who were severely ill; the majority were still rated as severely ill at both the 6- and 12-month follow-ups and few became non-cases. However, while the visual inspection suggests these differences, a multiple regression analysis conducted on the BDI scores at both 6 and 12 months detected no significant interactions between experimental and control groups and the initial severity score on the BDI.

Some studies have shown that the outcome of psychotherapy and counselling varies according to the severity of the initial depression,[53] while this has not been found in other studies.[74] However, it should be noted that most of these studies have not been undertaken on GP patients or even in the UK.[21] The authors of the National Institute of Mental Health study, which compared CBT, interpersonal therapy, antidepressant plus clinical management and placebo plus clinical management, concluded that minimal supportive therapy may be sufficient to bring about a significant reduction of depressive symptoms in less severely depressed patients. However, they suggest the use of antidepressant medication for the more severely depressed, perhaps in combination with psychotherapy or supportive therapy.

The second Sheffield Psychotherapy Project also found that severity of initial depression was important in determining short-term outcome.[75] At post-treatment, patients with mild or moderate depression did equally well with either 8 or 16 weeks of therapy, however, those with severe depression improved more when they received 16 rather than 8 weeks of therapy. The results of this study lend some support to the finding of Elkin and colleagues[53] that the less severely depressed may be helped by less intensive forms of support and therapy.

The therapy conducted in this study tended to be short term, as is often the case in general practice counselling, and most patients received eight sessions or less (the mean number was six). The number of GP visits between initial assessment and the 6-month follow-up was just over four in both experimental and control groups, and between three and four for the period between 6- and 12-month follow-ups. It is possible that a more intensive form of therapy would be necessary to bring about additional benefits above GP care for the more severely depressed.

Counselling approach

It was not possible to estimate whether one type of counselling was more effective than another because so few patients received CBT. While 19 patients were referred to counsellors using CBT, only 16 actually saw their counsellor. Although the results indicate that there was a similar degree of improvement for both groups, larger numbers of patients may have shown a different result. Systematic reviews comparing CBT to psychodynamic therapy suggest that CBT is more effective, although most of these trials have been conducted in the US and not in primary care settings. In addition, the extent of the effects seen has been shown to be related to the researchers' allegiance to a particular treatment;[51] Gaffan and colleagues[76] have suggested that the effectiveness of CBT for depression relative to other treatments has decreased significantly over time. They suggest that this may be due to publication biases, the quality of the therapists used or because alternative treatments are becoming more effective.

Patients' views

The majority of patients in the counsellor group were very positive about their treatment. They found it easy to talk to their counsellor and most felt that it had helped them. These findings are similar to other studies suggesting that patients perceive the therapy as helpful.[9,24,26] Only a few patients wanted a referral elsewhere, although many patients would have preferred more practical help and advice, and a number of patients would have preferred more sessions and were frustrated by the short-term nature of the help given. Only a very small minority of patients said that the counselling had made them feel worse, provoking powerful feelings that they found difficult to deal with. Similar results have been reported in many other studies and by clinicians.[77,78] It was not possible to identify any distinguishing features (for example, severity of depression or motivation to receive counselling) of the small group that thought that counselling had made things worse, although other types of initial assessments may have made this possible.

More than one-quarter of the patients in the control group would have preferred to have seen a counsellor instead of their GP. Views regarding the helpfulness of the GP were more variable and in many cases the patients mentioned their GP's lack of time to talk. As in the experimental group, many patients indicated that they would have liked more practical help and advice.

There is a paradox between patients' views and the results of the clinical outcome study; the majority of patients considered counselling to be helpful but this was not clearly shown in the results. It is possible that while the counselling was appreciated by clients, giving them an opportunity to talk about their problems, it may only have been enough to bring about minor or transitory changes in behaviour, understanding, thoughts and feelings. Alternatively, the type of assessments used may not have been sensitive enough to measure changes that are deemed to be important to the patient.

Economic evaluation

Within the cost-effectiveness component of this study, comprehensive costs were carefully estimated and cost-variations explored in terms of the burden imposed on various provider groups. Costs were then compared between the groups to which study members were randomly assigned in the context of roughly similar outcome gains. Bootstrap analyses were used to confirm the *t*-tests given the skewness of the cost data and the results of the retrospective power calculations.

Each person's support package was carefully recorded and comprehensive costs estimated to reflect the extent to which each person used services and support during each time period. Although quite a wide range of services were used overall, sample individuals tended to use only two or three services, and apart from outpatient appointments and primary care, the proportion using each service was low. Costs data provide a single summary measure of the extent of service use and reflect the pattern of support services used. However, despite a reduction in symptoms over the study period, which might imply a reduced need for support from mental health or other services, costs changed little over time.

As the clinical outcomes between groups were broadly similar, the primary focus in this study was to assess which option – GP-based or counselling treatment – was the least costly. Once the intervention costs were excluded, no significant cost-differences were found between the groups at any time period. However, receiving counselling increased the primary care costs during the first 6-month period after referral, and this additional cost was not offset by a reduction in service use (costs) during the treatment period and did not appear to result in cost-savings at 12 months.

Two cautions about the cost information should be taken into account that are linked to the changes made to the recruitment process. Study members were recruited by screening rather than by GP referral, which may have resulted in a different population from usual receiving this type of support and/or more people with depression having been identified for treatment. Comparison with the counsellor audit data suggested that study members might be slightly different from the population seen by counsellors in previous years. First, a higher proportion of the GP-referred (audit) population had used psychological therapies prior to seeing the counsellor and had been referred to other mental health professionals. This suggests that the estimation of the service costs relating to the support of the experimental group before receiving counselling (baseline) and after (12-month follow-up) might be lower than expected. Second, the study participants were found to have slightly lower non-attendance rates and to receive slightly more counselling sessions than the patients in the audit, causing the estimates of counselling costs at 6 months to be slightly higher than would have been found in previous years. It is difficult to quantify the impact that either of these factors had on the costs observed in this study, as the data are not available. However, the difference in percentage figures is quite small, and the audit data also included all referrals to counselling, not just those who fitted the clinical criteria employed to recruit people to this study.

A linked point is that the screening process may have identified people who would not in the normal course of events have received any treatment for their depression. If this is so, although it implies an increase in the total spend on mental heath care in the GP practices, the results from this study are particularly useful in the light of recent policy initiatives to help promote better mental health services in primary care. Standard 2 of the National Service Framework for Mental Health, for example, states that any service user who contacts their primary healthcare team with a common mental health problem should have their mental health needs assessed and be offered effective treatments.[79] The findings provide information relating to the costs of supporting people who attend GP practices with chronic depression and the likely distribution of costs between the primary healthcare team and other social and healthcare provisions.

Future work and the value of clinical trials

There is considerable debate on the value of conducting clinical trials in this area, which is fuelled by the discrepancy between patients' views and the results of trials. If GPs and patients both value the counselling that patients receive, why do trials fail to show any difference between counselling and routine GP care? A reason for this might be that the outcome measures used may not be sensitive enough to the types of changes that occur after therapy to enable any benefits to be seen. Many of the problems inherent in conducting clinical trials were encountered in this trial, including problems with the referral process. One criticism of trials is that the referral criteria for inclusion are often so strict that referrals are atypical to those commonly referred. However, broader referral criteria can be criticised on the basis that it then becomes difficult to classify the patient group included. It is also possible that the imposition of a clinical trial interferes with the normal referral process whereby GPs refer appropriate patients directly to counsellors, and with the working alliance set up between GP, patient and counsellor, which may be considered essential for improvement to take place.

A patient preference trial may have been more appropriate with patients being given the choice, and those with no strong preference randomised. Although results from recent trials suggest that patient preference may not be important in determining outcome (King M, Royal Free Hospital School of Medicine, London: personal communication, 1999), it may have meant that GPs would have been more willing to refer patients to the study. A patient preference trial could also attempt to deal with the problems related to patient motivation and demoralisation of patients allocated to a treatment that they do not want to receive.

There are also difficulties in generalising from any clinical trial to GP counselling in real-life practice. This study used a particularly well-organised scheme with experienced and highly trained counsellors, whereas counsellors attached to other GP practices are less likely to be as experienced or trained. In addition, the counsellors of this study predominantly used a psychodynamic model, whilst, in practice, GP counsellors use a whole range of models.

Clinical trials in this area are difficult to conduct, time consuming and expensive. They are also problematic in that the treatment offered by the GPs is likely to differ considerably (as mentioned in the patients' accounts) and it is not possible to control the psychotropic medication prescribed or that actually taken by patients. Although the clinical trial has been criticised as a means of evaluating counselling, no consensus had been reached on an adequate methodology to replace it. At the present time, it is appropriate to use a range of methodologies, including more qualitative approaches. The role of patient characteristics, associated social problems, social support networks and motivation may all be studied using a range of methods, and, similarly, factors in the treatment process need further investigation. However, these methods should be used to supplement and inform future clinical trials rather than to replace them.

Treatment of the chronic group included in this study remains a priority. While there was a reduction in patients' scores over time, a large proportion of patients included in this trial had not made substantial improvements by either 6 or 12 months, and their social problems persisted. Treatment of this group thus remains important, as many of these patients' symptoms and problems are not self-limiting.

The findings of this study are inconclusive and inconsistent. This may have been due, in part, to the inclusion criteria being too broad. More conclusive results may have been attained if the study had focused on patients with milder forms of chronic depression (a BDI score of between 14 and 23), as there was some post hoc evidence that the experimental group patients in this category improved more than the controls. The counselling provided in this study was short term, which is typical of most general practice counselling, but may have been less appropriate for more severe forms of chronic depression (a BDI score of 24 or more). A further clinical trial of counselling for patients with milder forms of chronic depression would be necessary to confirm this finding.

In the meantime, patients in this study are being followed up for 3 years after study entry, and are being sent postal questionnaires to assess symptoms and social adjustment. Although the attrition rates are expected to increase, it is hoped that the response rate will be high enough to compare groups and investigate overall outcome.

Conclusions

The findings from this study were inconclusive. Patients were generally appreciative of the

counselling received and considered it helpful. However, there was only limited evidence of an improved clinical outcome in those patients that had been referred to the counsellor and this was mainly at the 12-month follow-up assessment when the number of patients who ceased to be cases on the BDI was considered. There was less difference between groups at 6 months or when actual outcome scores were considered.

Stricter referral criteria excluding the more severely depressed may have yielded a more conclusive result. The lack of differences seen between groups may have been due to a variety of factors, including the short-term nature of the counselling offered, the GPs' interventions and the chronic nature of many of the problems. In addition, it is difficult to estimate the effect on outcome of the referral process whereby recruitment was undertaken through screening rather than by GP referral.

As the clinical outcomes between groups were broadly similar, the primary focus of the cost-effectiveness component of the study was to establish which treatment option was the least costly. No significant cost-differences were found between the groups at any time period once the intervention costs had been excluded. However, receiving counselling increased the primary care costs during the intervention period. This additional cost was not offset by a reduction in service use and costs during the treatment period and did not appear to result in cost-savings at 12 months.

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Appendix 1

Details of counselling received and patient's views

Differences between counselling approaches

The counsellors in the study adhered to one of two models of counselling – psychodynamic or CBT. The type of counselling that patients randomised to the experimental group received was not determined by random allocation, but by the model of counselling used by the counsellor attached to the patient's practice. There were 19 patients referred to CBT counsellors and 73 to psychodynamic counsellors. Of the patients referred to CBT counsellors, 16 actually saw the counsellor and 14 of these were followed up successfully at 6 months. Of the 73 patients referred to psychodynamic counsellors, 59 saw the counsellor and 57 of these were followed up at 6 months.

The psychodynamic and CBT approaches to counselling are very different and based on different models of human behaviour. The CBT model is seen as a more directive model with its roots in classical and social learning theories. The therapist is concerned with maladaptive beliefs and behaviours, and relies on self-monitoring, identifying and challenging negative thoughts. This CBT approach is concerned with how a person 'self-talks' and changing this is the goal of therapy,[1] by focusing on setting goals and solving problems. It attempts to produce changes in a person's behaviour by influencing their thinking. This perspective does not ignore the role of past history and prior experience, but suggests that the way in which a person interprets a situation influences how they subsequently react. This approach takes the view that the way a person thinks or interprets the situation plays a causal role in the origin and continuation of some disorders.[1]

Psychodynamic models of counselling originate from Freudian theory. The psychodynamic approach looks at internal relationships within a person and is concerned with understanding the effect of past events on the individual's present experience. The psychodynamic therapist aims to enable an individual to balance basic psychological needs with the demands of conscience and the external realities of the person's circumstances.[2] This approach attempts to change unconscious conflicts by using techniques such as transference and suggestion to explore both conscious and unconscious thoughts and feelings.

The CBT approach uses techniques such as goal setting, relaxation, the development of daily plans and cognitive restructuring, whereas the psychodynamic approach employs strategies such as making links to past history, interpreting transference, setting up and maintaining boundaries and containment. However, these therapies do have many basic counselling techniques in common, for example, listening, relationship building and empathy, and it must be recognised that, in clinical practice, few counsellors make use of these orientations in their pure form. Most experienced therapists will alter the therapy according to the needs, preferences and abilities of the patient.[3]

Problems identified and strategies used by the counsellor

The counsellors completed forms for every patient in the trial at initial and final assessments. In addition, they were requested to fill in a diary sheet each time they saw a patient. These forms collected information on the type and severity of patients' problems, types of counselling techniques used in each session, motivation of patients, progress made and contacts with the GP and other primary care staff.

The problems that the patients of the experimental group presented with are shown in *Table 67*, and counsellors could indicate more than one problem. These forms were completed by the counsellors for 71 patients. Apart from depression, the most common problems included difficulties with personal relationships and loss and bereavement. There were also a large number of patients who had problems with self-esteem, physical disabilities and anxiety. Other problems included difficulties with separation and fears of abandonment, general stress, social isolation, anger, guilt, work-related problems, health problems, life stage difficulties and financial problems.

TABLE 67 *Types of presenting problems (as assessed by the counsellors)*

Type of problem	Number of patients with the problems (according to the counsellors' notes)	
	Number	%
Family relationships	42	59
Marital relationships	36	51
Self-esteem	23	32
Depression	26	37
Anxiety	10	14
Loss/bereavement	28	39
Stress	11	15
Physical problems	14	20
Life-stage difficulties	10	14
Work	10	14
Anger	7	10
Guilt	5	7
Fears of abandonment and separation issues	8	11
Health problems	7	10
Social isolation	2	3

Counsellors completed forms every time they saw a patient and listed the strategies used, and their responses were coded according to several categories. Both approaches to counselling had many strategies in common, including reflecting back, empathy, coping strategies, assessing progress and establishing relationships. The most common strategies used by the psychodynamic counsellors were reflecting back, establishing and reinforcing the therapeutic alliance, empathy, interpretation, interpreting transference and counter-transference, maintaining boundaries and relationship building. The most common strategies used by the CBT counsellors were reflecting back, information giving and explanation, cognitive restructuring, daily scheduling of activities and strategies, setting and agreeing goals, empathy, challenging ideas and thoughts, coping strategies, assessing what has helped and relationship building. Although these terms suggest that the therapies were very different, this was partially due to the different words used by the therapists to describe the therapeutic process.

The counsellors contacted a number of different agencies regarding the patients in the trial. Most contacts were with the GP (57 times on behalf of 36 patients) to request information or to give feedback regarding the patient. There were also three contacts with the Women's Centre, one with the practice nurse and three with the CMHT.

Patients' views of the counselling process

This appendix includes more detailed information on patients' views than the main report including direct quotes from the questionnaires completed by patients.

Overall feelings about counselling

Patients were asked a number of open-ended questions, including "What are your overall feelings about counselling?" and "Do you have any suggestions on how the counselling could have been more helpful?" Most answers were very positive, although many patients indicated ways in which the counselling could have been improved. Only a minority of comments were negative.

Positive comments

Many patients felt that the counselling had helped them understand their problems more clearly and the possible causes of them:

> "It helped me understand the background to my current problems and the reasons for the way I felt. It helps you understand what is happening to you."
>
> "It made me realise it wasn't all my fault and to stop blaming myself."
>
> "It gave me insight into relationships within my family and where I was making mistakes and how to deal with friction. It has encouraged me to talk to my family."

Many patients felt that it gave them someone independent to talk to, who was non-judgmental, helpful, sincere and trustworthy:

> "It was really helpful because you could talk with someone and be really honest with this person who you could trust and who was understanding and non-judgemental. It helped me unload a lot of baggage I had been holding in for years. It helped me talk about things I have never spoken about before."

> "It helped build your confidence by talking to someone who is outside of everything."

> "It was just nice to talk to someone who did not judge you."

Others found that it had helped to share their problems, talk things over or to have a listener, and for some, it was the realisation that they were not the only ones with these difficulties:

> "It helped me realise I was not alone and that other people are in the same position and it helped me to cope."

> "It helped me see more clearly and that I should share my problems and not try to cope on my own. It made me realise that I can't do everything."

> "It helped put things in perspective and see things in a more positive light. I'd recommend it to anyone."

> "I was unsure at first and it was very different from what I expected, but it helped and made me feel listened to and heard."

Others felt that it gave them time and space to talk without distractions:

> "Seeing a counsellor helped because there were no interruptions from other family members."

> "The time with the counsellor was a space for me, a time to reflect on changes and move forward."

A number of patients said that they felt that counselling had given them more confidence and the impetus to be more positive and take more control over their life:

> "It taught me to stand up for myself and gave me confidence to do other things. It gave me a new outlook, made me more positive and made me realise I had to get on with my life."

> "It gave me confidence to go out and tackle problems. I used to keep it all inside but now I sort it out straight away."

> "I benefited greatly from the sessions, it gave me the life I needed and gave me the answers to prevent this occurring again in the future. It has helped me understand myself more."

Others indicated that it was more appropriate than medication:

> "I didn't like taking tablets, so it was a good treatment."

> "Counselling is really good, it really helps rather than just being given pills."

However, some patients indicated that they were cautious about the longer-term effect:

> "It was good to talk but he couldn't really help me with my main problems of housing and the boredom because I can't work."

> "Counselling was good at the time but it is hard to change the habits of a lifetime."

More negative comments

Ten patients had negative comments about counselling, eight of which saw a counsellor with a psychodynamic approach and two saw a CBT counsellor. Therefore, there was no difference according to therapy as many more people were referred to psychodynamic counsellors. In addition, many felt that they did not have enough sessions or that the sessions were not long enough.

> "If I'd had more sessions I would have been able to cover more issues, we had only really just started. If I'd had more time I would have made more progress."

> "I think I'd have liked longer sessions, more time, the hour goes fast."

> "The number of sessions should be based on the clients needs and not a stipulated time, I felt limited in the amount of time I was allocated."

Some patients felt that the sessions needed to be more flexible to suit working times and child minding. Another issue mentioned by several patients was the waiting times between being referred and assessment or between the first assessment and the main block of sessions.

> "I needed sessions to suit my time, without having to have time off work."

> "The time wasn't convenient for me with the children so I was coming reluctantly."

> "I had waited so long to see the counsellor, that I felt the problem had resolved itself."

Three of these 10 patients (two referred to psychodynamic counsellors and one to a CBT counsellor) felt that their counsellor had not helped them, but still believed in the value of counselling as a service. They felt that they would

have benefited from seeing a counsellor with a different approach.

"I'd have preferred the counsellor to have had more input giving suggestions on what I should do."

"I felt that the counselling didn't help me, a different counsellor with a different approach would have helped I think."

Seven patients had negative views of counselling:

"It's a waste of time and it made me feel worse rather than better."

"I felt he made me look stupid and I felt like I was digging my own grave."

"I thought that counselling would be someone who listened sympathetically and advise not take over the whole session."

"I was going through a bad patch and it just made me worse."

"I didn't like the counselling, it brought everything to the surface and made me feel awful."

Views regarding GP treatment

Patients were asked about the helpfulness of talking things over with the GP. Generally, this generated a mixture of views, of which, some were very positive:

"The treatment was very good, I feel very positive about myself. It made me feel better to talk, it helped me get things into perspective. She gave me plenty of time off to sort things out." (control group patient)

"My doctor was very helpful and understanding, she always has time to listen. I was pleased with the treatment I received, it was helpful and appropriate" (control group patient)

"Talking things through with the doctor helped me see things more clearly." (experimental group patient)

"The GP was really helpful she listened to me and didn't rush things, she made me understand that the way I felt was natural given the circumstances." (experimental group patient)

Others were not so positive about the treatment received from their GP:

"I wasn't happy because my GP was very dismissive and very rude." (control group patient)

"I don't really think my GP understands my problems" (control group patient)

Lack of time or the feeling of being rushed was commonly mentioned:

"You feel as if you are taking up all of their time. It would be better if you didn't have to worry about the time and you had a more relaxed environment" (control group patient)

"The main problems are the lack of time and the fact that not every GP is qualified to deal with psychological problems." (control group patient)

"The treatment was OK but it didn't really help and the GP doesn't have time." (experimental group patient)

"The GP is too busy to have time to talk about things properly." (experimental group patient)

Patients were asked if they had any ideas about how the treatment could be improved. Talking to someone else other than the GP was mentioned:

"I think I needed more advice on what to do and what would help me." (control group patient)

"I needed to talk to someone else, I didn't want to go back to my GP again, there is nothing that he can do." (control group patient)

"The treatment didn't really help, I may have benefited from talking to a counsellor. I would like to have talked to someone who was not closely involved." (control group patient)

Views on medication

Patients were also asked about the value of medication; over 50% of the control group patients who took medication were positive compared with slightly less than half of the experimental group.

"It made me feel more relaxed and gave me breathing space by shutting off my mind from worrying for a while." (control group patient)

"The pills have made me stronger and I am able to deal with things better." (experimental group patient)

"I wasn't happy about taking the pills in the beginning, but it helped me." (experimental group patient)

Others had mixed feelings about taking medication:

"The tablets have helped me cope but I needed more than that, I would have liked someone to talk to, someone to show me how to cope." (control group patient)

"It helps me cope, it gave me a prop but I know it isn't a solution, my problems are still there." (control group patient)

"It made me feel drowsy and doped but a bit calmer." (experimental group patient)

Other patients had more negative views of the medication:

"The side-effects are bad on the pills, it made me feel worse." (control group patient)

"I don't like taking medication, it may be addictive and I prefer to work things out on my own." (control group patient)

"It didn't really help me as I was left alone when I really needed someone to talk to." (control group patient)

"I felt that the pills might be addictive and was frightened of taking them. I didn't really want to take drugs, I'm reluctant to put drugs in my body." (experimental group patient)

Views of other treatment received

Finally, both groups were asked about any other treatment they might have had. Most of the comments regarding these treatments were positive:

"The homeopath cured my depression, it was very expensive and I would have appreciated a referral by my GP." (control group patient)

"The private counselling was helpful for me as I needed more than the 12 sessions to explore all the issues." (control group patient)

"The group therapy has helped me realise I am not alone and to see other people's problems and ways of coping." (control group patient)

"The reflexologist helps release all the tensions." (experimental group patient)

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Appendix 2

Unit costs methodology and price list

Unit costs

The first section of this appendix contains a list of services for which unit costs were taken from the annual compilation of nationally applicable costs.[1] The methodology for estimating service-specific costs for the counsellors and the medications taken by study members for their mental health problems is outlined. The former costs were built up from first principles[2] using data on the salaries of participating counsellors. For other services, estimates were based on previous evaluations or cost studies in which colleagues were involved (see below). These tended to be broader or less specific estimates, but the data were acceptable as few people used these services and/or the service costs made only a small contribution to total costs. Finally, the costs of accommodation and living expenses and wages and salaries by occupational groups are tabulated; all costs data are expressed at 1997–1998 prices for a non-London location.

Unit costs taken from an existing compilation

Hospital services

Seven inpatient specialties were mentioned in the data set: orthopaedics, ear, nose and throat, cardiology, maternity, mother and baby psychiatry, gynaecology and general. There are also some names of hospitals or wards entered that could not be identified as belonging to a specific specialty. Of these seven, only the cost per inpatient day for cardiology (£377) was available in the Unit Costs volume.[1] A generic cost for an inpatient day was used for all inpatient admissions.

Inpatient stay	£211 per inpatient day
Psychiatry, Accident and Emergency department:	£98 per attendance
Generic, Accident and Emergency department:	£98 per attendance
Psychiatric outpatients:	£97 per attendance
Generic outpatients:	£98 per attendance
Psychiatric day hospital:	£57 per attendance
Generic day hospital:	£62 per attendance

Community-based mental health services

CMHT member:	£50 per hour of patient contact. Travel £1.03 per home visit
CPN:	£52 per hour of client contact. Travel £1.03 per home visit
Community psychiatrist:	£207 per hour of patient contact
Psychologist:	£56 per hour of patient contact. Travel £1.03 per home visit
Psychotherapist:	£207 per hour of client contact

Community-based health services

District nurse:	£38 per hour of client contact. Travel £1.03 per home visit
Health visitor:	£52 per hour of client contact. Travel £1.03 per home visit
Midwife:	£45 per hour of client contact. Travel £1.03 per home visit
Other community nurse:	£15 per hour of client contact. Travel £1.03 per home visit
Occupational therapist:	£31 per hour of client contact. Travel £2.00 per home visit
Physiotherapist:	£31 per hour of client contact. Travel £1.03 per home visit

Social care services

Social worker:	£83 per hour of face-to-face contact
Home help:	£8.50 per hour of face-to-face contact
Other advice:	£9.00 per contact hour

Counsellors, GPs and practice nurses

Information on the hourly rate paid to counsellors was provided by the nine participating practices. To these data, other cost elements have been added using the Unit Costs[1] schema for practice nurses as a template, which provided the most appropriate overhead elements, as the counsellors were also based in GP surgeries.

The unit cost for a GP consultation was taken from the Unit Costs annual.[1] The costs of medication and practice nurse appointments were excluded and estimated separately, and all GP contacts were assumed to have taken place in the surgery, as the information provided by the GP notes did not distinguish between surgery appointments or home visits. The patients' recall data showed only 3–4% of GP contacts to be in their own homes.

Counsellor:	£27.00 per hour of client contact (range £23.40–£32.70)

GP consultation: £10 per contact
Practice nurse consultation: £8.80 per contact

Medications

The costs of drugs prescribed by GPs were calculated as a per-tablet cost.[3] For each study member at each time period, the appropriate per-tablet cost was multiplied by the per diem dose and the number of days each drug was prescribed during the previous 6 months. For the baseline data, prescription costs for the previous 12 months were divided by two to give a cost-estimate per 6 months (*Table 68*).

Unit costs for non-psychiatric medications were estimated in the same way, except for the costs of insulin and syringes for people with diabetes because data on dosage and frequency were unclear. Four people in the study (two in the

TABLE 68 *Cost-estimate per 6 months per tablet or injection for baseline prescription costs*

Medication	Cost per tablet/injection
Amitryptaline	10 mg = £0.14; 25 mg = £0.09; 50 mg = £0.41
Lofepramine	70 mg = £0.17
Chlordiazepoxide	5 mg = £0.26; 10 mg = £0.32; 25 mg = £0.70
Tamazepam	10 mg = £0.03; 20 mg = £0.01
Dutomin	100 mg = £0.30; 200 mg = £0.30
Diazepam	2 mg = £0.07; 5 mg = £0.08; 10 mg = £0.15
Paroxetine/seroxat	20 mg = £0.69; 30 mg = £1.04
Prothiadin	75 mg = £0.14
Fluoxetine/prozac	20 mg = £0.69; 60 mg = £2.07
Loralazepam	1 mg = £0.24; 2.5 mg = £0.36
Sertraline/lustral	50 mg = £0.95; 100 mg = £1.42
Procyclidine	5 mg = £0.06
Clomipramine	10 mg = £0.06; 25 mg = £0.05; 50 mg = £0.11
Trimipramine	10 mg = £0.04; 25 mg = £0.09
Thioridazine	25 mg = £0.02; 50 mg = £0.03; 100 mg = £0.07
Nitrazepam	5 mg = £0.16
Nortriptyline	10 mg = £0.14; 25 mg = £0.09; 50 mg = £0.41
Busipirone	5 mg = £0.31; 10 mg = £0.47
Venlafaxine	37.5 mg = £0.86; 50 mg = £0.57; 75 mg = £0.86
Dothiepin	75 mg = £0.12
Carbamazine	100 mg = £0.03; 200 mg = £0.05; 400 mg = £0.11
Imipramine	10 mg = £0.20; 25 mg = £0.15
Sumatriptan/imigran	50 mg = £0.17; 100 mg = £0.29
Prochlorperazine	5 mg = £0.03; 25 mg = £0.11
Fluvoxamine/faverin	50 mg = £0.32; 100 mg = £0.64
Propanolol	80 mg = £0.01
Zopiclone/zimovane	3.75 mg = £0.11; 7.5 mg = £0.16
Trazadone	50 mg = £0.21; 100 mg = £0.36
Mirtazapine/zispin	30 mg = £0.86
Chlorpromazine	10 mg = £0.14; 25 mg = £0.15; 50 mg = £0.27; 100 mg = £0.31
Clonazepam	500 µg injection = £0.04; 2 mg = £0.06
Promazine depot	25 µg injection = £0.26
Fluanxol	500 µg injection = £0.05; 1 mg = £0.08

experimental group and two controls) had been prescribed these drugs at some point.

Unit cost estimates drawn in from other studies

Day activity services

Costs were taken from recent surveys of day activity services for people with mental health problems,[4] Unit costs were expressed in 1996–1997 prices and inflated by the Personal Social Services pay and prices index (1.026) to reflect 1997–1998 prices. A session was equal to 3 hours, or a morning or afternoon attendance.

Social Services Department day centre:	£9.55 per session or £3.18 per hour

(Mean costs for all participating Social Services Department day activity services)

Voluntary organisation day centre:	£9.46 per session or £3.15 per hour

(Mean costs for all participating day activity services run by voluntary organisations)

Social club:	£7.53 per session or £2.51 per hour

(Mean costs for all day activity settings included in the survey citing their principle orientation as providing social support)

Self-help group:	£7.53 per session or £2.51 per hour

(Mean costs for all-day activity settings included in the survey citing their principle orientation as providing social support)

Volunteer/befriender

The value of volunteers from a number of organisations in Europe has recently been estimated.[5] Expenditure on advertising and recruitment, training, supplies, equipment and buildings, travel, subsistence and administration amounted to between £0.76 per hour worked for the Scouts movement in The Netherlands to £9.28 in a UK organisation for resettling offenders (1998 prices). This latter figure was selected to reflect the unit cost of befriending in this study adjusted to 1997 prices using the Personal Social Services pay and prices index (97.42). For employed staff undertaking similar types of tasks, the unit costs for a nursing auxiliary and a home care worker were £10 and £6.90 per hour, respectively.

Volunteer/befriender:	£9.04 per contact hour

Alternative therapies

Seven types of therapy were listed in the dataset. A brief survey of three of each type of practitioner in a non-London area elicited data on their fees for first and subsequent appointments. The median fee for each type of therapist for follow-up appointments was used.

Osteopathy	£18
Homeopathy	£27
Reflexology	£20
Aromatherapy	£20
Hypnotherapy	£40
Acupuncture	£23
Shiatsu/Reiki	£25
Chiropractor	£25

Employment services

No detail was available on the type of employment service used, and thus no costs were estimated. However, at baseline, 6 and 12 months, only three, four and five people used any employment services, respectively, and the costs, therefore, made up only a small proportion of total costs.

Police

A recent study used data from the 1997 Police Force Ready Reckoner to estimate a cost for arrests, and provided detailed estimates of time input and salary costs, the major determinants of total cost.[6] The following salary costs (excluding overtime) per day were given: inspector, £198.20; sergeant, £158.79; constable, £135.31. The unit cost below assumed police officers work an 8-hour day and overheads for Local Authority workers were included from the Unit Costs annual[1] to maintain parity with other unit costs used in this study. These overheads included 15% of salary costs for management and administration and 8% of salary costs for capital overheads.

Police sergeant:	£24.42 per hour

Solicitor/lawyer

Solicitor/lawyer	£55 per chargeable hour

Unit costs for domestic accommodation and living expenses

Capital value of domestic housing

All study patients lived in domestic accommodation, and the capital value for domestic housing was estimated from the House Price Index for 1998 (*Table 69*).

TABLE 69 *The capital value for domestic housing estimated from the House Price Index for 1998*

House size	Capital cost	Value per annum[a]	Value per 6 months[b]
One bedroom	£42,026	£2600.40	£1300.20
Two bedrooms	£51,969	£3215.63	£1607.82
Three bedrooms	£63,601	£3935.38	£1968.68
Four or more bedrooms	£107,759	£6667.70	£3333.85

[a] *Annuitisation rate: 6% over 60 years (multiplier 0.061876)*
[b] *52.18 weeks per year; 6 months = 26.09 weeks*

TABLE 70 *Cost per household and per study member, per week and per 6 months for different household composition categories*

Household composition (mean number per household)	Number of patients (*n* = 135)	Mean housing spend[a] per household (£)	Mean other spend[b] per household (£)		Total mean spend per person (£)
		Per week	Per week	Per 6 months	Per week
Single adult (1.0)	22	43.80	164.10	4,281.37	207.90
Single adult, 1 child (2.0)	7	25.60	147.90	3,858.71	86.70
Single adult, 2+ children (3.5)	5	28.60	176.60	4,607.49	59.00
Two adults (2.0)	37	64.10	337.30	8,800.16	200.70
Two adults, 1 child (3.0)	20	71.20	349.10	9,108.02	140.10
Two adults, 2 children (4.0)	21	80.10	381.40	9,950.73	115.40
Two adults, 3+ children (5.3)	7	74.00	368.30	9,608.95	82.90
Three or more adults (3.3)	13	57.50	465.50	12,144.90	159.20
Three+ adults with children (4.7)	3	70.40	502.20	13,102.40	121.60

[a] *Net housing expenditure, excludes housing and council tax benefit*
[b] *Includes the following categories: fuel and power, food and non-alcoholic drinks, alcoholic drink, tobacco, clothing and footwear, household goods, household services, personal goods and services, motoring, fares and other travel costs, leisure goods, leisure services and miscellaneous*

Living expenses

Data were taken from *Family Spending: A Report on the 1997–98 Family Expenditure Survey*, and presented as the cost per household and per study member, per week and per half-year for different household composition categories (*Table 70*). Family Expenditure Survey data excluded the costs of housing or council tax benefit (that is, net housing expenditure) and these data were also not provided within the study, thus foregone costs to the Local Authority were excluded.

Occupation and earnings

The data on occupational earnings (*Table 71*) were taken from *The New Earnings Survey, 1998*, UK Streamlined Analyses, Office for National Statistics, London, and include data for both sexes at full-time rates.

Variable list

On the database, baseline costs were estimated over the 6-month period prior to study entry. All baseline costs variable names were constructed as follows:

BC (name of service) Baseline variables have been used as examples throughout this appendix.

Sixth- and twelfth-month follow-up costs were estimated over the 6-month period prior to interview. Variable names were constructed as follows:

SC (name of service) For costs at the sixth-month interview

TC (name of service) For costs at the twelfth-month interview.

TABLE 71 *Occupational earnings taken from* The New Earnings Survey, 1998

Occupation group	Mean gross annual earnings	Mean gross weekly earnings	Mean hourly earnings (excluding overtime)	Mean weekly hours (including overtime)
1. Managers and administrators	£30,242	£568.10	£14.58	39.0
2. Professional	£26,344	£522.80	£14.71	35.7
3. Associate professional and technical	£23,898 £13,404	£454.30 £267.90	£11.72 £6.91	38.2 38.4
4. Clerical and secretarial	£17,124	£347.40	£7.67	43.8
5. Craft and related	£14,519	£288.90	£6.99	40.9
6. Personal and protective	£14,425	£288.70	£7.33	39.2
7. Sales	£15,600	£314.30	£6.79	45.0
8. Plant and machine operatives	£12,962	£262.40	£5.80	43.9
9. Other				
Manual occupations	£15,223	£306.10	£6.74	44.1
Non-manual occupations	£21,910	£423.70	£11.07	38.2
All occupations	£19,494	£383.10	£9.51	40.2
East Midlands region[a]	£17,766	£350.40	£8.45	–
All England	£19,868	£389.90	£9.68	–

[a] *Derbyshire, Leicester and Leicestershire, Lincolnshire, Northamptonshire, Nottingham and Nottinghamshire*

Accommodation and living costs

NUMHH1: Number of adults and children normally resident in the household, baseline interview.

BCHHCAP: Baseline cost, capital value of house over 6-month period using number of bedrooms.

BCHHLEXP: Baseline cost, living expenditure for household over 6-month period using Family Expenditure Survey data for number of children and adults in the household.

BCACCOM: Baseline cost, accommodation and living expenses per client over 6-month period estimated as follows:

$$\frac{\text{BCHHCAP} + \text{BCHHLEXP}}{\text{NUMHH1}}$$

Service costs

A range of services were coded under the 'other' category: mother and baby unit, practice nurse, dietician, midwife, occupational doctor, union solicitor, genitourinary clinic, chiropodist, neurologist, Cruse (bereavement support), support/self-help group, Citizens Advice Bureau, relaxation therapy, group therapy. For each of these services, the estimated cost has been allocated to the appropriate named service variable.

Note that BCPCOUN was the cost of counsellors based on patients' recall of frequency and duration of visits and clients' costs were estimated using the different unit costs in each practice. For most clients, the variation from the data recorded in the GP notes was small. At the baseline interview, only one control group patient reported seeing a practice counsellor but this was not reflected in the data gathered from the GP notes.

At the sixth-month interview point, 18 of the 20 experimental group patients had recalled a difference of only one or two appointments more or less than the GP notes. One client recalled five more appointments and one recalled six less than was recorded in the GP notes. One control group patient recalled 12 more appointments than was recorded in the GP notes.

At the twelfth-month interview, one control group member (not the same person) recalled 24 appointments that were not recorded in the GP notes and another recalled only a single appointment. In the experimental group, and in comparison with information recorded in the GP notes, four patients recalled one, two or three appointments less, two recalled one or two appointments more, one recalled four

appointments more, three recalled six appointments more and one patient recalled 10 appointments more than recorded in the GP notes. These were not the same people for whom differences were recorded at the sixth-month interview and the differences were not due to different understandings of when the relevant period began and ended.

BCGPCOU and TCGPCOU were also calculated. These showed the cost of providing the level of support from practice counsellors using the frequency data for each person as recorded in the GP notes. Duration information was not recorded in the GP notes so the average duration for each time period was used, calculated from patient recall data for all people who saw counsellors. For these variables, the unit cost used was the average across counsellors employed in all the participating practices. At the 6-month follow-up (covering the intervention period), the counsellors recorded accurate data on the length of face-to-face contact and other work undertaken for each client in the study. These data were used to estimate SCGPCOU, with unit costs (per minute) estimated for each surgery. These variables were used in the summary cost-variables and analyses.

The costs of GP contacts (BCGP, for example), however, were based on the frequency of contact recorded in the GP notes. This estimation was used in the cost-analyses unless otherwise stated. BCDRUG and BCODRUG were the cost of all mental health drugs and all non-mental-health drugs, respectively, prescribed to each study member in the 6 months prior to interview. Note that as information was provided covering a full year at baseline, an average cost for 6 months was employed.

Subtotal cost variables

A number of subtotal costs were estimated for the previous 6 months, and the prefixes BC*, SC*, and TC* continued to apply. The variables summed the costs across a group of services as follows (BC* is given below as an example):

BCTOT1: Total for costs of all accommodation and support services. Costs of prescribed drugs and counsellors were accurately estimated for each client.

BCTOTAC: Costs of accommodation and living expenses.

BCTOTSV: Costs of all services, excluding accommodation and living expenses.

BCTOTHOS: Costs of all hospital-based services.

BCTOTCJS: Costs of all criminal justice services.

BCTOTSC: Costs of all social care services, including costs of alternative therapies.

BCTOTHE: Costs of community health services.

BCTOTMH: Costs of all mental health services, excluding practice counsellors.

BCTOTPR: Costs of primary care services, including costs of GP contacts, prescription drugs, practice nurses, and practice-based counsellors.

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