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Randomised controlled trial of non-directive counselling, cognitive–behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care

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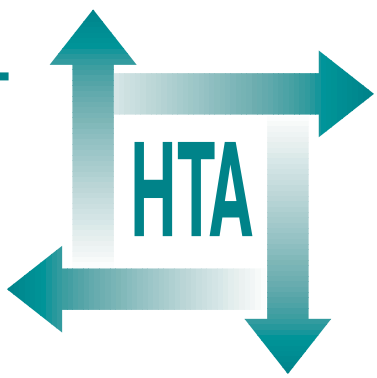
Health Technology Assessment
NHS R&D HTA Programme



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Randomised controlled trial of non-directive counselling, cognitive–behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care

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The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members 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 the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

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Contents

List of abbreviations

ANOVA	analysis of variance
BABCP	British Association for Behavioural and Cognitive Psychotherapies
BAC	British Association for Counselling
BDI	Beck Depression Inventory
BNF	British National Formulary*
BSI	Brief Symptom Inventory
CBT	cognitive–behaviour therapy
CI	confidence interval*
CIPFA	Chartered Institute of Public Finance and Accountancy*
CIS–R	Clinical Interview Schedule – Revised
COA	Certificate of Achievement*
CONSORT	Consolidated Standards of Reporting Trials
CTRS	Cognitive Therapy Rating Scale
df	degrees of freedom
GCSE	General Certificate of Secondary Education
GP	general practitioner
ICD-10	International Classification of Diseases, 10th revision
LOCF	last observation carried forward
NDC	non-directive counselling
OPCS	Office of Population Censuses and Surveys*
PN	practice nurse*
PSSRU	Personal Social Services Research Unit*
RSA	Royal Society of Arts*
SAS	Social Adjustment Scale
SD	standard deviation
SPSS	Statistical Package for the Social Sciences

* Used only in tables

Executive summary

Objectives

The aim of this study was to determine both the clinical and cost-effectiveness of usual general practitioner (GP) care compared with two types of brief psychological therapy (non-directive counselling and cognitive–behaviour therapy) in the management of depression as well as mixed anxiety and depression in the primary care setting.

Design

The design was principally a pragmatic randomised controlled trial, but was accompanied by two additional allocation methods allowing patient preference: the option of a specific choice of treatment (preference allocation) and the option to be randomised between the psychological therapies only. Of the 464 patients allocated to the three treatments, 197 were randomised between the three treatments, 137 chose a specific treatment, and 130 were randomised between the psychological therapies only. The patients underwent follow-up assessments at 4 and 12 months.

Setting

The study was conducted in 24 general practices in Greater Manchester and London.

Subjects

A total of 464 eligible patients, aged 18 years and over, were referred by 73 GPs and allocated to one of the psychological therapies or usual GP care for depressive symptoms.

Interventions

The interventions consisted of brief psychological therapy (12 sessions maximum) or usual GP care.

- Non-directive counselling was provided by counsellors who were qualified for accreditation by the British Association for Counselling.
- Cognitive–behaviour therapy was provided by clinical psychologists who were qualified for accreditation by the British Association for Behavioural and Cognitive Psychotherapies.
- Usual GP care included discussions with patients and the prescription of medication, but GPs were asked to refrain from referring patients for psychological intervention for at least 4 months.

Most therapy sessions took place on a weekly basis in the general practices. By the 12-month follow-up, GP care in some cases did include referral to mental healthcare specialists.

Main outcome measures

The clinical outcomes included depressive symptoms, general psychiatric symptoms, social function and patient satisfaction. The economic outcomes included direct and indirect costs and quality of life. Assessments were carried out at baseline during face-to-face interviews as well as at 4 and 12 months in person or by post.

Results

At 4 months, both psychological therapies had reduced depressive symptoms to a significantly greater extent than usual GP care. Patients in the psychological therapy groups exhibited mean scores on the Beck Depression Inventory that were 4–5 points lower than the mean score of patients in the usual GP care group, a difference that was also clinically significant. These differences did not generalise to other measures of outcome. There was no significant difference in outcome between the two psychological therapies when they were compared directly using all 260 patients randomised to a psychological therapy by either randomised allocation method.

At 12 months, the patients in all three groups had improved to the same extent. The lack of a significant difference between the treatment groups at this point resulted from greater improvement of the patients in the GP care group between the 4- and 12-month follow-ups.

At 4 months, patients in both psychological therapy groups were more satisfied with their treatment than those in the usual GP care group. However, by 12 months, patients who had received non-directive counselling were more satisfied than those in either of the other two groups.

There were few differences in the baseline characteristics of patients who were randomised or expressed a treatment preference, and no differences in outcome between these patients.

Similar outcomes were found for patients who chose either psychological therapy. Again, there were no significant differences between the two groups at 4 or 12 months. Patients who chose counselling were more satisfied with treatment than those who chose cognitive–behaviour therapy at 12 months. There were no significant differences in Beck Depression Inventory scores at either outcome point between participants who were randomised and those who chose each psychological therapy.

No differences in direct or indirect costs between the three treatments were observed at either 4 or 12 months. However, the finding of no difference in costs must be interpreted with caution. As is usual, cost data were highly variable, and the study may have been underpowered to detect differences in costs that would be considered important by decision-makers.

Conclusions

In the primary care setting, non-directive counselling and cognitive–behaviour therapy were both significantly more effective clinically than usual GP care in the short term. However, there were no differences between these three treatments in either clinical outcomes or costs at the 12-month follow-up.

Psychological therapy provided in primary care was found to be a cost-effective method of reducing depressive symptoms in the short term, but the comparative benefits were relatively circumscribed and did not endure over the long term. Compared with usual GP care, no differences in overall costs were observed. The additional costs associated with providing practice-based psychological therapy were recouped due to savings in visits to primary care, psychotropic medication and other specialist mental health treatments.

Implications for healthcare

Based on this study's observed equivalence in the clinical and economic outcomes of usual GP care compared with on-site psychological therapies in primary care, the commissioners of psychological services would be justified in considering additional factors when determining service configuration. These factors could include patient satisfaction, the preferences of practitioners and staff availability.

Recommendations for future research

Future research is needed in the following areas:

1. the long-term outcome for patients treated with psychological therapies
2. the relationship between the quality of psychological therapies and patient outcomes
3. the effectiveness of other therapies, different modes of treatment administration and the comparative effectiveness of psychological and pharmacological treatments
4. statistical techniques and methods for dealing with issues such as missing data and clustering of patients around therapists, GPs and practices
5. the psychological and social processes involved in patient preferences and how these relate to other psychological processes of relevance to controlled trial research, such as the placebo and Hawthorne effects
6. the content and interpretation of 'usual GP care'
7. patients who refuse to consider participation in trials, even when treatment preference arms are available.

Chapter 1
Background

Introduction

Disorders involving symptoms of anxiety and depression are prevalent in the primary care setting in the UK and impose a significant burden on patients, families and the primary healthcare team. The management of such disorders has traditionally been the responsibility of the general practitioner (GP) and has involved the use of therapeutic listening or the prescription of antidepressant and anxiolytic medication; referral for specialist treatment by secondary psychiatric services is relatively infrequent.[1]

Mental health professionals in primary care

Although the exact role of specialist mental health professionals in primary care has been under consideration for many years,[2–5] such professionals are increasingly substituting for the GP in the role of mental health treatment provider in primary care. Fundholding encouraged expansion of the primary care team to include non-medical professionals such as practice counsellors. GP-led commissioning of specialist services has allowed primary care providers greater involvement in the shaping of services, which has included bringing mental health professionals (e.g. psychiatrists and clinical psychologists) out of secondary locations and into the primary care setting.[6]

Additionally, despite the role accorded to medication by the psychiatric and general practice professions,[7] patients have far less favourable attitudes towards pharmacological treatment and instead stress the effectiveness of psychological therapies such as counselling.[8] Such perceptions, when combined with recent NHS policy focussing on the need for health services to be responsive to patient preferences,[9] have further encouraged the influx of specialist mental health professionals into primary care.

In 1993, a survey of general practices in England and Wales indicated that one-third of practices had an individual on-site who was involved in the provision of psychological therapies in primary care.[10,11] Community psychiatric nurses, practice counsellors and clinical psychologists were the groups most frequently identified as providing these services. Psychological services were more likely to be located in larger practices and training practices, and were also unevenly distributed among health regions. No comparable survey has been published recently in England and Wales, although anecdotal evidence suggests that the number of such professionals working in primary care has risen significantly since the survey was completed.

The expansion of mental health professionals into primary care has led to controversy over a number of issues. Some of these issues involve professional disputes, such as the demarcation between counsellors, other mental health professionals (e.g. clinical psychologists and psychotherapists) and other helping professionals who use counselling skills (e.g. GPs and nurses).[12,13] Concerns have also been raised about the qualifications and professional accountability of practice counsellors who are employed directly by GPs[11,14,15] and the impact of such practice attachments on the long-term clinical skills of GPs.

Clinical effectiveness and cost-effectiveness

The second controversy concerns both the clinical and cost-effectiveness of psychological therapies in primary care, compared with either the routine care provided by GPs or the established pharmacological treatments.[16] The relative effectiveness of different psychotherapies is also unclear. Some authors suggest that psychotherapies are of similar effectiveness,[17,18] although others claim superiority for particular treatment modalities, either in general or for specific disorders.[19–22]

A number of controlled trials and quasi-experiments of relevance to questions of effectiveness have been conducted, and reviews of the literature have also been published.[23–28] Balestrieri and co-workers[24] conducted a meta-analysis of trials (randomised or not) and found that specialist

mental health treatment (including but not restricted to psychological therapies) had a 10% greater success rate than routine GP care (variance-weighted mean effect size of 0.22). However, the Department of Health review of the psychotherapies concluded that, in primary care, "very few investigations demonstrate any consistent benefit to patients from counselling, and no studies show generic counselling to add to standard general practice care" (Roth and Fonagy, page 261).[26] This conservative conclusion was echoed by two other recent reviews.[27,28] A systematic review concerned with counselling in primary care has been registered with the Cochrane Collaboration,[29] but the results have not yet been reported. It is a common finding in trials of primary care psychological therapy that patient satisfaction with specialist mental health treatment is high, notwithstanding the clinical impact of the treatments.

Four randomised controlled trials of counselling have been conducted since the publication of these reviews. Harvey and co-workers,[30] Hemmings,[31] and Friedli and co-workers[32] all conducted trials of similar size in primary care populations. All three studies failed to demonstrate any clinical benefit associated with counselling compared with routine GP care, although Friedli and co-workers presented a *post hoc* analysis that suggested superior outcomes in the more severely depressed patients who were randomised to counselling. Boot and co-workers[33] did report a significantly greater clinical benefit associated with counselling compared with routine GP care; however, the study used a follow-up of only 6 weeks, and 44% of the patients were lost to the study in this short period of time.

The focus of evaluative studies has widened in recent years to include issues of cost, and a number of economic analyses of psychological therapy in primary care have been undertaken. Some studies have reported changes in health service utilisation, without providing a full economic analysis.[31,33] Other trials have conducted economic analyses of varying sophistication. For example, Scott and Freeman[34] found few differences in the clinical outcome of the four treatments they investigated: cognitive–behaviour therapy (CBT), social casework, routine GP care and medication prescribed by a psychiatrist. They calculated that additional benefits were not commensurate with the costs of therapists, secondary specialists and prescribed drugs.

Robson and co-workers[35] as well as Ginsberg and co-workers[36] conducted more comprehensive cost analyses. The former group found significant reductions in GP consultations and psychotropic prescriptions in the short term (24 weeks) and suggested that 28% of the cost of employing a behavioural psychologist could be recouped in terms of reduced drug costs alone.[35] Ginsberg and co-workers conducted a formal cost–benefit analysis. The financial benefits of nurse-provided behaviour therapy did not outweigh the costs, although a scenario was presented suggesting that the cost–benefit ratio would reach 1 if certain assumptions about patient throughput and maintenance of clinical gains were met.[36]

Gournay and Brooking[37] as well as Mynors-Wallis and co-workers[38] found that patients receiving psychological therapies took less time off work than those under GP care. However, Gournay and Brooking[37] reported that the cost per quality-adjusted life-year was extremely high for the psychological therapy, and neither study found significant differences in clinical outcome or other healthcare costs. Harvey and co-workers[30] found no significant differences in clinical outcome in patients receiving treatment from a counsellor or their GP. There was no clear cost advantage associated with either intervention, as economic outcome depended on the assumptions used to cost services such as referrals and counsellor time. Friedli and co-workers[39] reported essentially the same clinical and economic findings. The overall conclusions that can be drawn from these studies are limited because of variations in the study design, patient samples, treatments and conduct of the economic analysis (e.g. the type of analysis, range of costs included and calculation of benefits).

Indirect benefits

The addition of a mental health professional to primary care also represents an organisational change, which may have benefits beyond immediate patient outcomes. For example, closer relationships between primary care and mental health professionals may lead to changes in roles, the alteration of established clinical routines and improvements in professional practice. These changes, in turn, may impact on the wider practice population as well as patients specifically under the care of the mental health professional, bringing about so-called indirect[40] or spillover[41] effects. A systematic review of the

impact of on-site mental health professionals on the clinical behaviour of primary care providers[42] found that there was some evidence of short-term, limited effects on the prescribing and referral behaviour of GPs.

Issues in the evaluation of primary care psychological therapy

All the published reviews point out the need for more research in this area, reflecting in part the many difficulties associated with the rigorous evaluation of psychological therapies.[43] These problems are compounded by the particular difficulties associated with clinical trials in the primary care context. In particular, there is tension between the need to ensure high internal validity in trials, through procedures such as randomisation and standardisation, and the need to ensure that such procedures do not irreparably threaten external validity, if the conditions of the trial are to be representative of the contexts to which the results are to be generalised.[26,44,45] Some of the key issues of relevance to primary care psychological therapy trials are discussed below.

Definition of psychological therapy

The issue of defining psychological therapy concerns both what constitutes a psychological therapy (compared with generic listening skills practised by many health professionals) and the distinction between different psychological therapies (e.g. non-directive counselling [NDC], psychodynamic therapies, behaviour therapies, cognitive therapies and problem-solving approaches). There is also a degree of divergence between the types of treatments evaluated by researchers, which focus on standardisation and integrity, and the realities of the therapy practised by clinicians, which is characterised by eclecticism.[46] Other conditions that may distinguish research and clinical practice concern the format of therapies (e.g. the number, length and spacing of therapy sessions) and the training and experience of the therapists.

Identification of an appropriate control or comparison condition

The search for an appropriate control group, which can account for non-specific treatment effects and test the 'true' effectiveness of therapeutic techniques, has caused much controversy in mainstream psychotherapy research[47] but is of less relevance to primary care. Patients have far greater freedom of treatment and are always able to seek help from their GP. Although psychological therapies have been compared among themselves and with established pharmacological treatments in 'explanatory-type' trials,[48] most studies have involved a pragmatic comparison between the treatment under study and what is called 'routine' or 'usual GP care' (i.e. the care that patients would have received if the specialist therapy was not available). However, the behaviour of individual GPs tends to be variable: some may use techniques akin to those of psychological therapists, and the prevalence and quality of antidepressant prescribing may vary widely[49,50] or be influenced by participation in the trial.[51] These variations have important implications for the analysis and interpretation of results.

Outcome measures

The choice of outcome measures has always been a controversial issue in psychotherapy research,[43,52] and the situation is similar in primary care.[53,54] Without consensus as to the optimal measure, it is generally agreed that a range of instruments should be used covering the key domains of psychiatric symptomatology, social function and patient satisfaction. Economic analyses additionally require measures of health service utilisation and quality of life.[54]

Patient preferences

Randomisation protects against threats to internal validity by ensuring there are no systematic differences in patient characteristics at baseline that could conceivably account for any differences in outcome. However, randomisation can be a threat to validity in its own right. In relation to internal validity, when patients cannot be blinded to treatment and the randomisation process can affect important patient characteristics, randomisation may actually decrease **internal validity**. For example, psychological therapies require patients to be motivated to participate in the treatment, but randomisation may result in a loss of choice and control. If patients are randomised to treatments they do not want, they may suffer **resentful demoralisation**,[55] which could lead to non-compliance with the treatment protocol, refusal to complete assessments, lowered satisfaction or even worsened outcome.[56,57] In relation to **external validity**, there are significant problems in ensuring participation in trials when patients must risk randomisation to treatment by their GP; a recent trial collapsed because of low

recruitment attributed in part to this problem.[58] Even if sufficient patients are recruited, doubts remain about the representativeness of patients who agree to enter such trials.

Randomisation procedures

Schulz and co-workers[59] have highlighted the importance of the randomisation procedure in ensuring accuracy of the estimates from clinical trials. If bias is to be avoided, the procedure should ensure that decisions about the entry of a patient into a trial are made independent of any knowledge of the next treatment allocation (i.e. the separation of the generator of allocation from the executor). Such procedures may not always be followed if randomisation is under the control of the GP.[31]

Follow-up

Because of the pattern of recovery and relapse evident in psychological disorders such as depression, long-term follow-up of patients is preferable to ensure that information on short-term clinical benefits can be interpreted in the context of information concerning outcome over the longer term. However, such long-term follow-up increases the frequency of treatments outside the trial protocol and loss to research follow-up, which may make the interpretation of results more difficult.[26]

Groups of patients studied

Considerations of statistical power and specificity have led many mainstream psychotherapy trials to be conducted on relatively homogeneous groups of patients, for example, patients with a diagnosis of major depression and no significant co-morbidity.[45] However, patients receiving primary care treatment for psychiatric morbidity may not present with symptoms that fit diagnostic systems developed in specialist settings.[1,60] Some trials have included a more representative group of patients, such as those identified by the GP as requiring specialist assistance. Although the application of these criteria increases the external validity of trials, it also increases variance in outcomes, thereby requiring the use of larger sample sizes to achieve the same statistical precision in reported effect sizes[46] and complicating the interpretation of results.[61]

Rationale for proposed design of present study

The NHS review of psychotherapy concluded that, "although demand for all forms of psychotherapy outstrips supply, there was also evidence of poorly targeted, inappropriate interventions and ineffective organisation and delivery of services which are wasteful of resources."[9] The expansion in the provision of psychological therapies in primary care has been driven by GP and patient demand rather than evidence concerning effectiveness, to the degree that there is concern these services are diverting care away from patients with greater need and capacity to benefit.[16] The present study aimed to provide a rigorous comparison of the cost-effectiveness of three types of commonly used interventions, within the context of a pragmatic design reflecting current models of service delivery, in order to offer information relevant to the commissioning of services for mild-to-moderate mental health problems in primary care.

Any controlled trial design in psychological therapy represents a trade-off between the competing demands of internal and external validity.[62] This section will highlight the rationale behind the various decisions made concerning the design and conduct of the trial in relation to these issues.

The present study was a pragmatic, patient preference/randomised controlled trial of the clinical effectiveness and cost-effectiveness of CBT, NDC and usual GP care in the management of depression as well as mixed anxiety and depression in primary care.

Choice of therapies

The choice of therapies under study was influenced by a number of factors. Psychological therapy practised in primary care is often described as 'eclectic' in nature, using a mixture of theoretical approaches, depending on the clinical context.[6,9,46] However, such therapy is difficult to evaluate because wide variations in the format, process and goals of therapy make it difficult to attribute efficacy to a generic therapy rather than to the particular therapist or therapist–patient relationship. A compromise between internal and external validity necessitates the use of common therapies that are also sufficiently specified to enable them to be reliably distinguished. The present study thus evaluated CBT and Rogerian NDC, both of which are widely practised in primary care.[6,10,11,14]

There are suggestions that CBT has received greater empirical support in primary care trials,

compared with Rogerian counselling, because of a greater number of studies with significant results.[35,63–68] However, this pattern of results could relate to differences in the studies other than the therapies under investigation. In only one study have both therapies been examined in the same context, and the results of that study suggested that counselling provided through social casework was superior to CBT provided by a clinical psychologist,[34] although methodological problems made interpretation of that study less clear.[51]

Finally, the two therapies are also traditionally, although not exclusively, associated with different professional groups; CBT is routinely conducted by clinical psychologists, while Rogerian NDC is more often practised by counsellors who are not trained in clinical psychology or medicine.[6] This difference has important implications for the skill mix in primary care, professional and interprofessional education, and the overall costs of treatment provision.[69]

Therapy format and therapist training and experience

Other issues concerning the treatments relate to the format of the therapies as well as the training and experience of the therapists. There is evidence that counselling treatments provided in primary care cover a duration of 6–12 sessions,[6] and such a format has often been used in clinical trials. Although CBT in primary care has traditionally used more sessions both in practice[6] and in trials,[64] it can be delivered in a shorter format.[35,68] The training and qualifications of counsellors in primary care have been found to vary widely, with some levels of training so low as to raise concern.[6,14] Although the evidence linking training to improved outcome from psychological therapy is inconclusive,[26,70] the present study required the minimum levels of training and experience suggested by the relevant professional organisations.[71–74] Such levels are not highly representative of routine practice, but they do ensure a degree of standardisation of service provision, with a consequent increase in internal validity. These levels of training and experience also have external validity, to the degree that such standards are increasingly being **demanded** of psychological therapy providers in primary care, and will thus better represent routine practice in the future.

Mental health problems

Depression, and mixed anxiety and depression were chosen as the mental health problems under investigation because both are common in primary care settings,[1] co-exist to a large degree[75,76] and are frequently the cause of patient referrals to on-site mental health professionals in primary care.[11] Although the category of 'major depression' has been identified as important by recent GP educational initiatives[7] and is sometimes used as an inclusion category in primary care trials,[77] such categorical psychiatric diagnoses do not necessarily represent the models of psychosocial problems used by GPs.[78,79] For this reason, the present study used a more pragmatic criterion.

Patient preference design

Because a number of commentators have suggested that the issue of patient preference is a potential problem for the interpretation of trials of psychological therapy,[26,80] the Brewin and Bradley patient preference design[56] was adopted. Only patients without a strong preference for treatment were randomised, while those with a strong preference were allocated to their preferred treatment group and followed in the same way as the randomised group. This design protects against internal and external validity threats by ensuring that (a) patients are not randomised to treatments they do not want to receive, thus reducing demoralisation effects, and (b) the trial is made as acceptable as possible to GPs, patients and mental health professionals, thus reducing selective recruitment. Such a design cannot provide an unbiased estimate of the influence of preference on outcome, because the preference arms are vulnerable to selection bias.[81] However, this design can give an indication of the degree to which preferences are likely to be a significant issue in the interpretation of the trial results.

Long-term follow-up

The study used a relatively long-term follow-up (12 months from entry into the trial) because it is known that some depressive problems have a cyclic course, which cannot be detected by short-term designs.[26] Such long-term follow-up has been used infrequently in trials in this area of study. Additionally, one of the hypothesised advantages of psychological therapies (and CBT in particular) is their potential to prevent relapse in the long term because the skills and insights developed during treatment can assist the patient to manage new or recurring problems.[82,83]

Economic analysis

The need for evidence of the cost-effectiveness of psychological therapies is increasingly accepted.[9,26]

Although a number of studies with economic components have been published, most have identifiable drawbacks in terms of methodology,[84] and few have undertaken to examine the costs of different psychological therapies in relation to a common outcome metric (i.e. a cost–utility analysis).[85] Such analyses have the advantage of allowing comparison between alternative procedures used within a trial, as well as with alternative procedures provided by the NHS that have also been examined using the same metric.

Aims of the study

The aims of the present study were to:

- determine the comparative clinical effectiveness and cost-effectiveness of usual GP care, NDC and CBT in the management of depression as well as mixed anxiety and depression in the primary care setting
- examine the effect of patient preference on the outcomes of patients undergoing these three treatments.

Chapter 2
Methods

The present study was conducted in two centres: the Department of Psychiatry and Behavioural Sciences, Royal Free Campus of the Royal Free and University College Medical School, London, and the National Primary Care Research and Development Centre (NPCRDC) at the University of Manchester. The study design and methods were based on extensive experience gained by the main applicant in two previous primary care psychological therapy trials.[32,86]

Recruitment of psychological therapists

Different procedures were used to recruit psychological therapists in each centre. In Greater Manchester, relatively few independent clinical psychologists were available, and the cost of therapy provided by these psychologists was significantly higher than that of routine NHS provision. Therefore, service provision was negotiated with a local clinical psychology department (Psychology Services of Mental Health Services of Salford).

The Salford team had clinical psychologists already working in primary care and hired qualified counsellors for their team, to participate in both routine and trial provision. Because of problems associated with patient recruitment in the practices served by the Salford team (see *Recruitment rates* below), a similar agreement was reached during the trial with Stockport Psychology Services, which also had clinical psychologists and counsellors available who had worked in the primary care setting.

In London, psychological therapists were recruited through personal contacts and advertisements in the press. Each therapist negotiated an individual contract with the research team for payment on a sessional basis. The research team arranged for therapists to be attached to one or more surgeries, depending on the sessional availability of the therapist and the recruitment of patients at each participating practice.

Recruitment of GPs

Again, the process of recruitment of GPs differed in the two trial centres. In Manchester, both the Salford and Stockport clinical psychology teams agreed to make the initial contact with practices with which they were already working or where they wished to supply routine services, which would be augmented by the services available through the trial.

Overall, 11 practices and 45 GPs were involved in the study in Manchester. Only ten practices and 25 individual GPs actually referred patients. The number of eligible referrals from individual GPs ranged from one to 17, with three GPs responsible for 33% of the total referrals.

In London, the research team contacted GPs by letter inviting them to participate in the study and followed up with telephone contacts. When appropriate, members of the research team met with GPs to explain the project in greater detail.

Overall, 13 practices and 48 GPs were involved in the study in London, and all these GPs actually referred patients. The number of eligible referrals from individual GPs ranged from one to 34, with three GPs responsible for 27% of the total referrals.

In both centres, information packs and meetings were used to inform GPs and other practice staff about the study protocol, and to answer specific queries relating to the project. Also provided were small laminated reminders containing the inclusion and exclusion criteria, in order to assist in the recruitment of patients.

Ethical approval

Ethical approval for the study was gained from the Local Research Ethics Committees in each area in which the general practices were situated.

Recruitment of patients and inclusion/exclusion criteria

Patients were recruited by the GPs and provided with an information sheet concerning the study

(see appendix 1). GPs were asked to refer patients who they diagnosed as suffering from depression, or mixed anxiety and depression, and for whom a brief psychological intervention was indicated. Other inclusion and exclusion criteria are shown in *Box 1*.

BOX 1 Trial inclusion and exclusion criteria

Inclusion criteria

Age of 18 years or over

Depressed or depressed/anxious, as assessed by a score of 14+ on the BDI

Exclusion criteria

Serious suicidal intent

Psychological therapy in the last 6 months

Currently taking antidepressant medication

Restricted mobility

Organic brain syndrome

Unable to complete questionnaires owing to language difficulties, illiteracy or learning disability

BDI, Beck Depression Inventory

If patients refused to take part in the study, doctors were asked to complete a form detailing the reason for refusal. On securing agreement in principle to participate, GPs returned a referral form with the patient's details to the study team. The referral form asked the GP to indicate the nature of the patient's problems (from a list of 15 common problems), the 'main' problem (as perceived by the GP) and the GP's prediction of the likelihood of success of each of the three treatments in the study (on 7-point scales). Patients were contacted by telephone, letter or home visit, and an appointment was made to meet the patient and discuss the study. These interviews took place at patients' homes or, more infrequently, at GP surgeries or the research centres. Patients determined to be ineligible to participate in the study were referred back to their GP for care.

Eligibility interview

A researcher assessed patients referred by the GP. Patients reread the information sheet in the presence of the researcher and provided written consent to take part in the study. The medication, psychological therapy and suicide criteria (*Box 1*) were rechecked, and a specific suicide protocol was used. Only those patients scoring 14 or above on the Beck Depression Inventory (BDI)[87] were entered into the study.[*] Following this assessment, the researcher took each patient through a series of written and verbal explanations about the nature of treatments and allocation procedures, allocated the patient to treatment and then sent the patient's details to the relevant service provider. GPs were informed of the patient's allocation at the same time.

Recruitment rates

Patients were recruited from February 1996 to November 1997. There was significant variation in the referral rates of different general practices in the study and a significant disparity between the overall referral rates in Manchester and London. Overall, 74.4% of eligible patients were referred from London practices. All practices agreeing to take part were originally optimistic about the number of patients who would be referred, but the referral rate in Manchester was below that required by the study protocol. In order to improve the referral rates, GPs were sent regular reminders about current recruitment and targets, practice managers were requested to raise the issue of recruitment at practice meetings, and practices were offered visits to discuss difficulties in recruitment. However, there was little evidence that such measures had a significant impact on referral rates, and initial referral rate remained a strong predictor of the general level of participation in the trial.

The problems experienced in Manchester were compounded by the fact that these practices also had access to 'routine' psychological therapy services, which involved the same therapies and were delivered by the same providers used for the trial. The lack of clear demarcation between these forms of service delivered by the Salford team meant that there was less of an incentive to refer to the trial because it was not perceived as an 'additional' service. It was also difficult to recruit new practices because trial provision could not be transferred to new practices without disruption to routine services. A similar situation was also present in the Stockport service.

[*]The original study protocol set a threshold score of 17+ on the BDI. This threshold was reduced to 14+ for two reasons. First, there was a concern that patients with mixed anxiety and depression might be excluded if they had significant anxiety symptoms but insufficient depressive symptoms to register as high as 17 on the BDI. Second, this reduced threshold allowed comparison between the results of the present trial and the *post hoc* analysis conducted by Friedli and co-workers,[32] which also used a criterion of 14+.

The slow recruitment and disparity between the centres led to the lengthening of the trial recruitment period by 3 months and a shift of work between the centres in terms of overall responsibility for recruitment, data collection and data entry.

Baseline assessment

Assessors

Six assessors were used for baseline and follow-up assessments, four in Manchester and two in London. They included three research assistants/associates with backgrounds in psychology (EW, PB and SF), two research technicians (SH and JH) and one practising GP/clinical lecturer (MG).

Baseline assessment procedure

The BDI functioned as both an eligibility criterion (see *Eligibility interview* above) and the primary outcome measure in the baseline assessment package. The assessment instruments are listed below. Copies of unpublished scales can be found in appendix 2.

1. BDI.[87] The BDI is a 21-item measure of depressive symptomatology. A score of 14 or above was used as a criterion for entry into the trial, and a score of 23 or above served as a stratifying variable during randomisation.
2. Demographic and economic questionnaire.[32] This questionnaire provided information on education, ethnicity, housing and employment status, time lost from work due to sickness, consultations with health professionals, hospital appointments and medication use.
3. Computerised Clinical Interview Schedule – Revised (CIS–R).[88,89] The CIS–R is a computerised version of the Clinical Interview Schedule, which is a standardised interview used for the assessment of minor psychiatric symptoms in community settings. As well as providing an overall measure of severity, scoring algorithms combine symptom patterns to produce diagnoses based on the International Classification of Diseases, 10th revision (ICD-10), criteria.
4. Brief Symptom Inventory (BSI).[90,91] The BSI is a 53-item scale that measures a range of symptoms, including somatisation, obsessive symptoms, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideas and psychoticism.
5. Modified Social Adjustment Scale (SAS).[92] This 45-item scale has been modified from an interview format to self-report. The SAS has subscales measuring the respondent's functioning in relation to housework, social and leisure activities, and relationships with partner, parents, extended family and the family unit.
6. EuroQoL.[93] The EuroQoL is a brief 7-item scale used for the measurement of generic quality of life. Five dimensions are used to define 243 unique health states. Each health state can be weighted with reference to statistics derived from a population survey.
7. Expectations of treatment questionnaire. Patients were asked to indicate the nature of their difficulties, choosing from a list of 15 common problems,[94] and to indicate how successful they thought their treatment would be. They were also asked about what treatment they had hoped to receive when they visited their GP and were referred to the study. This questionnaire was completed after allocation to treatment.

Allocation to treatment

Allocation procedure

Originally, the allocation procedure distinguished between two types of patients: those with no preference for treatment and those with a preference for a specific treatment. After reading the descriptions of the treatments and dealing with queries, patients were asked whether they wished to choose their treatment or were willing to be randomised. Participants were encouraged to accept randomisation unless they had a strong preference for treatment.

Modifications to the allocation procedure

A number of difficulties were associated with the original allocation procedure. Eight and a half months into the trial, the preference arms were close to being filled, especially the CBT arm. Continuing to recruit patients into the preference arms would have increased the cost of the project, if the original sample size and statistical power were to be achieved in the randomised sample. However, there was concern that closing the preference arms would lead to changes in the types of patients referred by GPs, because of the loss of choice regarding allocation.

Discussions with patients choosing treatment indicated that the vast majority had no specific preference for psychological treatment but were reluctant to accept the possibility of allocation to the GP. Therefore, a new procedure was instigated in which all patients were offered three allocation choices: specific preference, randomisation between the three treatments and randomisation

between the two psychological therapies (CBT and NDC). Because studies comparing psychological therapies often have less power to detect differences than those comparing treatment and control,[95] this procedure had the advantage of increasing the number of patients available for the randomised comparison of the two psychological therapies. Patients who continued to desire a specific psychological therapy were offered a single 1-hour assessment session with the professional of their choice, but they were not retained in the study. The overall flow of the patients into each arm of the trial is shown in *Figure 1*.

Randomisation procedure

The patient was the unit of analysis. Randomisation was conducted through the use of numbered, sealed, opaque envelopes. Allocation was blocked and stratified for BDI score. Low severity was defined as BDI scores between 14 and 22, and high severity as scores equal to or above 23. Separate randomisation schedules were created for the randomisation between three treatments and the randomisation between the two psychological therapies, and for each assessor.

Interventions

Psychological therapies

Non-directive counselling

All the counsellors involved in the trial had the necessary qualifications and experience to be accredited by the British Association for Counselling (BAC). Accreditation can involve three methods: (a) completion of a BAC-recognised course and 450 hours of supervised practice over 3 years, (b) 450 hours of counselling training (comprising 200 hours of skill development and 250 hours of theory) and 450 hours of supervised practice, or (c) 7 years of experience, with a minimum of 150 hours per year under formal supervision and 450 hours of subsequent counselling practice over 3 years. The counsellors complied with a non-directive approach,[96] which was outlined in a brief manual provided by the research team. All the counsellors received an explanation of the study in full, with special attention paid to the need to avoid providing treatment that could be confused with CBT (see *Psychological therapy integrity* below). Although it was agreed that CBT techniques might be used very occasionally (e.g. if they were required to overcome a therapeutic impasse), it was stressed that the treatment must be predominantly non-directive in nature. All counsellors agreed to 1 hour of supervision for every 6 hours of patient contact time. Overall, there were 14 counsellors available to the study, all of whom were women. One counsellor did not see any study patients.

In Manchester, delays in provision associated with illness and holidays meant that one patient was seen by a private counsellor who was not part of the Salford/Stockport services. This counsellor met the qualification criteria, agreed in principle to provide NDC and provided tapes of sessions for quality control purposes (see *Psychological therapy integrity* below).

Cognitive–behaviour therapy

All the psychologists involved in the trial had the necessary qualifications and experience to be accredited by the British Association for Behavioural and Cognitive Psychotherapies (BABCP) and were eligible for registration with the United Kingdom Council for Psychotherapy. The requirements include core professional training in therapeutic and interpersonal issues, additional training in CBT and a period of closely supervised clinical practice. Because CBT is a more structured treatment, the therapists were given detailed manuals (for both therapist and patient) that described a problem-formulation and staged-intervention approach.[97,98] Psychologists in Salford also received a brief training session from a psychologist employed at Manchester University (Dr Adrian Wells) to further assist in standardising their clinical methods. Attempts to involve the London therapists were unsuccessful because of scheduling difficulties. All the psychologists agreed to 1 hour of supervision for every 6 hours of patient contact time. Overall, there were 12 psychologists available to the study: eight women and four men. One psychologist did not see any study patients.

Psychological therapy provision

It was agreed with the service providers that patients would be contacted with an appointment within 1 week of their baseline interview and treatment would be started a maximum of 2 weeks after receipt of the appointment letter. Therapists were informed that the treatment should be provided over an average of six sessions per patient, with a maximum of 12 sessions. Failure of the patient to respond to appointment letters or attend treatment was to be dealt with using the therapist's usual method (e.g. follow-up letters requiring patients to 'opt into' treatment after an initial failure to attend). Sessions were offered, as far as possible, on a weekly basis at the general practice. Longer intervals were used on

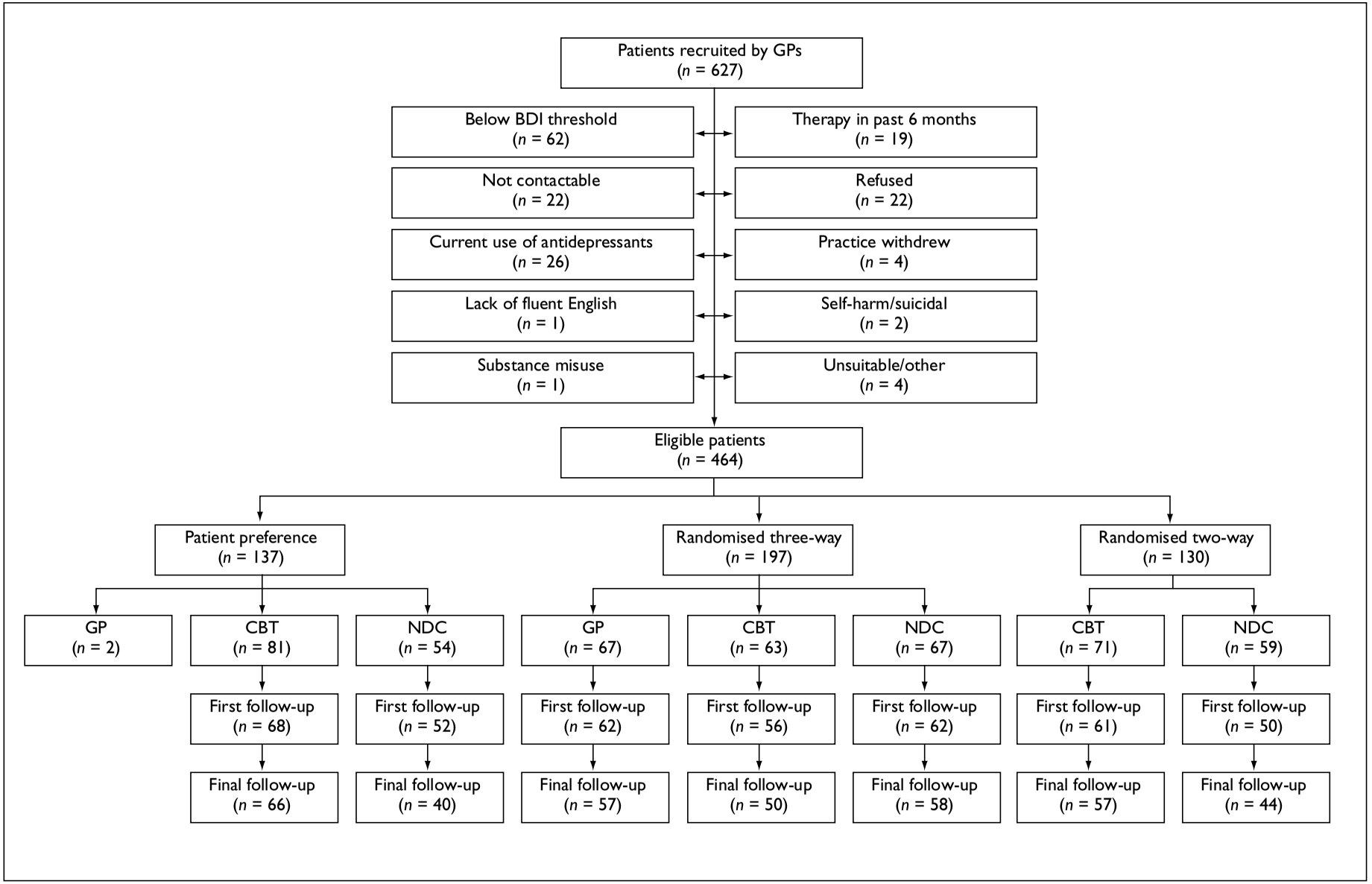

FIGURE 1 *Trial profile*

occasion with the agreement of the patient. In Manchester, a small proportion of sessions had to be conducted outside the context of general practice (i.e. in hospital settings or local community facilities) because of problems in finding space for therapy within the practices themselves. The vast majority of appointments lasted 50 minutes, although some CBT sessions in Manchester lasted 30 minutes.

For each patient, therapists completed a form concerning the length, process and outcome of therapy (see appendix 3, *Therapist's process notes*).

Participants allocated to active treatments were free to see their GP as usual. However, the research team requested that GPs refrain from routinely prescribing antidepressant medication to patients in the psychological therapy groups until it was clear that these patients were not responding to the therapy and thus required medication as a 'rescue'.

Psychological therapy integrity

Because of the prevalence of 'eclectic' models of psychological therapy in primary care, it was necessary to ensure significant differentiation between the therapies so as to make the results interpretable. Direct audio recording of therapy sessions was chosen to augment the therapist training requirements and protocol instructions. Therapists were asked to record all therapy sessions with the second and fifth patient allocated to their care who gave consent to taping. Written consent to taping was gained from the patient following allocation to treatment. Taping of all sessions and random sampling of sessions would have been the optimum method, in order to minimise potential differences in therapist behaviour between taped and non-taped sessions. However, the cost of providing tapes and recorders required a more limited approach.

The tape-recorded sessions were rated using the Cognitive Therapy Rating Scale (CTRS).[99] An independent psychologist with experience in the use of the CTRS assessed two sessions per therapist. The CTRS provides a rating of the quality of several components of cognitive therapy as well as a general rating of interpersonal effectiveness of relevance to both cognitive and non-directive therapies. The CTRS thus provided a check on the adequacy of CBT and would also allow detection of significant use of cognitive techniques by NDC therapists. A score of 39 out of 78 was used as a cut-off for 'adequate' CBT. There was no separate rating of the quality of NDC. Although some relevant scales do exist,[100] there is no agreed, reliable method of rating NDC that is equivalent to the CTRS. The measurement of integrity requires that it is possible to determine therapeutic behaviours that are 'unique and essential' to one therapy (e.g. 'homework' in CBT) or 'proscribed' in others (e.g. 'agenda setting' in NDC).[101] The CTRS provided measures of both attributes and thus adequately assessed the differentiation between the therapies, ensuring that distinct therapies were being delivered. Because NDC involves behaviours that are 'essential but not unique' (e.g. 'empathic listening' and 'establishing a therapeutic alliance'), it is more complex to determine the integrity of this therapy separately, and thus the present approach was considered most efficient given the limited resources available to this aspect of the project.

Usual GP care

GPs were asked to provide their routine care to patients allocated to this group. GPs were able to talk to their patients and discuss their problems, or prescribe anxiolytic or antidepressant medication. The research team asked GPs to refrain from referral of these patients for psychological interventions (by on-site or secondary care professionals) for at least the first 4 months and, if possible, for the whole 12-month follow-up period, unless such treatment was required urgently.

Follow-up assessments

The patients underwent follow-up assessment 4 and 12 months after the baseline interview. Whenever possible, the patients were interviewed in person. However, patients who refused a face-to-face meeting or had moved out of the study area were offered postal interviews. In the majority of postal interviews, all questionnaires were completed, although missing data and error rates were inevitably increased because the research assistant was not present to check the responses. In a small number of cases, follow-up was restricted to the main outcome measure (the BDI) administered by post or telephone. The full follow-up assessment included:

1. BDI[87]
2. Demographic and economic questionnaire[32]
3. BSI[90,91]
4. Modified SAS[92]

5. EuroQoL[93]
6. Measure of patient satisfaction.[32] This 15-item questionnaire was based on Elliott and Shapiro's impact of events scale[102] and required patients to rate a number of aspects of the help they received from the therapist or GP (e.g. increased understanding of problems and perceived support).
7. Experience of treatment. Patients were asked to indicate the nature of their problems based on a scale of 15 common problems (including new problems arising since allocation) and to rate whether or not these problems had been dealt with in therapy, the amount of change in these problems and the degree to which these changes were perceived to be due to their therapy.
8. A qualitative interview concerning their treatment, any previous experience of psychological therapy and views about treatment preferences. In relation to treatment preferences, patients' responses to the following questions were recorded: "When the researcher first came to see you, can you tell me if you had a treatment preference? What was it? And why?"

Data analysis

Quantitative data were entered into Statistical Package for the Social Sciences (SPSS) PC+ datasets, and the qualitative responses were entered into a Microsoft® ACCESS database (Microsoft Corporation, USA). All quantitative data were entered and checked on separate occasions to ensure accuracy. Missing items were dealt with using imputed scores, if possible (e.g. BDI and BSI), except when a significant number of items were incomplete. Any missing items on the EuroQoL meant the scale could not be scored so was omitted.

Economic data

For the purposes of economic analysis, the general practice medical records of all patients entered into the trial were examined to record health services utilisation in the 12 months before and after the date of GP referral to the trial.

The exact requirements governing consent to access medical records for research purposes are ambiguous, and individual practices varied in their response to the request for access. Some London practices required separate written consent from patients or only allowed practice managers to extract data for the research team. Others allowed access based on the consent obtained for overall study participation at baseline.

Three researchers were involved in the medical records search (EW, PB and MG). MG provided assistance to the non-medically trained researchers in the extraction of data from medical records. When possible, both paper and computer records were searched. Notes were made of all consultations, referrals, prescriptions and investigations. Incomplete sources of data were noted (e.g. temporary resident records, computer notes only and records unavailable for the entire 24-month period). Utilisation data concerning consultations, psychological therapy, hospital visits and medication were also collected at baseline and follow-up interviews through patient self-report. Data were entered into SPSS for Windows® (Microsoft Corporation, USA). Separate codes were used for data derived from record searches only, self-report only and both sources of data.

Chapter 3

Recruitment results and treatment processes

Patient recruitment details

Seventy-three GPs referred a total of 627 patients to the trial. Of this total, 163 patients were excluded from the study (*Figure 1*) for the following reasons: scored below 14 on the BDI (38.0%), current antidepressant use (16.0%), could not be contacted (13.5%), chose to withdraw (13.5%), reported having received psychological therapy in the past 6 months (11.7%), practice withdrew for practical reasons such as a lack of space (2.5%), unsuitable (2.5%), self-harm/suicidal (1.2%), substance abuse (0.6%) and lack of fluent English (0.6%).

A total of 119 patients were recruited in Manchester and 345 in London. Patients were seen within a mean of 11 days (interquartile range, 8 days) of referral to the study. Two patients chose treatment by their GP, giving too small a group to be included in the analysis. There were also two protocol violators: one patient was mistakenly allocated despite a BDI score below the specified inclusion criteria, and the second patient consented to randomisation but, on allocation to GP care, displayed significant resistance and was allowed access to CBT through the trial. These patients were included in the analysis in their original randomised groups.

Baseline characteristics of patients

Demographic characteristics of the entire sample of 464 patients are shown in *Table 1*. The mean age of the participants was 36.8 years (standard deviation [SD], 12.2), and 74.8% were women. Nearly 90% of the sample described their ethnic origin as white, and 62.1% were classified as either social class II or III (non-manual). At the time of the baseline interview, nearly two-thirds of the patients reported being in either full- or part-time work. Only 16.4% of the patients reported having no educational qualifications, nearly one-third were educated to General Certificate of Secondary Education (GCSE) level or equivalent, and one-quarter reported a degree or higher-degree qualification.

TABLE 1 *Demographic characteristics of 464 patients at baseline*

Characteristic	
Age (years)	
Mean (SD)	36.8 (12.2)
Range	18–79
	n (%)
Gender	
Male	117 (25.2)
Female	347 (74.8)
Ethnicity	
White	417 (89.9)
Non-white	41 (8.8)
Missing data	6 (1.3)
OPCS classification	
Social class I	9 (1.9)
Social class II	158 (34.1)
Social class III (NM)	130 (28.0)
Social class III (M)	54 (11.6)
Social class IV	65 (14.0)
Social class V	12 (2.6)
Student	19 (4.1)
Armed forces	1 (0.2)
Housewife	10 (2.2)
Missing	6 (1.3)
Work status	
Full-time	213 (45.9)
Part-time	88 (19.0)
Housewife	36 (7.8)
Unemployed	66 (14.2)
Retired	18 (3.9)
Long-term sickness	24 (5.2)
Student	19 (4.1)
Marital status	
Single	144 (31.0)
Married/cohabiting	215 (46.3)
Widowed	14 (3.0)
Separated	33 (7.1)
Divorced	56 (12.1)
Missing data	2 (0.4)
Education	
COA or RSA	19 (4.1)
GCSE/O-level	149 (32.1)
GCSE/A-level	66 (14.2)
Degree	96 (20.7)
Higher degree	23 (5.0)
HE below degree	33 (7.1)
None of the above	76 (16.4)
Missing data	2 (0.4)

OPCS, Office of Population Censuses and Surveys; NM, non-manual; M, manual; COA, Certificate of Achievement; RSA, Royal Society of Arts; HE, higher education

Diagnoses from the clinical interview schedule were available for 435 (93.8%) of the patients (*Table 2*). For the remainder, either the patients did not complete the computerised interview or the data were lost through computer failure. Anxiety and depression were the main diagnoses in 62.3% of participants, with the remainder falling into the categories of 'no overall psychiatric diagnosis' (19.5%) or 'behavioural' difficulties (18.2%). 'Depressive symptoms' was a secondary diagnosis in 10.8% of referrals.

Treatment allocation

As shown in *Figure 1*, 42.5% of the patients were randomised between the three treatments, 29.5% chose a specific treatment, and 28.0% were randomised between the two therapies. Data on demographic factors for the different allocation methods (i.e. characteristics of patients who were fully randomised, were randomised between psychological therapies or expressed a preference) are shown in *Table 3*. There is overlap between the first and last allocation

TABLE 2 *ICD diagnoses at baseline for 435 patients*

Diagnosis type (%)	Primary diagnosis	*n* (%)	Secondary diagnosis (*n*)
No specific diagnosis (19.5%)	No psychiatric disorder	85 (19.5%)	NA
Behavioural diagnoses (18.2%)	F410 Panic disorder	9 (2.1%)	No psychiatric disorder (3) F412 Mixed anxiety and depression (6)
	F400 Agoraphobia	11 (2.5%)	No psychiatric disorder (3) F412 Mixed anxiety and depression (5) F410 Panic disorder (3)
	F401 Social phobia	16 (3.7%)	No psychiatric disorder (1) F412 Mixed anxiety and depression (11) F410 Panic disorder (3) F320 Mild depressive disorder (1)
	F402 Specific (isolated) phobia	13 (3.0%)	No psychiatric disorder (2) F412 Mixed anxiety and depression (7) F410 Panic disorder (3) F320 Mild depressive disorder (1)
	F420 Obsessive–compulsive disorder	30 (6.9%)	No psychiatric disorder (3) F412 Mixed anxiety and depression (12) F400 Agoraphobia (4) F401 Social phobia (4) F402 Specific (isolated) phobia (3) F320 Mild depressive disorder (4)
Anxiety and depression diagnoses (62.3%)	F412 Mixed anxiety and depression	102 (23.5%)	No psychiatric disorder (102)
	F320 Mild depressive disorder	28 (6.4%)	No psychiatric disorder (28)
	F321 Moderate depressive disorder	77 (17.7%)	No psychiatric disorder (50) F410 Panic disorder (8) F400 Agoraphobia (4) F401 Social phobia (5) F402 Specific (isolated) phobia (1) F420 Obsessive–compulsive disorder (9)
	F322 Severe depressive disorder	64 (14.7%)	No psychiatric disorder (20) F410 Panic disorder (2) F400 Agoraphobia (4) F401 Social phobia (9) F402 Specific (isolated) phobia (2) F420 Obsessive–compulsive disorder (27)

TABLE 3 *Demographic profiles at baseline, by allocation method and treatment group*

	R/3 (*n* = 197)			PP (*n* = 137)			R/2 + R/3 (*n* = 260)	
Treatment group	**GP**	**CBT**	**NDC**	**GP**	**CBT**	**NDC**	**CBT**	**NDC**
n	67	63	67	2	81	54	134	126
Age (years)								
Mean (SD)	37 (12.3)	36 (12.6)	39 (11.6)	44 (6.4)	38 (13.6)	39 (11.2)	35 (11.4)	33 (11.2)
Gender								
Women: *n* (%)	50 (75)	49 (78)	53 (79)	0 (0)	63 (78)	43 (80)	100 (75)	91 (72)
Men: *n* (%)	17 (25)	14 (22)	14 (21)	2 (100)	18 (22)	11 (20)	34 (25)	35 (28)
Ethnicity								
White: *n* (%)	59 (89)[a]	57 (91)	61 (92)[a]	1 (50)	77 (96)[a]	48 (89)	122 (92)[a]	110 (89)[a]
OPCS classification								
Social classes I–III (NM): *n* (%)	45 (67)	40 (66)[a]	46 (69)	1 (50)	57 (70)	35 (67)[a]	76 (58)[a]	83 (66)[a]

R/3, patients randomised between all three treatments; PP, patients expressing a specific treatment preference; R/2, patients randomised between the two psychological therapies only; OPCS, Office of Population Censuses and Surveys; NM, non-manual

[a] *There were small numbers of patients with missing data regarding ethnicity or OPCS classification (< 2%). The percentages are based on the numbers of patients for whom data were available*

categories in this table. There were no major differences between the randomised groups at baseline. More detailed comparisons of the characteristics of patients for whom different allocation methods were used are presented later in this chapter (see *Differences between randomised patients and those with treatment preferences* below).

Patient follow-up rates

The follow-up assessment rate for completion of the main outcome measure (i.e. the BDI) at 4 months was 88.9%, of which 15% were completed by post or telephone. At 12 months, the follow-up assessment rate was 80.5%, of which 25% were completed by post or telephone. When patients were unable or unwilling to complete all the follow-up scales, the BDI and economic schedule were prioritised. The exact numbers of responses available for assessing the main outcome measures are shown in *Table 4*.

Differences between randomised patients and those with treatment preferences

Because the randomisation procedure was changed during the trial, it is likely that many patients expressing a specific preference in the first part of the trial would have consented to randomisation between the two psychological therapies, had that option been initiated earlier. Equally, later in the trial, patients with specific preferences for a psychological therapy may have opted for randomisation between the two therapies in order to obtain their preferred treatment, rather than be restricted to a single assessment session. Therefore, the two groups cannot be considered absolutely distinct in terms of overall preferences. The following analysis focuses on the differences between patients who expressed any sort of preference (i.e. patients with a specific preference and those randomised between the psychological therapies) and patients who were randomised between the three therapies. Continuous variables were analysed using *t* tests, and categorical variables were compared using chi-squared tests (χ^2).

The preference option was not associated with higher rates of follow-up: at 4 months, follow-up rates for the main outcome measure were 91.4% in the fully randomised groups, 88.9% in the preference groups and 85.4% in the patients randomised between two therapies. The rates for the 12-month follow-up were 83.8%, 78.5% and 77.7%, respectively. The fully randomised patients were prioritised because of their importance to the investigators, and thus the follow-up procedures were not strictly comparable. However, the data do suggest that, if sufficient effort is expended in tracking randomised patients, then 'resentful demoralisation' does not **necessarily** lead to higher rates of attrition in randomised groups,

TABLE 4 *Data availability for 462 patients (excluding two patients choosing GP care)*

Measure	Baseline	4-month follow-up	12-month follow-up
	n **(%)**	***n*** **(%)**	***n*** **(%)**
Assessment data			
BDI	462 (100.0)	411 (88.9)	372 (80.5)
BSI	455 (98.5)	391 (84.6)	349 (75.5)
EuroQoL	457 (98.9)	389 (84.2)	351 (76.0)
CIS–R	434 (93.9)	NA	NA
SAS[a]	455 (98.5)	386 (83.6)	345 (74.7)
Patient satisfaction[b]	NA	354 (76.6)	299 (64.7)
Medical record data	For 12 months before and 12 months after GP referral to trial		
Comprehensive medical records		364 (78.8)	
Limited notes		39 (8.4)	
Access to records not granted		39 (8.4)	
No notes available		22 (4.8)	
Therapist report data	For 395 patients allocated to therapy		
Therapist returned process notes		363 (91.8)	
Session data from patient self-report		21 (5.3)	
Missing session data		11 (2.8)	

[a] *Patients complete only the SAS subscales that are relevant, thus the amount of missing data is highly variable; data were considered unavailable for patients who provided no responses*
[b] *Patients who did not attend therapy did not complete the questionnaire measuring patient satisfaction*

compared with patients who receive their choice of treatment.

Comparison of patient characteristics

Patient characteristics at baseline are shown in *Table 5*. Patients with any sort of preference were significantly less likely to be married than fully randomised patients ($p = 0.01$), scored higher on the total CIS–R and the SAS, scored lower on the EuroQoL and reported more problems on the checklist of difficulties.

Expectations of treatment at baseline

Patients were asked about what they had hoped for from their GP during the consultation at which they were referred to the study. Patients in the combined preference group were less likely to expect the GP to provide support, and they were more likely to expect the GP to prescribe sedatives and to refer them to a psychologist or counsellor (*Table 6*).

Qualitative data

Qualitative data were available from 248 of 464 (53.5%) patients. The low response rate is due in part to attrition. Additionally, some patients were not interviewed using the qualitative questionnaire because they chose to return questionnaires by post, and others only had time to complete the main outcome instruments. There were no significant differences between responders and non-responders in terms of baseline BDI or SAS scores, sex, method of allocation or treatment group. Respondents were slightly older than non-respondents (mean age, 38.0 and 35.5 years, respectively; $p < 0.05$), and far more responses were received from patients in Manchester than from those in London (75% compared with 44%).

One researcher (PB) analysed the full text of patient responses to the interview and developed a preliminary coding scheme. The applicability of the scheme was tested with a second coder (JH). Data concerning information about treatments, previous experience and limitations of the GP were coded with 90% or greater agreement, while views about the differences between therapists were coded with 70–80% agreement. *Table 7* shows the frequency of responses in each category, based on the responses with which there was full agreement.

In deciding between therapies, a significant proportion of patients made distinctions relating to the style of therapy, which may relate to the descriptions provided (see appendix 1). Some patients suggested that counsellors were less

TABLE 5 *Baseline characteristics and assessment results of randomised patients and those with a treatment preference*

	Randomised group (*n* = 197)	**Combined preference group (*n* = 267)**	***p*-value**
Age (years)			
Mean (SD)	37.5 (12.1)	36.2 (12.2)	0.24
	%	%	
Patients at each site			
London	73.6	74.7	0.79
Manchester	26.4	25.3	
Gender			
Women	77.2	73.6	0.38
Men	22.8	26.4	
Ethnicity			
White	90.8	91.6	0.77
Non-white	9.2	8.4	
OPCS classification[a]			
Social class I–III (NM)	70.8	68.5	0.60
Social class III (M)–V	29.2	31.5	
Marital status			
Married or cohabiting	54.3	41.1	0.01
Single or separated	45.7	58.9	
Education			
None, COA or RSA	20.3	20.9	0.22
GCSE/O-level	37.1	28.1	
GCSE/A-level or HE	19.3	23.2	
Degree or higher	23.4	27.8	
CIS–R primary diagnosis[b]			
No diagnosis	20.7	18.9	0.88
Anxiety/depression	60.9	63.1	
Behavioural	18.5	18.1	
	Mean (SD)	**Mean (SD)**	***p*-value**
Assessment results			
BDI score[c]	26.5 (8.6)	27.9 (8.4)	0.08
BSI score[d]	1.70 (0.68)	1.78 (0.69)	0.25
EuroQoL score[e]	0.63 (0.28)	0.58 (0.29)	0.05
SAS score[f]	2.56 (0.49)	2.65 (0.48)	0.05
CIS–R total score[g]	25.4 (10.0)	27.5 (9.1)	0.02
No. of patient problems[h]	5.5 (2.3)	6.1 (2.4)	0.00
Predicted success of treatment[i]	3.3 (1.3)	3.5 (1.2)	0.07
No. of GP consultations in previous 12 months	5.9 (4.4)	5.6 (3.9)	0.44

OPCS, Office of Population Censuses and Surveys; NM, non-manual; M, manual; COA, Certificate of Achievement; RSA, Royal Society of Arts; HE, higher education

[a] *Students, housewives and members of armed forces were excluded* (n = *428)*

[b] *Three categories were derived from ten diagnoses; behavioural category includes obsessive–compulsive disorder and phobic disorders* (n = *435)*

[c] *Range, 0–63 (score of 0–3 on each of 21 items; high scores indicate dysfunction)*

[d] *Range, 0–4 (average response per item; high scores indicate dysfunction)*

[e] *Range, 1.0 (optimal health) to –0.594 (low scores indicate dysfunction)*

[f] *Range, 1–5 (average response per item; high scores indicate dysfunction)*

[g] *Range, 0–57 (scores of 0–5 on one item and 0–4 on 13 items; high scores indicate dysfunction)*

[h] *Patient self-report regarding 13 common problems and two 'other' categories* (n = *457)*

[i] *Rating of 0–6 per problem (averaged over the total number of problems reported; high scores predict success of treatment* (n = *457)*

TABLE 6 *Patients' expectations of treatment, by allocation method (n = 457)*

Patient report of what they had hoped for during the consultation at which they were referred to the trial	Randomised group (%)	Preference group (%)	*p*-value
GP listen and advise	57.1	45.6	0.02
GP examine and treat physical symptoms	27.6	20.7	0.08
GP arrange tests	11.7	12.6	0.77
GP prescribe medication to calm patient	15.3	23.8	0.03
GP prescribe medication to help sleep	12.8	14.6	0.58
GP prescribe medication for depression	21.9	19.2	0.47
GP refer to counsellor	34.7	48.7	0.00
GP refer to psychologist	13.3	36.0	0.00
GP refer to psychiatrist	8.2	11.1	0.30
GP refer to other	5.1	6.9	0.43
GP write letter to other	4.6	3.4	0.53
Patient did not know	15.3	11.9	0.29
Patient had no preference	4.6	3.1	0.39

TABLE 7 *Frequency of patients' qualitative responses concerning treatment preferences (n = 248)*

Category of responses	%
Concerning type of information received about which allocation to choose	
Advice from professionals	4.4
Advice from friends and relations	3.6
Information from study sources (e.g. information sheets)	2.0
Concerning other sources of information (e.g. magazine articles)	0.8
Concerning previous experience of treatment	
GP	6.1
Therapy[a]	9.7
Concerning perceived limitations of GP	
Lack of training and expertise	3.2
Lack of time available	8.5
Negative attitudes about medication	8.1
Concerning differences between therapies	
Training and expertise of therapists	3.6
Type of problem (e.g. severity, diagnosis and depth)[b]	12.5
Preference for directive approach as opposed to non-directive approach	11.3
Preference for non-directive approach as opposed to directive approach[c]	5.2
Other responses	
No preference	17.8
Do not know or cannot remember	5.2

[a] *Includes any direct experience of therapy, therapists or approach (e.g. courses)*

[b] *Includes either the type of problem that patients were experiencing or the type of problems for which therapists were seen as appropriate*

[c] *A number of patients' responses concerned 'wanting to talk' or similar responses, which potentially reflected a non-directive approach but could relate to either therapy; these responses were not coded here unless they specifically distinguished between non-directive and directive approaches*

useful because of their non-directive stance and that direction, practical advice and teaching of skills were viewed positively. For example:

- "Didn't want a counsellor – to sit and listen and in doing so guide me to working it out. Needed to be given more direction since I'd dissected it a lot before and hadn't managed to solve it."
- "...with counselling, I knew what my problems were and I needed help in dealing with them, not having someone say 'Yes, I understand'."

Other patients perceived that the non-directive stance was exactly what was required. For example:

- "Needed emotional exploration…CBT too superficial."

As well as viewing psychologists as generally more qualified, some patients also seemed to accept a lay 'model' of therapy that construed counsellors as offering a less specialised form of help, with psychologists seen as more appropriate for a certain type of problem. This perception could relate positively or negatively to preferences. For example:

- "Thought I was a total lost cause and thought I'd go to the top – psychology appeared to be a bit more, the next one up the ladder is a psychiatrist, counsellor [is] more of a friend really."
- "Need for something removed from problem, someone to talk to and because I was feeling bad anyway, and didn't want to feel it was any more serious. Psychology I looked on as a step further than counselling."
- "Terrified of seeing a psychologist – it relates to 'Oh my God, you're mad!'."

Finally, there were some expectations about psychological therapy that seemed to be based on misconceptions, especially the relationship between CBT and traditional 'depth' psychotherapy. For example:

- "Didn't want psychoanalysis, which is what I thought the psychologist would give me..."
- "Psychologist because they would deal with my childhood problems more."
- "Generally think that psychologists might have got to the core of it, the problem with counsellors is they only deal with now. Thought my problems went back a long way."

Process of psychological therapy

Data on the number of protocol therapy sessions are given in *Tables 8* and *9*. Of the 395 patients allocated to therapy, 362 had at least one session with the therapist. In 22 cases (6%), the patients could not be matched to a particular therapist because of a lack of identifying information or therapist failure to return forms. The number of patients seen by individual therapists ranged from 1 to 65. Three London therapists were responsible for 176 of the 340 identified treatments (51.8%). *Table 8* shows the number of sessions provided by each type of psychological therapist. Between 1% and 14% of patients in each group did not attend any treatment sessions, while a further 2–10% attended only a single session. When no data were available, the relevant values were imputed using the means from the relevant group (CBT or NDC) and site (London or Manchester).

Table 9 specifies the mean number of sessions (and SD), broken down by site and various

TABLE 8 *Number and proportion of patients attending a specific number of treatment sessions, by allocation method and therapy type*

Allocation method and treatment	No. of sessions attended			
	0	1	2–6	7 or more
	n (%)	*n* (%)	*n* (%)	*n* (%)
R/3 CBT	9 (14.3)	3 (4.8)	32 (50.8)	19 (30.2)
R/3 NDC	7 (10.4)	3 (4.5)	25 (37.3)	32 (47.8)
R/2 CBT	1 (1.4)	5 (7.0)	26 (36.6)	39 (54.9)
R/2 NDC	3 (5.1)	1 (1.7)	13 (22.0)	42 (71.2)
PP CBT	7 (8.6)	8 (9.9)	34 (42.0)	32 (39.5)
PP NDC	6 (11.1)	2 (3.7)	12 (22.2)	34 (63.0)

R/3, patients randomised between all three treatments; R/2, patients randomised between the two psychological therapies only; PP, patients expressing a specific treatment preference

TABLE 9 *Number of CBT and NDC treatment sessions, by site and allocation method*

Allocation method	Sessions/non-attendance	CBT group		NDC group	
		Mean (SD)	*n*	Mean (SD)	*n*
Both sites combined					
All types of allocation (*n* = 395)	Sessions only	5.6 (3.5)	215	7.1 (4.1)	180
	Sessions plus non-attendance	7.0 (3.6)	215	8.3 (3.9)	180
R/3 only (*n* = 130)	Sessions only	5.0 (3.5)	63	6.4 (4.2)	67
	Sessions plus non-attendance	6.3 (3.5)	63	7.4 (4.1)	67
R/2 only (*n* = 130)	Sessions only	6.4 (3.2)	71	8.0 (3.9)	59
	Sessions plus non-attendance	7.8 (3.2)	71	9.3 (3.7)	59
PP only (*n* = 135)	Sessions only	5.4 (3.7)	81	7.0 (4.0)	54
	Sessions plus non-attendance	6.8 (4.0)	81	8.2 (3.7)	54
London					
All types of allocation (*n* = 294)	Sessions only	6.1 (3.6)	155	7.7 (4.0)	139
	Sessions plus non-attendance	7.5 (3.6)	155	8.9 (3.7)	139
R/3 only (*n* = 96)	Sessions only	5.3 (3.5)	48	7.1 (4.0)	48
	Sessions plus non-attendance	6.5 (3.5)	48	8.1 (3.8)	48
R/2 only (*n* = 114)	Sessions only	6.8 (3.2)	59	8.1 (3.8)	55
	Sessions plus non-attendance	8.2 (3.3)	59	9.4 (3.5)	55
PP only (*n* = 84)	Sessions only	6.1 (3.9)	48	7.9 (4.0)	36
	Sessions plus non-attendance	7.7 (4.1)	48	9.1 (3.7)	36
Manchester					
All types of allocation (*n* = 101)	Sessions only	4.4 (3.1)	60	5.2 (4.0)	41
	Sessions plus non-attendance	5.6 (3.1)	60	6.3 (4.1)	41
R/3 only (*n* = 34)	Sessions only	4.1 (3.4)	15	4.8 (4.4)	19
	Sessions plus non-attendance	5.6 (3.5)	15	5.6 (4.5)	19
R/2 only (*n* = 16)	Sessions only	4.5 (2.2)	12	6.0 (5.0)	4
	Sessions plus non-attendance	5.8 (1.8)	12	8.3 (6.2)	4
PP only (*n* = 51)	Sessions only	4.5 (3.3)	33	5.4 (3.4)	18
	Sessions plus non-attendance	5.5 (3.4)	33	6.6 (3.2)	18

R/3, patients randomised between all three treatments; R/2, patients randomised between the two psychological therapies only; PP, patients expressing a specific treatment preference

combinations of the allocation procedures. As can be seen from the table, treatment durations were generally longer in London for both therapies, while NDC was provided over a greater number of sessions, compared with CBT. This pattern is found in most of the comparisons shown in *Table 9*.

Integrity of psychological therapies

The CTRS provided both a measure of the adequacy of CBT and a check on significant use of cognitive techniques by counsellors.[99] Because of problems with patient consent and equipment malfunction, only 18 therapists (72%) provided useable session recordings. Two sessions were used for quality control for each therapist, with the sessions chosen randomly if more than two useable sessions were available. Based on the scoring performed by an independent psychologist, who was experienced in the use of the rating scale, all the CBT sessions but none of the counselling sessions were above the predetermined cut-off (39) indicative of adequate cognitive therapy. It was not always certain that the scorer was blind to the type of therapist

recorded, because on occasion therapists might refer to themselves as a counsellor or psychologist. There was no check on the reliability of the CTRS ratings, although previous studies suggest that the scale has satisfactory reliability.[103,104] There were no significant differences in the scores from the two trial sites (*Table 10*). Two recorded samples of NDC, provided by two different therapists, were rated as atypical, but not to the extent that the therapy could be considered CBT.

Termination of psychological therapy

The therapists were asked to record the reasons for the termination of protocol therapy. The results are shown in *Table 11*. Counsellors most often gave the reason as 'end of specified time', which is reflected in the fact that counselling treatments generally involved more sessions. In contrast, psychologists most often reported 'agreement between patient and therapist'. Counsellors were also more likely to suggest further referrals.

TABLE 10 *CTRS scores, by therapy type and site*

Treatment group	Manchester (*n* = 22)			London (*n* = 14)			Overall (*n* = 36)		Sessions with CTRS score ≥ 39 (%)
	n	Mean (SD)	Range	*n*	Mean (SD)	Range	*n*	Mean (SD)	Range
CBT	12	52.4 (7.1)	41–61	6	50.5 (8.3)	39–63	18	51.8 (7.3)	39–63	100
NDC	10	28.4 (3.2)	23–33	8	28.0 (5.4)	21–35	18	28.2 (4.1)	21–35	0

TABLE 11 *Frequency of reported reasons for termination of therapy for patients who attended at least one session, by allocation method and treatment group*

	R/3 CBT	R/3 NDC	R/2 CBT	R/2 NDC	PP CBT	PP NDC
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Patients referred for therapy	63	67	71	59	81	54
Patients who attended therapy	54	60	70	56	74	48
Reported reason for termination						
Client's request	5 (9.3)	5 (8.3)	1 (1.4)	6 (10.7)	4 (5.4)	3 (6.3)
End of specified time	5 (9.3)	24 (40.0)	15 (21.4)	26 (46.4)	12 (16.2)	25 (52.1)
Client failed to attend	9 (16.7)	9 (15.0)	14 (20.0)	7 (12.5)	14 (18.9)	6 (12.5)
Agreement between therapist and client	23 (42.6)	23 (38.3)	24 (34.3)	15 (26.8)	33 (44.6)	15 (31.3)
Therapist decision	1 (1.9)	0 (0.0)	5 (7.1)	1 (1.8)	2 (2.7)	0 (0.0)
Further referral suggested	0 (0.0)	5 (8.3)	4 (5.7)	8 (14.3)	1 (1.4)	5 (10.4)
Other	7 (13.0)	2 (3.3)	3 (4.3)	2 (3.6)	4 (5.4)	0 (0.0)

R/3, patients randomised between all three treatments; R/2, patients randomised between the two psychological therapies only; PP, patients expressing a specific treatment preference

Chapter 4

Clinical outcome results

Analysis methods

The allocation procedure produced three groups of patients:

- patients fully randomised between three treatments (R/3)
- patients randomised between the two psychological therapies (R/2)
- patients who expressed a specific preference for treatment (PP).

The main analysis concerned the patients randomised between three treatments. The patients randomised between the two psychological therapies would also provide an unbiased assessment of outcome in these treatments. Therefore, these patients were combined with patients fully randomised to the three treatments, for tests comparing the two therapies only, in order to increase the sample size available for the comparison.

Data were analysed using SPSS for Windows and SPSS PC+. The analysis was performed on an intention-to-treat basis, with last observation carried forward (LOCF) used as a conservative estimate of outcome when data were missing at either follow-up point. However, numbers of patients and mean or median scores without LOCF are presented for the purposes of comparison. When data were not normally distributed (e.g. BSI), square roots were used to normalise them. General linear modelling (repeated measures procedure) was used, with between-subjects factors randomised group (three levels) and site (two levels, Manchester and London) and within-subjects factor time (three levels). *A priori* within-subjects contrasts were defined using the repeated contrast to compare adjacent time-points, in this case baseline versus 4 months and 4 months versus 12 months. An alternative strategy would have been to use general linear modelling (repeated measures procedure) with two levels for time (4 and 12 months), while covarying for BDI score at baseline as a constant covariate. However, the former approach more clearly reflects the clinical questions involved, namely, are there group differences in the main outcome between baseline and 4 months and between 4 and 12 months?

Power calculation

A prestudy power calculation indicated that the inclusion of 65 patients in each group would allow detection of a difference in outcome between the groups of 3.5 (SD, 8) for the BDI score, at 90% power and a 5% level of significance.

Analysis of clinical outcome

Patients fully randomised between three treatments

In our between-subjects comparison on the BDI, there was no main effect for treatment group ($F = 1.41$; degrees of freedom [df] = 2, 191; $p = 0.25$) (*Table 12*). There was no time-by-site interaction. We found a significant main effect for time (Wilks $\lambda = 0.411$; $F = 135.90$; df = 2, 190; $p = 0.000$) and for the time-by-group interaction (Wilks $\lambda = 0.923$; $F = 3.874$; df = 4, 380; $p = 0.004$). There were significant within-subjects contrasts for the time-by-group interaction between baseline and 4 months ($F = 4.91$; df = 2, 191; $p = 0.008$) and between 4 and 12 months ($F = 5.29$; df = 2, 191; $p = 0.006$). This difference means that the groups changed at different rates between each time-point, with both psychological therapy groups improving more than the GP group between baseline and 4 months, while the GP group made more change between 4 and 12 months.

In summary, both psychological therapy groups improved significantly more rapidly than the GP group in the first 4 months; however, in the following 8 months, the GP group made up the difference. In our secondary outcomes, there was a trend in the same direction for the BSI. Additionally, at 12 months, patients in the usual GP care and CBT groups had made significantly greater gains on the SAS than those receiving NDC ($p = 0.048$).

Patients randomised between two psychological therapies

All patients who were randomised to either psychological therapy group, using either

randomised allocation method, were combined in this analysis. There were no significant differences in clinical outcomes at either follow-up (*Table 13*).

Patient preference groups

Very similar outcomes were found for patients who chose either psychological therapy arm (*Table 14*). Again, there were no significant differences between the two arms at 4 or 12 months. There were also no significant differences in BDI scores at either outcome point between participants who were randomised and those who chose either type of psychological therapy.

Satisfaction outcome

Data on patient satisfaction with treatment are shown in *Table 15*. Statistical comparisons used one-way analysis of variance (ANOVA) and *t* tests, with data restricted to those patients returning satisfaction questionnaires after sessions with the relevant therapist. In the main comparison of the patients randomised between three treatments, satisfaction differed significantly between the three groups at 4- and 12-month follow-ups. *Post hoc* tests (using the conservative Scheffe criterion) showed that satisfaction was lower in the usual GP care group than in either of the two psychological therapy groups at

TABLE 12 *Numbers of patients participating and scores on main outcome measures in patients randomised between the three treatment groups*

Outcome measure	CBT group			NDC group			GP group		
	n[a]	Actual[b]	LOCF[c]	*n*	Actual	LOCF	*n*	Actual	LOCF
BDI[d]									
Mean (SD)									
Baseline	63	27.6 (8.4)	27.6 (8.4)	67	25.4 (8.6)	25.4 (8.6)	67	26.5 (8.9)	26.5 (8.9)
4 months	56	12.7 (9.5)	14.3 (10.8)	62	11.5 (7.7)	12.9 (9.3)	62	17.2 (11.9)	18.3 (12.4)
12 months	50	9.3 (8.8)	11.4 (10.8)	58	11.1 (9.3)	11.8 (9.6)	57	10.2 (8.5)	12.1 (10.3)
BSI[e] ***general severity index***									
Median									
Baseline	62	1.73	1.73	67	1.62	1.62	67	1.55	1.55
4 months	51	0.59	0.86	62	0.69	0.74	56	0.71	0.94
12 months	46	0.45	0.54	56	0.68	0.68	53	0.53	0.57
SAS[f]									
Mean (SD)									
Baseline	62	2.63 (0.47)	2.63 (0.47)	67	2.50 (0.42)	2.50 (0.42)	67	2.54 (0.57)	2.54 (0.57)
4 months	49	2.20 (0.54)	2.25 (0.56)	61	2.15 (0.47)	2.20 (0.51)	54	2.22 (0.65)	2.31 (0.65)
12 months	45	1.98 (0.50)	2.06 (0.55)	55	2.10 (0.51)	2.13 (0.54)	54	1.98 (0.55)	2.05 (0.61)
EuroQoL[g]									
Median									
Baseline	62	0.73	0.73	67	0.73	0.73	67	0.73	0.73
4 months	50	0.85	0.81	62	0.85	0.85	57	0.81	0.80
12 months	47	0.85	0.85	57	0.85	0.85	54	0.85	0.81

[a] *Number of patients with full actual data available*
[b] *Data from patients with full actual data available*
[c] *Data with last observation carried forward*
[d] *Range, 0–63 (score of 0–3 on each of 21 items; high scores indicate dysfunction)*
[e] *Range, 0–4 (average response per item; high scores indicate dysfunction)*
[f] *Range, 1–5 (average response per item; high scores indicate dysfunction)*
[g] *Range, 1.0 (optimal health) to –0.594 (low scores indicate dysfunction)*

Analysis of LOCF data:
BDI: Baseline to first follow-up (therapy groups compared with usual GP care group), F = *4.91, df = 2,* p = *0.008*
BDI: Between first and final follow-up (therapy groups compared with usual GP care group), F = *5.29, df = 2,* p = *0.006*
BSI: Baseline to first follow-up (therapy groups compared with usual GP care group), F = *2.77, df = 2,* p = *0.065*
SAS: Between first and final follow-up (CBT and usual GP care groups compared with NDC group), F = *3.08, df = 2,* p = *0.048*

TABLE 13 *Numbers of patients participating and scores on main outcome measures in patients randomised between the two psychological therapies*

Outcome measure	CBT group			NDC group		
	n[a]	Actual[b]	LOCF[c]	*n*	Actual	LOCF
BDI[d]						
Mean (SD)						
Baseline	134	27.6 (7.9)	27.6 (7.9)	126	27.6 (9.0)	27.6 (9.0)
4 months	117	12.5 (10.0)	14.7 (11.8)	112	12.3 (8.5)	14.2 (10.1)
12 months	107	9.9 (10.2)	12.5 (12.1)	102	11.2 (9.1)	12.8 (9.9)
BSI[e] ***general severity index***						
Median						
Baseline	130	1.76	1.75	124	1.68	1.68
4 months	108	0.58	0.80	107	0.77	0.89
12 months	99	0.45	0.60	96	0.67	0.79
SAS[f]						
Mean (SD)						
Baseline	132	2.63 (0.51)	2.63 (0.51)	123	2.59 (0.44)	2.59 (0.44)
4 months	108	2.14 (0.54)	2.24 (0.60)	105	2.20 (0.46)	2.28 (0.49)
12 months	96	1.96 (0.50)	2.12 (0.61)	94	2.12 (0.52)	2.19 (0.53)
EuroQoL[g]						
Median						
Baseline	132	0.69	0.69	124	0.69	0.69
4 months	108	0.83	0.81	106	0.85	0.83
12 months	99	0.85	0.85	96	0.85	0.85

[a] *Number of patients with full actual data available*
[b] *Data from patients with full actual data available*
[c] *Data with last observation carried forward*
[d] *Range, 0–63 (score of 0–3 on each of 21 items; high scores indicate dysfunction)*
[e] *Range, 0–4 (average response per item; high scores indicate dysfunction)*
[f] *Range, 1–5 (average response per item; high scores indicate dysfunction)*
[g] *Range, 1.0 (optimal health) to –0.594 (low scores indicate dysfunction)*

4 months ($p = 0.001$). However, at 4 months, there was no significant difference between either psychological therapy group; at 12 months, the difference was significant between NDC and GP care only ($p = 0.03$) (*Table 15*). When satisfaction with psychological therapies was compared in patients allocated by either randomised method, there were no significant differences in satisfaction. When patients with a specific preference for an individual psychological therapy were compared at 12 months, patients choosing NDC were significantly more satisfied than those choosing CBT ($p = 0.01$). Finally, when all patients expressing a preference (either specific preference or randomisation between psychological therapies) were compared with patients randomised between three treatments, there were no significant differences in satisfaction.

TABLE 14 *Numbers of patients participating and scores on main outcome measures in patients allocated to their preferred therapy*

Outcome measure	CBT group			NDC group		
	n[a]	Actual[b]	LOCF[c]	*n*	Actual	LOCF
BDI[d]						
Mean (SD)						
Baseline	81	26.9 (9.2)	26.8 (9.2)	54	27.4 (7.4)	27.4 (7.4)
4 months	68	13.0 (10.2)	15.0 (11.1)	52	14.0 (9.1)	14.3 (9.1)
12 months	66	10.7 (8.1)	13.3 (10.7)	40	12.3 (9.6)	14.4 (9.9)
BSI[e] ***general severity index***						
Median						
Baseline	81	1.53	1.53	53	1.64	1.63
4 months	68	0.62	0.79	52	0.87	0.87
12 months	64	0.48	0.57	37	0.68	0.81
SAS[f]						
Mean (SD)						
Baseline	81	2.63 (0.49)	2.63 (0.49)	52	2.64 (0.44)	2.64 (0.44)
4 months	68	2.17 (0.52)	2.26 (0.56)	51	2.22 (0.48)	2.24 (0.48)
12 months	63	2.05 (0.48)	2.17 (0.56)	38	2.08 (0.43)	2.23 (0.51)
EuroQoL[g]						
Median						
Baseline	81	0.69	0.69	53	0.73	0.73
4 months	68	0.81	0.80	50	0.83	0.83
12 months	63	0.85	0.85	39	0.85	0.83

[a] *Number of patients with full actual data available*
[b] *Data from patients with full actual data available*
[c] *Data with last observation carried forward*
[d] *Range, 0–63 (score of 0–3 on each of 21 items; high scores indicate dysfunction)*
[e] *Range, 0–4 (average response per item; high scores indicate dysfunction)*
[f] *Range, 1–5 (average response per item; high scores indicate dysfunction)*
[g] *Range, 1.0 (optimal health) to –0.594 (low scores indicate dysfunction)*

TABLE 15 *Patient satisfaction outcomes for various groupings of allocation method and treatment*

Follow-up	Group 1			Group 2			Group 3		
	Allocation and treatment	*n*	Mean (SD)	Allocation and treatment	*n*	Mean (SD)	Allocation and treatment	*n*	Mean (SD)
4 months[a]	R/3 GP	43	3.27 (0.56)	R/3 CBT	44	3.71(0.82)	R/3 NDC	57	3.93 (0.57)
12 months[b]	R/3 GP	41	3.40 (0.71)	R/3 CBT	36	3.75 (0.74)	R/3 NDC	50	3.79 (0.76)
4 months	R/2 + R/3 CBT	101	3.75 (0.73)	R/2 + R/3 NDC	101	3.90 (0.59)			
12 months	R/2 + R/3 CBT	85	3.64 (0.81)	R/2 + R/3 NDC	85	3.80 (0.70)			
4 months	PP CBT	60	3.64 (0.72)	PP NDC	47	3.88 (0.71)			
12 months[c]	PP CBT	55	3.62 (0.75)	PP NDC	32	4.00 (0.55)			
4 months	R/3 GP + CBT + NDC	144	3.67 (0.70)	R/2 + PP CBT + NDC	208	3.78 (0.68)			
12 months	R/3 GP + CBT + NDC	127	3.65 (0.75)	R/2 + PP CBT + NDC	171	3.71 (0.73)			

R/3, patients randomised between all three treatments; R/2, patients randomised between the two psychological therapies only; PP, patients expressing a specific treatment preference

Range, 1–5 (average response per item; high scores indicate satisfaction)

Analysis:
[a] $F = 12.46$, $df = 2$, $p = 0.001$ (post hoc *Scheffe test, GP < NDC and CBT)*
[b] $F = 3.66$, $df = 2$, $p = 0.03$ (post hoc *Scheffe test, GP < NDC)*
[c] $t = 2.52$, $df = 85$, $p = 0.01$

Chapter 5

Economic outcome results

Analysis methods

The economic analysis was designed as a cost-effectiveness study, using the BDI as the main outcome measure and the EuroQoL[93] as a secondary outcome measure. A societal perspective was taken for the calculation of costs, which included direct treatment costs, direct non-treatment costs and indirect costs of lost production.

Costs

Direct treatment costs included all contacts with primary and secondary healthcare services, psychotropic medication and private sector health services. Details of healthcare utilisation were collected from two sources. The patients' general practice medical records were searched for the 12 months before and after referral, in order to collect information on consultations with the GP and other members of the primary healthcare team, certificated sickness absence, hospital referrals and investigations, and prescribed psychotropic medication. Details were also gathered from the patients' self-reports at baseline and at 4- and 12-month follow-ups, and included visits to health professionals, hospital referrals (both inpatient and outpatient care) and prescribed medication. Data from both sources were entered for use in the analysis. Two psychologists (PB and EW) and a GP (MG) collected medical record data. No formal test of the reliability of the data extraction was undertaken.

Direct non-treatment costs included child care and travel costs for visits to both primary and secondary care. Only four patients reported payment for child care, and thus these costs were ignored for the purposes of the analysis. Although information on travel to secondary care was sought, data were not reported by a significant number of patients who nevertheless had such specialist visits recorded in the medical notes. For this reason, these costs were ignored, and the travel costs included only visits to primary care professionals and protocol psychological therapy sessions.

Indirect costs (i.e. lost productivity costs) were calculated on the basis of information gathered by face-to-face or postal interview at baseline and at 4- and 12-month follow-up interviews. Data collected included employment status, weeks worked, current wage rate and/or benefits received, and an estimate of time lost from work through illness (both in general and specific to the problem for which they were referred).

Unit costs were determined for the financial year 1997–98 and came from a variety of sources, including the Personal Social Services Research Unit database,[105] the Chartered Institute of Public Finance and Accountancy database,[106] and the British National Formulary.[107] Travel costs were based on either self-reported costs of bus or train fares or mileage (with a unit cost of £0.335 per mile, according to the Automobile Association guidelines). The cost of time off work was based on self-reported annual, monthly or weekly pay before tax.

Data

Full medical record searches were available for 364 patients (78.4%), a combination of incomplete notes (e.g. computerised prescribing record only and incomplete temporary patient notes) and self-report were used for 39 patients (8.4%), and patient self-report was the only form of data available for 61 patients (13.1%). Missing data for GP and practice nurse consultations, wages, time off work and primary care travel were imputed using the mean from the relevant group (GP, CBT and NDC) and site (London and Manchester). Missing prescribing and referral data were not imputed. Partial data (e.g. patient's report of antidepressant use without specific details and missing hospital information) were completed on the basis of a number of decision rules (e.g. clinical judgement regarding commonly prescribed dosages for drugs).

Statistical techniques

There was no specific power calculation for the cost component of the trial; sample size was based on expected clinical outcomes on the BDI. All clinical and economic analyses were carried out on an intention-to-treat basis. Although costs were not normally distributed,

analyses compared the mean costs in two groups by using standard *t* test and ANOVA methods, with the validity of results confirmed using bootstrapping.[108] Bootstrap methods are 'distribution-free' in that they make no assumptions about the distribution of statistics of interest. Instead, the original data are used to provide an empirical estimate of the sampling distribution, through repeated resampling from the observed data.[109] Such an approach allows inferences to be made about the arithmetic mean,[110] unlike logarithmic transformation or conventional non-parametric tests. The primary analysis was of total costs, but individual resource use components (e.g. primary care and protocol psychological therapy) are detailed. The primary analysis involved costs in the 12 months post-baseline, but results were also adjusted for the total cost of care in the 12 months prior to study entry, using multiple regression. Sensitivity analyses were carried out to assess the robustness of results in relation to assumptions made in the costing procedure. Discounting was unnecessary because neither costs nor benefits were recorded beyond 12 months.

Analysis of economic outcome

Review of clinical outcome

In the main analysis of the 197 randomised patients, the patients in all three treatment arms improved, but the patients in both psychological therapy groups made significantly greater clinical gains in the first 4 months following allocation. However, all groups had equivalent outcomes at 12 months. Therefore, a cost-effectiveness analysis was appropriate at 4 months, and a cost-minimisation analysis at 12 months. There were no differences between the three groups in quality of life outcome measured by the EuroQoL. At 4 months, the patients in either psychological therapy group were more satisfied with treatment than the patients treated with usual GP care; however, at 12 months, only patients receiving NDC were significantly more satisfied than patients receiving usual GP care.

Costs

Table 16 details the use of resources over 12 months by the 197 patients randomised between three treatments, together with the source of unit costs. Patients under the care of the GP recorded more consultations, antidepressant medication and psychiatric referrals in the year after recruitment to the study. *Table 17* details the lost productivity (indirect costs) in each group.

Tables 18 and *19* detail the total societal costs in each group for the 4- and 12-month periods, respectively, together with the costs broken down by type (direct versus indirect, and specific source of the costs).

At 4 months (*Table 18*), no significant difference was found between the randomised groups in total societal costs (ANOVA significance, $p = 0.60$), total direct care costs ($p = 0.83$) or total indirect costs ($p = 0.68$). In no cases did these results differ when adjusted for pre-baseline costs.

Equally, at 12 months (*Table 19*), no significant difference was found between the randomised groups in total societal costs (ANOVA significance, $p = 0.63$), total direct care costs ($p = 0.89$) or total indirect costs ($p = 0.68$). Again, in no cases did these results differ when adjusted for pre-baseline costs.

Detailed conventional and bootstrap *t* test results are detailed in *Tables 20, 21* and *22* for direct, indirect and societal costs, respectively. In no case did the bootstrap results suggest that the use of the *t* test was invalid.

Cost-effectiveness analysis

As there was no difference in costs between the three treatment arms, the superior clinical outcomes on the BDI in the psychological therapy groups suggest that these treatments are the most cost-effective at 4 months. At 12 months, there was no difference between the three treatments in terms of outcomes (based on the BDI and EuroQoL) or total costs, thus it is not possible to conclude that either NDC or CBT is relatively more cost-effective than GP care in the long term.

Sensitivity analyses

A number of sensitivity analyses were carried out to test assumptions made in the main analysis and to improve the generalisability of the results (*Table 23*). None of these analyses altered the main conclusions of the study.

Cost per session

To evaluate the influence of the cost of counsellors and psychologists, a threshold analysis was conducted in order to determine the cost per session that would make the psychological therapy options more or less

TABLE 16 *Resource use per patient during the 12 months after entry into the trial*

Service	Use of resources per patient during 1 year (*n* = 197) Mean (SD) or proportion			Source of unit cost
	GP group	CBT group	NDC group	
Primary care services				
GP surgery contacts	9.12 (5.10)	6.48 (4.60)	7.71 (6.60)	PSSRU
GP appointments not attended	0.29 (0.66)	0.26 (0.55)	0.34 (0.81)	PSSRU
GP out-of-hours contacts	0.02 (0.12)	0.03 (0.13)	0.02 (0.06)	PSSRU
GP cooperative use	0.16 (1.10)	0.07 (0.25)	0.07 (0.30)	PSSRU
GP home visits	0.05 (0.27)	0.03 (0.18)	0.04 (0.27)	PSSRU
PN contacts	0.53 (1.10)	0.69 (0.95)	0.41 (0.68)	PSSRU
PN appointments not attended	0.02 (0.12)	0.03 (0.18)	0.002 (0.010)	PSSRU
Protocol therapy				
Sessions attended	NA	4.97 (3.50)	6.44 (4.20)	Trial service costs
Sessions not attended	NA	1.36 (1.50)	0.97 (1.10)	Trial service costs
Medication				
Antidepressants	49.3%	27.0%	29.9%	BNF
Minor tranquillisers	17.9%	6.3%	14.9%	BNF
Beta blockers	4.5%	7.9%	3.0%	BNF
Major tranquillisers	0.0%	0.0%	1.5%	BNF
Specialist services				
Mental health referrals (including primary care-based therapy)	0.52 (0.88)	0.22 (0.52)	0.25 (0.59)	CIPFA for secondary services, trial service costs for primary care[a]
Non-psychiatric referrals	0.93 (1.28)	0.92 (1.26)	0.93 (1.13)	CIPFA

PN, practice nurse; PSSRU, Personal Social Services Research Unit;[105] *BNF, British National Formulary;*[107] *CIPFA, Chartered Institute of Public Finance and Accountancy*[106]

[a] *In one case, a London trial therapist was provided free of charge by a local trust, but a cost equal to the average cost in London was applied*

TABLE 17 *Lost productivity: indirect costs per patient*

	GP group	CBT group	NDC group
	Mean (SD)	Mean (SD)	Mean (SD)
At 4 months			
Average weekly wage: full-time (£)	293.6 (166.9)	306.6 (131.3)	391.2 (236.0)
Average weekly wage: part-time (£)	114.9 (79.4)	123.8 (85.9)	112.4 (72.6)
Time off work (days)	14.2 (19.9)	10.5 (17.1)	15.1 (24.7)
At 12 months			
Average weekly wage: full-time (£)	302.4 (150.4)	327.2 (173.5)	383.0 (252.5)
Average weekly wage: part-time (£)	86.7 (34.2)	151.0 (96.2)	96.2 (56.9)
Time off work (days)	13.8 (27.4)	11.0 (22.6)	15.5 (37.2)

cost-effective than GP care at the 12-month follow-up. When the session costs of both psychological therapies were set to zero, these therapies were still not significantly less expensive than usual GP care, and thus their relative cost-effectiveness was unchanged. CBT would have to cost £149 per session in order for that option to be significantly more expensive than usual GP care in terms of societal costs, and £66 per session for CBT to be significantly more expensive than GP care in terms of direct costs. The figures for NDC were £105 and £52, respectively. The mean costs per

TABLE 18 *Total costs per patient over 4 months, by cost sector*

Cost sector	GP group		CBT group		NDC group	
	Mean (SD) (£)	Proportion of total societal costs (%)	Mean (SD) (£)	Proportion of total societal costs (%)	Mean (SD) (£)	Proportion of total societal costs (%)
Primary care	64.5 (73.0)	10.3	39.5 (27.4)	7.9	37.7 (26.2)	5.4
Medication	13.1 (26.9)	2.1	5.2 (16.5)	1.0	6.6 (18.3)	1.0
Outpatient services	98.1 (237.8)	15.6	32.1 (66.9)	6.4	23.9 (51.6)	3.4
Inpatient services	65.6 (372.5)	10.5	1.8 (14.5)	0.4	39.3 (297.6)	5.6
Protocol therapy	0.0 (0.0)	0.0	133.3 (71.8)	26.6	143.5 (72.0)	20.4
Travel	2.6 (4.5)	0.4	3.5 (5.9)	0.7	6.5 (9.6)	0.9
Total direct costs	**244.0 (597.5)**	**38.9**	**215.5 (108.6)**	**43.0**	**257.5 (356.7)**	**36.7**
Total indirect costs	**383.7 (1194.3)**	**61.1**	**286.1 (701.3)**	**57.0**	**444.4 (1127.2)**	**63.3**
Total societal costs	**627.7 (1359.8)**	**100.0**	**501.6 (715.3)**	**100.0**	**701.9 (1228.4)**	**100.0**

TABLE 19 *Total costs per patient over 12 months, by cost sector*

Cost sector	GP group		CBT group		NDC group	
	Mean (SD) (£)	Proportion of total societal costs (%)	Mean (SD) (£)	Proportion of total societal costs (%)	Mean (SD) (£)	Proportion of total societal costs (%)
Primary care	118.5 (93.7)	9.7	86.6 (59.7)	8.2	98.4 (84.5)	7.0
Medication	40.7 (77.8)	3.3	12.2 (37.5)	1.2	24.1 (54.2)	1.7
Outpatient services	201.2 (344.9)	16.5	105.9 (251.9)	10.0	90.3 (175.8)	6.5
Inpatient services	107.6 (425.1)	8.8	74.2 (381.8)	7.0	106.6 (428.6)	7.6
Protocol therapy	0.0 (0.0)	0.0	164.3 (104.1)	15.5	171.2 (97.1)	12.2
Travel	4.8 (7.8)	0.4	5.5 (8.8)	0.5	10.7 (17.8)	0.8
Total direct costs	**472.9 (779.3)**	**38.8**	**448.9 (471.6)**	**42.3**	**501.4 (614.8)**	**35.9**
Total indirect costs	**744.7 (1796.4)**	**61.2**	**611.6 (1370.4)**	**57.7**	**897.2 (2336.1)**	**64.2**
Total societal costs	**1217.6 (2013.0)**	**100.0**	**1060.5 (1471.1)**	**100.0**	**1398.6 (2474.1)**	**100.0**

session in the trial were £26.50 for CBT (£42 in Manchester, £21.67 in London) and £23.60 for NDC (£24–33 in Manchester, £21.67 in London). The cost of psychological therapy sessions will undoubtedly vary across the country, being provided by a range of professionals, both independent and as part of organisations. The results of this analysis, however, suggest session costs can be varied quite significantly without influencing the differences in costs between the three treatment groups.

Non-attendance

The second sensitivity analysis concerned non-attendance. Because all protocol psychological therapy sessions were paid for whether they were attended or not, all sessions and those not attended were costed in the main analysis. It was assumed that the cost of non-attendance in other primary care and specialist facilities was zero (i.e. the clinician was able to fill the time with alternative activities). This assumed cost was changed to the full cost of the relevant service contact (i.e. the time could not be put to an alternative productive use), with no effect on the study conclusions.

Drug costs

Data collected on the use of medications were categorised by class of drug, not by individual named drugs. It was therefore not possible to calculate a precise cost for each drug used.

TABLE 20 *Total direct costs over 12 months: results of conventional and bootstrap t test analyses*

	At 4 months	At 12 months
GP group vs CBT group		
Mean (SD) direct costs (£)		
GP group	244.0 (597.5)	472.9 (779.3)
CBT group	215.5 (108.6)	448.9 (471.6)
Mean difference in direct costs (£)	28.5	24.0
p-value	0.70	0.83
95% CI	–119.6 to 176.6[a]	–201.3 to 249.3
Bootstrap *p*-value	0.69	0.83
Bootstrap CI	–74.6 to 195.8	–165.5 to 260.1
GP group vs NDC group		
Mean (SD) direct costs (£)		
GP group	244.0 (597.5)	472.9 (779.3)
NDC group	257.5 (356.7)	501.4 (614.8)
Mean difference in direct costs (£)	–13.5	–28.5
p-value	0.87	0.81
95% CI	–181.7 to 154.7	–268.4 to 211.3
Bootstrap *p*-value	0.87	0.81
Bootstrap CI	–155.1 to 175.9	–256.4 to 205.0
CBT group vs NDC group		
Mean (SD) direct costs (£)		
CBT group	215.5 (108.6)	448.9 (471.6)
NDC group	257.5 (356.7)	501.4 (614.8)
Mean difference in direct costs (£)	–42.0	–52.5
p-value	0.37	0.59
95% CI	–134.7 to 50.7	–243.6 to 138.5
Bootstrap *p*-value	0.36	0.58
Bootstrap CI	–161.6 to 24.6	–237.2 to 128.4

CI, confidence interval

[a] *Unequal variance estimate*

Instead, the cost of the least expensive alternative, usually generic, was used in the main analysis, and this cost was changed to the most expensive alternative in sensitivity analyses, to provide a maximum and minimum range. This change did not influence the main results.

Wage rates

Indirect costs in the main analysis were calculated using actual self-reported wage rates. Therefore, the cost of lost time due to illness for the unemployed, retired, long-term disabled and housewives was assumed to be zero. It is argued, however, that all life is valued, irrespective of employment status, and for this reason, a national average weekly wage rate of £367.60[111] was applied to all lost time due to illness, with no effect on the main results.

Missing data

Finally, to remove the uncertainty of imputed values for missing data, the analysis was restricted to those patients who had complete medical record searches available ($n = 170$). The differences in total cost between the three groups remained non-significant.

Cost comparisons based on different allocation methods

The randomised and preference allocation procedures were distinct. However, as described in chapters 3 and 4, randomisation between the active psychological therapies could be considered an expression of a preference (i.e. not to return to the care of the GP) or a form of randomisation (in that comparisons of these groups are protected against selection bias). Because of this ambiguity, *Table 24* includes details of the societal costs, direct costs and indirect costs based on different combinations of these allocation procedures. There were no significant differences in any costs for any of the comparisons calculated.

TABLE 21 *Total indirect costs over 12 months: results of conventional and bootstrap* t *test analyses*

	At 4 months	At 12 months
GP group vs CBT group		
Mean (SD) indirect costs (£)		
GP group	383.7 (1194.3)	744.7 (1796.4)
CBT group	286.1 (701.3)	611.6 (1370.4)
Mean difference in indirect costs (£)	97.6	133.1
p-value	0.56	0.64
95% CI	–245.1 to 440.3	–424.0 to 690.2
Bootstrap *p*-value	0.58	0.63
Bootstrap CI	–209.3 to 492.3	–387.7 to 690.3
GP group vs NDC group		
Mean (SD) indirect costs (£)		
GP group	383.7 (1194.3)	744.7 (1796.4)
NDC group	444.4 (1127.2)	897.2 (2336.1)
Mean difference in indirect costs (£)	–60.7	–152.5
p-value	0.76	0.67
95% CI	–457.6 to 336.1	–864.7 to 559.6
Bootstrap *p*-value	0.78	0.65
Bootstrap CI	–463.7 to 353.9	–852.3 to 495.1
CBT group vs NDC group		
Mean (SD) indirect costs (£)		
CBT group	286.1 (701.3)	611.6 (1370.4)
NDC group	444.4 (1127.2)	897.2 (2336.1)
Mean difference in indirect costs (£)	–158.3	–285.6
p-value	0.34	0.40
95% CI	–486.6 to 169.9	–955.7 to 384.5
Bootstrap *p*-value	0.32	0.39
Bootstrap CI	–507.4 to 130.0	–1047.9 to 277.4

CI, confidence interval

TABLE 22 *Total societal costs over 12 months: results of conventional and bootstrap t test analyses*

	At 4 months	At 12 months
GP group vs CBT group		
Mean (SD) societal costs (£)		
GP group	627.7 (1359.8)	1217.5 (2013.0)
CBT group	501.6 (715.3)	1060.5 (1471.1)
Mean difference in societal costs (£)	126.1	157.0
p-value	0.51	0.61
95% CI	–254.5 to 506.7	–458.0 to 772.2
Bootstrap *p*-value	0.52	0.61
Bootstrap CI	–235.7 to 517.7	–432.7 to 759.3
GP group vs NDC group		
Mean (SD) societal costs (£)		
GP group	627.7 (1359.8)	1217.5 (2013.0)
NDC group	701.9 (1228.4)	1398.6 (2474.1)
Mean difference in societal costs (£)	–74.2	–181.1
p-value	0.74	0.64
95% CI	–517.1 to 368.6	–951.9 to 589.7
Bootstrap *p*-value	0.76	0.62
Bootstrap CI	–539.3 to 385.8	–970.8 to 521.4
CBT group vs NDC group		
Mean (SD) societal costs (£)		
CBT group	501.6 (715.3)	1060.5 (1471.1)
NDC group	701.9 (1228.4)	1398.6 (2474.1)
Mean difference in societal costs (£)	–200.3	–338.1
p-value	0.26	0.35
95% CI	–547.4 to 146.7[a]	–1050.2 to 373.9
Bootstrap *p*-value	0.24	0.35
Bootstrap CI	–554.6 to 98.3	–1167.0 to 275.2

CI, confidence interval

[a] *Unequal variance estimate*

TABLE 23 *Sensitivity analyses for costs over 12 months*

	GP group	CBT group	NDC group	*p*-value
	Mean (SD) (£)	Mean (SD) (£)	Mean (SD) (£)	
Societal costs				
Main analysis	1217.5 (2013.0)	1060.5 (1471.1)	1398.6 (2474.1)	0.63
Non-attended sessions included	1227.4 (2014.3)	1072.4 (1471.9)	1415.1 (2475.9)	0.63
Most expensive alternative drug	1218.7 (2015.0)	1060.7 (1471.2)	1398.8 (2474.1)	0.64
National wage rate	2526.5 (3042.0)	2034.8 (2629.3)	2750.9 (4155.3)	0.46
Complete data	1202.8 (2075.7)	954.9 (1047.2)	1409.6 (2595.2)	0.49
Direct costs				
Main analysis	472.9 (779.3)	448.9 (471.6)	501.4 (614.8)	0.89
Non-attended sessions included	482.7 (783.5)	460.8 (473.8)	517.9 (641.1)	0.88
Most expensive alternative drug	474.0 (784.9)	449.1 (471.6)	501.6 (614.9)	0.90
Complete data	419.9 (484.4)	470.5 (498.9)	532.3 (654.6)	0.55
Indirect costs				
Main analysis	744.7 (1796.4)	611.6 (1370.4)	897.2 (2336.1)	0.68
National wage rate	2053.6 (2730.6)	1585.9 (2551.4)	2249.5 (4012.4)	0.48
Complete data	782.9 (1923.3)	484.4 (908.5)	877.3 (2442.2)	0.52

p-*values from ANOVA*

TABLE 24 *Costs per patient over 12 months: comparisons of various combinations of allocation method and treatment*

Allocation and treatment		Societal costs				Direct costs				Indirect costs			
Group 1 (*n*)	Group 2 (*n*)	Group 1 Mean (SD) (£)	Group 2 Mean (SD) (£)	Mean difference (group 1–2) (£)	*p*-value	Group 1 Mean (SD) (£)	Group 2 Mean (SD) (£)	Mean difference (group 1–2) (£)	*p*-value	Group 1 Mean (SD) (£)	Group 2 Mean (SD) (£)	Mean difference (group 1–2) (£)	*p*-value
R/3 CBT (63)	PP CBT (81)	1060.5 (1471.1)	1073.1 (1056.2)	–12.6	0.95	448.9 (471.6)	580.6 (692.2)	–131.7	0.20	611.6 (1370.4)	492.5 (803.9)	119.1	0.516
R/3 NDC (67)	PP NDC (54)	1398.6 (2474.1)	1457.6 (1612.2)	–59.0	0.88	501.4 (614.8)	660.1 (849.0)	–158.7	0.24	897.2 (2336.1)	797.6 (1368.7)	99.6	0.78
R/3 + R/2 CBT (134)	PP CBT (81)	1300.3 (2057.6)	1073.1 (1056.2)	227.2	0.36	600.7 (1621.9)	580.6 (692.2)	20.1	0.92	699.6 (1346.9)	492.5 (803.9)	207.1	0.159[a]
R/3 + R/2 NDC (116)	PP NDC (54)	1707.1 (2939.5)	1457.6 (1612.2)	249.5	0.56	751.1 (1777.0)	660.1 (849.0)	91.0	0.72	956.1 (2366.0)	797.6 (1368.7)	158.5	0.65
R/3 + R/2 CBT (134)	R/3 + R/2 NDC (116)	1300.3 (2057.6)	1707.1 (2939.5)	–406.8	0.20[a]	600.7 (1621.9)	751.1 (1777.0)	–150.4	0.48	699.6 (1346.9)	956.1 (2366.0)	–256.5	0.288[a]
R/3 CBT (63)	PP + R/2 CBT (144)	1060.5 (1471.1)	1278.6 (1853.4)	–218.1	0.41	448.9 (471.6)	652.9 (1570.8)	–204.0	0.31	611.6 (1370.4)	625.7 (1087.9)	–14.1	0.94
R/3 NDC (67)	PP + R/2 NDC (113)	1398.6 (2474.1)	1770.8 (2689.9)	–372.2	0.36	501.4 (614.8)	855.6 (1896.9)	–354.2	0.07[a]	897.2 (2336.1)	915.2 (1981.5)	–18.0	0.96

R/3, patients randomised between all three treatments; R/2, patients randomised between the two psychological therapies only; PP, patients expressing a specific treatment preference

[a] *Unequal variance estimate*

Chapter 6
Discussion

The discussion will consider the clinical and economic analyses in turn, in relation to both the present study and previously published trials. Then, general issues concerning the internal and external validity of the study findings are discussed.

Clinical outcome

Usual GP care vs CBT and NDC

The clinical outcome data suggest that both psychological therapies produce a greater reduction in depressive symptoms than usual GP care in the short term, but that any superiority in effectiveness disappears over the 12-month follow-up because of the continued improvement of those in the GP care group. When the two psychological therapies were compared directly (in an analysis that included patients randomised by either allocation method, to provide almost twice the effective sample size), there were no significant differences in clinical outcome between the therapies at either the 4- or 12-month follow-up.

Several recent trials have reported no significant difference in outcome between patients under the care of a counsellor or GP.[30–32] The current trial supports the finding of Boot and co-workers[33] (i.e. that a short-term benefit is associated with NDC) but without the methodological problems (e.g. low rates of follow-up) that hampered interpretation of that earlier study. It also provides some support for the *post hoc* finding of Friedli and co-workers[32] that NDC is more effective than GP care for the subgroup of patients with depressive symptoms of sufficient severity (i.e. BDI score > 14, the criterion of entry into the current trial). Sufficient severity of presenting symptoms may be one reason for the positive results of that study. Catalan and co-workers[112] also found a positive outcome associated with brief counselling in patients whose problems had persisted for 1 month. Mild emotional problems may be especially likely to remit spontaneously or may be of insufficient severity for specialist treatments to produce significantly greater improvements than informal care processes from non-specialists and lay people over the long term. However, other primary care trials that have used inclusion criteria of enduring problems[38] or diagnostic thresholds such as major depression[34] have failed to report robust benefits associated with psychological therapies compared with GP care.

CBT vs NDC

The current trial does not support the view that CBT in primary care offers clinical effectiveness superior to that of NDC.[19] Some of the previously published CBT studies[35,36,63,113] have involved behaviour therapy rather than CBT, and it is unclear the degree to which these results apply to the more 'modern' form of therapy because discussions of the content of treatment within the trials have been brief. Additionally, some trials have screened patients for suitability for behaviour therapy. Marks[63] found that 104 of 220 (47%) patients referred to their trial were considered unsuitable. Although positive results have been reported for CBT in primary care and community settings,[65,66] other studies have reported similar outcome resulting from GP care[34] or ambiguous findings.[68] CBT may still have a significant advantage over counselling for specific problems, such as phobias and panic disorder, although there are no published controlled comparisons in primary care to date.

Patient preference vs randomisation

Finally, there was no evidence that patients expressing a preference were significantly different from patients who agreed to be randomised to treatment, in terms of their baseline characteristics or their clinical outcome. This result is similar to previous studies that have compared patients choosing treatment with those randomised.[114,115]

Economic outcome

Costs and cost-effectiveness

There were no differences in costs associated with any of the treatments, either when direct and indirect costs were considered separately or when combined together to give total societal costs. None of the sensitivity analyses gave any indication that the results were dependent on particular analytic assumptions.

In the light of the cost data, the significantly greater clinical effectiveness of the psychological therapies at 4 months means that these treatments are more cost-effective methods of reducing depressive symptoms in the short term. There was no clinical or cost advantage associated with either of the treatments at the 12-month follow-up.

As is usual, the cost data were highly variable, and the study may have been underpowered to detect more modest differences in costs, which may still be of economic importance. However, it must be noted that the comparisons of patients randomised to psychological therapy using either allocation method effectively doubled the sample size available to the analysis of cost differences between these specialist treatments, and no significant findings were recorded (*Table 24*).

Resource use and indirect costs

As can be seen from *Table 17*, no treatment seemed to be associated with markedly lower rates of time off work. There was also little variation in specialist service utilisation for non-psychiatric problems (*Table 16*). The main rates and costs for which there was significant variation between groups were psychotropic medication, and the use of primary care and other specialist mental health facilities. The costs of provision of the psychological therapies were recouped through reduced use of these treatments in the psychological therapy groups, especially referral to specialist facilities, which accounted for approximately two-thirds of the total direct treatment costs in the GP care group during the 4- and 12-month follow-up periods.

The inclusion or exclusion of indirect costs in economic analyses of this kind is still a matter of debate. These costs accounted for nearly two-thirds of the total societal costs in some analyses. The calculation of indirect costs suggests that productivity losses are a linear function of time lost from work and wage rates, which may not be an accurate reflection of the actual cost incurred. Nevertheless, there was no difference in the results when such productivity costs were included or excluded from calculations. Equally controversial is the method by which zero value was placed on productivity losses for patients not in paid employment. However, this method would be expected to impact on the analysis only when a significant proportion of patients are out of work. At baseline in the current study, 64.9% of the total sample reported full- or part-time work in the 6 months preceding the interview. Additionally, there was no evidence that the more equitable analysis (using an average wage rate for **all** patients) significantly changed the results.

Unused or missing data

Travel costs associated with specialist referrals were not used in the current analysis, and patients with missing data were assumed to have zero referral and psychotropic medication costs. Non-psychotropic medication was also not used in the analysis because of the significant resources required to collect such data. Therefore, the calculated costs are probably lower than actual incurred costs. Nevertheless, travel costs were a small proportion of total costs. The number of patients with missing data was relatively low, and the sensitivity analysis again provided no evidence that missing data had a significant influence on the results. It is unlikely that the inclusion of such costs would significantly affect the overall results of the study, and they would be extremely unlikely to increase differences between the groups. No account was taken in the analysis of differences between the groups in terms of the proportion of psychotropic prescriptions actually dispensed (and thus incurred costs) or the actual time spent with the GP. It is possible that patients in the psychological therapy groups would be less likely to obtain prescribed medicines or to spend as long with the GP when they did attend primary care. However, these costs were not a major proportion of direct treatment costs, and such differential utilisation is speculative in the absence of objective data.

Suppport for previous findings

The current study's economic results support the results of two recent trials[30,39] suggesting that there were no major differences in costs associated with counselling and GP care. The possibility that these individual economic analyses were underpowered suggests that meta-analysis of cost data might be useful, although it is unclear the degree to which the costing methodologies are sufficiently similar to make such an analysis interpretable.

Satisfaction outcome

The present study confirmed the findings of previous studies in reporting comparatively higher satisfaction in patients allocated to psychological therapies compared with those remaining with their GP.[32,33] This result is unsurprising. Patients' general attitudes to psychological therapies are very positive.[8] It is likely that GPs referred patients who were already seeking psychological therapy,

rather than those who simply fulfilled the inclusion criteria for whom such therapy would be appropriate. Furthermore, patients allocated to psychological therapy have access to specialist treatment **and** the option of consulting with the GP. Finally, patients allocated to psychological therapy generally receive a much greater amount of time with a health professional, which is regularly identified as a key predictor of satisfaction with healthcare.[116,117] However, the importance of such satisfaction outcomes in determining the overall value of a treatment is controversial. Recent policy has highlighted the important role of patients' views of and satisfaction with the health service, but such outcomes are generally viewed as secondary to clinical and economic outcomes in the research literature.[118] Nevertheless, when treatments do not differ in terms of overall outcomes or costs, satisfaction data may be the one remaining issue that discriminates between them.[32]

With patients randomised to the psychological therapies, there was no difference in overall satisfaction, but patients who specifically chose NDC were more satisfied than those who chose CBT. The qualitative data suggest that misconceptions as to the nature of the treatment may have been more common in relation to CBT, which may account for this difference, although such a hypothesis requires more detailed work given the weakness of the qualitative data.

Other possible outcomes

There are a number of possible benefits of psychological therapies that were not measured in the current trial. The impact of psychological therapies on the families of patients was not measured; although social function was measured, it was done so purely from the perspective of the patient. Psychological therapists may provide patients with skills that may help protect them against relapse and recurrence of their problems in the longer term. Only studies with longer follow-ups could determine the existence of these effects, which may impact on both clinical and economic results. Equally, the presence in the practice of a psychological therapist may reduce the GP's overall work stress. Although it is clear that patients under the care of the psychological therapist use less GP consultations in the 12 months following referral, it is not known whether such effects have a substantive impact on the overall workload of the GP. However, there are anecdotal suggestions that such effects are **perceived** as significant by GPs.[6]

Internal validity

Methodology

A number of issues concerning the internal validity of the findings deserve note. In terms of overall methodology, the use of sealed, opaque envelopes met accepted criteria for 'concealment of allocation', although randomisation by a central agency may have been preferable to the use of envelopes held by the assessors to ensure a distinction between the generator of allocation and its executor.[119,120] Although 'envelope tampering' is always a theoretical possibility, it is likely that clinicians would have more to gain in terms of allocation to preferred treatments than the researchers used in the present study. Nevertheless, the groups were well balanced at baseline in terms of their clinical and demographic characteristics. High rates of follow-up were attained, and the use of 'last observation carried forward' in the analysis also avoided bias associated with loss to the study (exclusion bias).

Treatment integrity

Findings of no difference between treatments are difficult to interpret when there are concerns about the quality and integrity of the treatments provided.[121] The present study was one of the few in primary care to examine the issue of treatment integrity. The results suggested that sufficient differentiation between the therapies was achieved. This differentiation may be due to both the existing level of training of the therapists and the provision of treatment manuals for guidance. There was no specific rating of NDC, and the degree to which CBT sessions included aspects of NDC was not examined, although the CTRS has some items that deal with related issues such as empathy and interpersonal effectiveness. The relationship between specific therapeutic processes and patient outcome is important but beyond the scope of the present report.

Treatment duration

NDC was generally provided over a greater number of sessions than CBT. The relatively short nature of the CBT, especially in Manchester, might lead some to suggest that an insufficient 'dose' may have been provided, and it is possible that longer treatment duration might have further increased the superiority of the psychological therapies over GP care. However, agreement between the therapist and client that therapy should be terminated was the most commonly reported reason for ending treatment in the CBT

group (*Table 11*). In contrast, in the NDC group, therapy was more often reported to have ended because of the 'end of specified time', although there was less difference between the patients randomised between all three treatments in this regard. It might be that the clinical psychologists accepted that there was likely to be little additional advantage in the use of their specialist skills for a proportion of referred patients, and the psychologists thus provided shorter treatment durations that were still appropriate given the nature of the patients' problems. An 'on-treatment' analysis might have been considered, although such analyses are vulnerable to bias because of the possibility of selection effects associated with attendance.

Although the greater number of sessions may have given an advantage to NDC in the clinical analysis, this difference would also serve to increase the direct costs associated with that treatment arm, thus handicapping NDC in the economic analysis.

Treatment delivery: lack of control

Pragmatic trials such as the present study aim to provide an interpretable comparison of two broad treatment 'policies' rather than strictly defined and implemented treatments. The goal is to provide conditions as close as possible to clinical practice so as to increase the external validity of the study findings. However, the lack of control in treatment delivery in such trials does complicate the interpretation of the findings to some extent. For example, the relatively high rates of referral to psychological therapies in the usual GP care group and the rates of the use of antidepressants in all groups did make it extremely difficult to determine the influence of psychological therapies alone. The fact that patients under usual GP care may have received psychological treatments very similar to those provided to the other groups (especially by the 12-month follow-up, when there were no clinical differences between the groups) and that patients under usual GP care were more likely to receive an antidepressant prescription may have reduced differences between the groups compared with those that might have been found in a more highly controlled trial. Alternatively, at least some of the benefits found in patients allocated to the psychological therapies may have been due to antidepressant or anxiolytic use post-allocation. Again, however, treatments additional to protocol psychological therapy that may have had a beneficial impact on outcome would also impact negatively on the overall cost-effectiveness of treatment.

Therapist quality

Although there were a number of therapists used in the study, the work was not distributed equally, and a small number of therapists were responsible for the management of a significant proportion of the study patients. This factor may make the results dependent on the skill of a small number of therapists. Although the integrity check did indicate that there was sufficient differentiation of therapies and that all the rated CBT sessions were adequate, there was no specific check on the quality of a significant proportion of therapeutic sessions. No formal test was conducted of the possibility of effects associated with the therapists.[122]

Patient preference vs randomisation

The internal validity of the comparison of randomised patients and those with a treatment preference requires discussion. The preference arms in the Brewin and Bradley design are still vulnerable to selection bias, and thus it cannot be stated with certainty that preference does not impact on outcome.[81] It is possible that the differences in symptom severity or treatment expectations that were found at baseline impacted on outcomes. For example, patients with a preference reported greater dysfunction at baseline. However, preferences may have increased the benefits of treatment, such that there was no difference between randomised and preference patients at 4 and 12 months. It is also possible that preference and randomised patients differed on some important **unmeasured** variable. However, the lack of major differences in baseline characteristics between the preference and randomised arms suggests that it is justified to have reasonable confidence in the result of 'no difference' between randomised and preference arms in terms of both costs and outcomes.

External validity

Trials of complex interventions are difficult to conduct when treatments are available outside the trial and patients must make an investment of time and effort. Patients or clinicians may simply decline to take part.[58] If randomised to a non-preferred arm, patients may become demoralised or drop out. Patient preference trials are more expensive to conduct than routine trials but may lead to increased recruitment. The inclusion of patients with preferences in the overall design means that analysis can estimate the representativeness of the core randomised sample **and**

compare outcomes between those who are randomised and those who are not. However, trials costs are greatly increased.

In terms of external validity, the similarity in baseline characteristics between randomised and preference samples does suggest that the results from the randomised arms may be generalised to the patient population as a whole, even though these results take no account of preference issues. However, there were a number of other threats to external validity. It is likely that a number of patients refused to take part in the trial altogether. In these cases, doctors were asked to complete a form detailing the reason for refusal. However, compliance was poor, and it is not absolutely certain that trial participants were representative of eligible patients generally.

Treatment duration

As noted in the discussion of internal validity, the psychological therapies in the trial were brief in duration. In a general practice survey, the average number of sessions provided by counsellors was close to six, but this therapy duration was shorter than the mean of 16.5 sessions reported by psychologists, a significant proportion of whom were probably using some kind of CBT.[6] In the present study, NDC treatments were generally longer than CBT, and treatments in London tended to be of longer duration than those provided in Manchester. These differences may reflect variations in the organisation of services (and the associated incentives). Independent therapists in London would receive greater rewards for providing a greater number of sessions. Therapists in Manchester worked for a service provider and had a routine caseload as well as trial work. This situation may have led to an incentive to provide a lower number of sessions in order to keep their workloads within reasonable bounds. However, there were no differences in outcomes between the two centres in the study.

Therapist quality

The external validity of the quality of psychological therapy requires discussion. The results of the present study may generalise only to therapy provision by therapists with levels of training and experience similar to those of the therapists in the current trial, although the research evidence on the relationship between training and outcome is ambiguous.[26,70]

Patient characteristics

Although the study practices were based in a range of socio-economic areas, examination of the baseline characteristics of the patients suggests some bias towards middle-class patients with higher levels of education. For example, one-quarter of the patients reported having a degree or higher degree. Although the results may not generalise to other patient groups differing significantly in composition from the present sample, these patients may be representative of patients normally referred by GPs for practice-based, brief psychotherapy.

'Routine care'

As suggested above, pragmatic trials are unable to provide unambiguous answers to questions about the cause of change, but have enhanced external validity in that they represent 'routine' practice. Some authors have questioned the degree to which 'routine care' trial arms actually reflect routine treatment. For example, the Edinburgh primary care trial[34] found a rate of antidepressant prescription of 66% in the GP care arm, which was significantly higher than the 16% found in a prospective study of depressed patients.[51] The rates found in the current trial were closer to that found in the Edinburgh trial. Trial procedures (such as the confirmation of the severity of depressive symptoms, or the raised expectations of patients) may have a significant impact on GP behaviour, which may improve the outcome of patients in the GP care arm of the trial.

Chapter 7
Conclusions

Implications for mental health service provision in primary care

The results from the present study suggest that the provision of brief psychological therapies in general practice is associated with greater short-term clinical benefit, compared with GP care. Over a 12-month period, psychological therapies produce outcomes and costs largely similar to those associated with the more traditional form of care (i.e. GP management, with referral to mental healthcare specialists for a proportion of patients). With such equivalence, commissioners of services are in a position to decide upon service configuration based on other factors. These factors may include the perceived importance of patient satisfaction, the preferences of practitioners (i.e. the GP and primary healthcare team, as well as specialist providers) and staff availability.

Recommendations for future research: clinical issues

Long-term outcomes

Research into the long-term outcome in patients treated with psychological therapies is the main priority. Little is known about the long-term clinical and economic impacts of psychological therapies in primary care. Therapies that enhance coping skills and self-efficacy (e.g. CBT)[82] have been hypothesised to impact on the relapse and recurrence rates of disorders such as depression. However, these benefits have yet to be demonstrated in primary care settings. Therefore, new trials or the extended follow-up of patients already included in published trials may be required.

Therapy quality and outcome

The relationship between the quality of psychological therapies and patient outcome is another issue that may benefit from research. Very few psychological therapy trials in primary care have examined these issues. Important 'quality' factors might include therapist qualifications and experience, therapist skill or the provision of key therapeutic processes (e.g. changes in cognitions in CBT).[123] Research methodologies could include conventional controlled trials, 'dismantling' designs,[124] and observational or qualitative research based on actual therapeutic processes.[125] Such issues may have important implications for clinicians and managers of psychological therapy services.

Comparisons with other therapies

The current trial compared two common psychological therapies in primary care. Decisions about the commissioning of research on other psychological therapies are complex, requiring information on their prevalence in actual practice, as well as systematic consideration of their overall clinical effectiveness and cost-effectiveness. Further research may involve the evaluation of different therapies and different modes of treatment administration.

Therapies other than those assessed in the current study include brief psychodynamic therapy, which is frequently used in primary care[6] but has been infrequently evaluated.[126] Problem-solving therapy is less widespread in routine service contexts but has undergone a number of controlled evaluations.[38,77,127] Interpersonal therapy is a manualised treatment that received a positive evaluation in the large-scale US National Institute of Mental Health outpatient depression study,[128] and a modified version ('interpersonal counselling') has been evaluated in primary care.[129] The comparative effectiveness of psychological and pharmacological treatments has been the subject of one recent trial[130] and might also deserve further attention.

As regards treatment administration, the question of who should deliver psychological therapy remains crucial.[70] Should mental health specialists provide therapy, or should primary care professionals (i.e. GPs, practice nurses and health visitors) be trained to deliver psychological therapy?[38,131] There has also been recent interest in the development of self-help treatments (supervised by a mental health professional, in some cases, or used alone by patients), which can be provided in a book or computer format, or through email or the Internet.[132–135] Structured therapies such as CBT are especially amenable to administration in such formats. Further comparative studies are required in order to offer

information to decision-makers concerning the relative value of the different modalities and methods of providing psychological therapy in primary care.

Recommendations for future research: methodological issues

Patient preferences

The impact of patient preferences in the current trial was minimal, both in terms of the characteristics of patients who underwent randomised as opposed to preference allocation and in terms of the eventual clinical and economic outcomes. Given the large additional costs associated with preference trials, it is unlikely that repeated use of the preference design in relation to the broad issue of psychological therapies would be a cost-effective use of research resources.

Nevertheless, a fuller understanding of preference issues will result from further research. For example, the psychological and social processes involved in patient preferences require further clarification, as the qualitative data presented in the current study suggest that preferences may be based on a number of sources of information, which have different implications for their relationship with trial participation and patient outcomes. Developing a more robust conceptual framework might also highlight links to other psychological processes of relevance to controlled trial research, such as the placebo[136] and Hawthorne effects.[137] This would be assisted by more sophisticated qualitative work on preference issues than was possible in the current study. The NHS R&D HTA programme has funded a systematic review of completed preference trials, and this review will provide crucial information concerning the conceptualisation and measurement of preferences and their impact on recruitment and outcome.

When feasible, some sort of preference measurement should be part of the baseline assessment in all controlled trials of psychological treatments, so that preferences can be examined in relation to outcome in studies without specific preference arms.[138] Although the measurement of preference is at present rudimentary, even the routine addition of simple Likert scales measuring perceived attractiveness of treatment would be of use. The qualitative data collected in the present study may provide ideas relating to the content of more sophisticated instruments that might be able to separate the issues of expectation (which is to some degree based on knowledge and can be of varying accuracy) and preference (which is more of an evaluative concept).

Qualitative data gathered as part of the assessment suggested that a proportion of patients may have had misconceptions as to the nature of the treatments. Although such misconceptions are part of routine service delivery (and, as such, have external validity), they may impact on both the process of treatment and the issue of preferences, as baseline preferences based on misconceptions would not be expected to have the theorised relationship with outcome. More information and more specific examples of the actual process of treatment (e.g. audio tapes of role-played treatment sessions) might be required in order to ensure that patients are sufficiently informed and that the logic of the preference design is coherent. Such procedures would not seem incompatible with good referral practice.

GP recruitment and external validity

One piece of information that is missing from almost all trials is the proportion of eligible patients in primary care who are not offered the trial by their GP or who decide not to participate after discussion. In the current trial, as well as in trials by Friedli and co-workers[32] and Harvey and Peters,[139] researchers did attempt to gather information on this issue, but GPs did not consistently return data. Without such data, the overall external validity of the trial will remain unclear, and important information about patient decision-making concerning trial participation will also be missed. Unfortunately, it is also unclear which procedural or financial incentive will encourage GPs to provide such information. Screening patients in surgeries is an alternative recruitment method, which may increase overall recruitment rates as well as produce more information on eligible patients who decline to participate. However, such a procedure is staff-intensive and highly likely to reduce external validity. Screened patients are likely to differ significantly from those identified by the GP, because of the particular issues that influence GP recognition of mental health problems.[140]

'Usual GP care'

The content and interpretation of 'usual GP care' have been questioned. Roth and Fonagy (page 261)[26] suggested that the "success or otherwise of [psychological therapy] treatments may depend as much on the quality of treatment as usual as the characteristics of the [therapy]

offered." It is known that GPs' attitudes towards mental health as well as their skills in detection and management vary widely.[141,142] However, it is not clear whether GPs with a special interest in, or antipathy to, mental health work are more likely to take part in clinical trials in which such treatment is available. If GPs with special interest or skill in mental health issues were to take part, then their participation might further reduce differences in both the process and outcome of 'usual GP care' and specialist therapies. Although the current trial did attempt to provide comprehensive information on GPs' medical behaviours, there was little information on GPs' use of psychological therapy techniques within the consultation itself (apart from the patient satisfaction data). Greater descriptive data concerning 'usual GP care' would undoubtedly aid in the interpretation of findings.

'Usual GP care' is a problematic comparison condition, in that the content of usual practice may change over time because of advances in knowledge and other therapeutic trends in the practitioner population. An alternative to uncontrolled GP care involves definition of minimum standards of care (e.g. relating to prescribing and follow-up), which may go some way to ameliorating these interpretative problems.

Other methodological issues

There are a number of aspects of methodology that might benefit from a greater degree of standardisation. At a minimum, all future trials should use procedures and reporting methods consistent with current guidelines, such as the Consolidated Standards of Reporting Trials (CONSORT)[119] and the *BMJ* economic guidelines.[143]

Decisions concerning the appropriate outcome measures are complex. However, it is striking that four recently published trials assessing counselling in primary care did not share a single measure in common.[30–33] Statistical techniques and methods for dealing with issues such as missing data are also very variable. Although there is a genuine lack of consensus among methodologists over some of these issues, the non-uniformity of approach does reduce the information that can be drawn from reviews and meta-analyses of multiple trials.

The problems associated with clustering of patients around therapists, GPs and practices have also received significant attention in the methodological literature in recent years.[144–146] Future analyses should take account of these clustering effects.

Finally, no primary care economic analysis has reported a power analysis based on economic outcomes. Although primary research would be preferred, it is likely that meta-analysis of economic outcomes from published trials may be an appropriate response to this problem, if there is sufficient comparability in data collection and costing methodologies to make such an analysis interpretable.

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Appendix 1

Information provided to patients

Patient Information Sheet

General practitioners have recently started employing therapists in their practices. Some studies show that these therapists are very helpful. Other studies show that general practitioners can provide an equally good service. We need to understand more about the similarities and differences between the care that therapists and general practitioners provide to people. That is why a team of researchers at the [site title] are doing a study to find out more about this. They invite you to take part in the study which has been funded by research and development funds within the NHS.

Taking part in the study will initially involve meeting with a researcher either at the surgery or at your home. This will give you an opportunity to learn more about the study and ask any questions that you have at this time. You will be asked some questions about your health and well-being to see if you are suitable to take part in the study. If you are suitable, you will then make an appointment to see either your GP or a therapist. If you have a very strong preference to see a therapist or remain with your GP we will give you that choice. If you do not have a strong preference, however, we will randomly allocate you to one of them. This means you will have an equal chance of seeing any one of them. We need as many people as possible to be randomly allocated to make the research as useful as possible. So unless you have very strong preferences for one particular therapist or your GP we would urge you to consider being randomly allocated.

The researcher will contact you again 4 months and 12 months later to see how you have been getting on and ask you some questions about the treatment. This is to see how well the treatment has worked.

During your meetings with the researcher you will be asked to fill in some questionnaires about how you have been feeling in the past few weeks and how you have been coping with day to day life. Some of the questions are of a personal and private nature. It is very important that we gather this information in order to understand the work of GPs, counsellors and psychologists. All information will be treated in the strictest confidence and only used for this research. Information will only be shared with the GP if we feel that a patient may be a danger to themselves or others, and patients will be informed if this occurs. All questionnaires are assigned a code, and information such as your name and address is kept separate from the questionnaires when they are stored so that you cannot be identified.

I do hope you will decide to take part in this important study. However, if you would rather not take part, you do not have to give a reason and it will not affect your future care. If you decide to take part and later change your mind, you can withdraw without giving a reason and without affecting your future care. You are welcome to ask any questions about the study at any time.

GPs, Counsellors and Psychologists

General practitioners (GPs):

GPs will treat patients according to their normal practice, in consultation with the patient. Such treatment may involve talking to people about their problems, the use of medication, or referral to other agencies for further help.

Counselling:

Counsellors provide the patient with time and support. They help them explore and understand their problems. Counsellors listen and encourage people to work out their own ways of helping themselves using their own abilities and strengths.

Psychology:

Psychologists provide the patient with time and support. They examine the way people think and act, explore alternative ways of thinking and behaving, and together with the patient develop practical ways in which people can help themselves.

All therapists in the study have had training and experience and meet the strict guidelines of the British Association for Counselling (BAC) or the British Association for Behavioural and Cognitive Psychotherapies (BABCP). All the therapists will have regular team meetings and supervision, and all are funded by the study.

The therapists will have contact with general practices on a regular basis and will see patients on a one-to-one basis, ideally in the surgery. Patients will be seen for an average of six sessions.

Counselling

Information for Patients

The therapist's task is to give you the opportunity to talk about what is troubling you, so that you can explore your thoughts and feelings about it, in a way that is not always possible with family and friends. Being listened to by someone who is respectful of you, non-judgmental and accepting, can help you to see things in a fresh light. The therapist will help you to decide what you want to do and to consider what possible steps you might take to reach a solution to your difficulties or, if the situation cannot be changed, to come to terms with it. The therapist's job is not to give you advice or to tell you what to do.

Whatever you choose to say will be kept in strictest confidence by the therapist and s/he will only disclose any information you give after seeking your permission. The only exceptions would be if there was any question of serious harm caused either to yourself or someone else.

For the purpose of the study, some taped material will be randomly selected and checked by a research assistant, to make sure that the therapists are working in the same way. This is done anonymously.

When the counselling has finished, the therapist will write a short report about the process, not the content of the work, that is, how it went, not what you said. In the same way as you will be asked to assess if it has been helpful to you.

Each session lasts for 50 minutes. You may find that one session with the therapist is enough. The average number of sessions might be 6, but we could extend that to a maximum of 12 sessions.

Please notify the GP's surgery, if you are unable to keep an appointment, so that the session can be used by someone else.

Cognitive–Behaviour Therapy

Information for Patients

The therapist's task is to identify thoughts, feelings and behaviours that affect your mood and to help you to develop practical ways to develop a more positive approach to those thoughts, feelings and behaviours. S/he will involve you in deciding what targets you should aim for, and will ask you to carry out practical exercises at home, such as diary keeping and thought monitoring. As with counselling, being listened to by someone who is respectful of you, non-judgmental and accepting, can help you to see things in a fresh light. The therapist will help you undertake a practical programme designed to improve your feelings of worth and your ability to combat negative thoughts, feelings and behaviours. You may also learn other skills such as problem solving and relaxation techniques.

Whatever you choose to say will be kept in strictest confidence by the therapist and s/he will only disclose any information you give after seeking your permission. The only exceptions would be if there was any question of serious harm caused either to yourself or someone else.

For the purpose of the study, some taped material will be randomly selected and checked by a research assistant, to make sure that the therapists are working in the same way. This is done anonymously.

When the cognitive–behaviour therapy has finished, the therapist will write a short report about the process, not the content of the work, that is, how it went, not what you said. In the same way as you will be asked to assess if it has been helpful to you.

Each session lasts for 50 minutes. You may find that one session with the therapist is enough. The average number of sessions might be 6, but we could extend that to a maximum of 12 sessions.

Please notify the GP's surgery, if you are unable to keep an appointment, so that the session can be used by someone else.

Appendix 2

Unpublished scales

Patient problem list – first interview

1. Please indicate using the list below what you feel to be your current problem(s).

   If you feel there is more than one, please underline the main one.

   Please indicate for each problem how successful you think the treatment will be. Use the scale below.

   0 1 2 3 4 5 6

   Not work at all — Work moderately well — Work extremely well

PROBLEM	Present? Tick if yes	Success 0–6
Depression / Feeling low or sad / weepy		
Anxiety / Nerves		
Stress		
Physical illness		
Work related problem		
Unemployment/redundancy		
Social Problems e.g. housing, financial		
Relationship difficulties		
Family problems		
Problems from childhood		
Bereavement or loss		
Confusion about life or the future		
A feeling of going mad		
Other (please specify)		
Other (please specify)		

Patient problem list – first interview

2. When you went to your GP what had you been hoping for when you decided to see them?

Please tick one or more boxes which match what you wanted from your GP.

To listen to me and advise/counsel me themselves	☐
To examine me and treat any physical cause for my symptoms	☐
To arrange tests	☐
To prescribe me something to calm me down	☐
To prescribe me something to help me sleep	☐
To prescribe me something for my depression	☐
To refer me to a counsellor	☐
To refer me to a psychologist	☐
To refer me to a psychiatrist	☐
To refer me to (other, please specify).....	
To write a letter for me to (please specify).....	
I didn't know	☐
I had no preference	☐

Patient problem list – follow-up interview

1. Please indicate below in the first column which of the problems were present when treatment started.

   Please indicate in the second column which of the problems have occurred since treatment started.

PROBLEM	Present at start of treatment? Tick if yes	New problem? Tick if yes
Depression / Feeling low or sad / Weepy		
Anxiety / Nerves		
Stress		
Physical illness		
Work related problem		
Unemployment/redundancy		
Social Problems e.g. housing, financial		
Relationship difficulties		
Family problems		
Problems from childhood		
Bereavement or loss		
Confusion about life or the future		
A feeling of going mad		
Other (please specify)		
Other (please specify)		

Patient problem list – follow-up interview

2. Please tick which problems you tried to deal with during the treatment.

For each of these please indicate in the next column, how much change there has been in that problem. Please use the scale below.

0 1 2 3 4 5 6

Much worse Same Much better

In the last column please indicate how successful you think the treatment has been. Please use the scale below.

0 1 2 3 4 5 6

Not worked at all Worked moderately well Worked extremely well

PROBLEM	Dealt with? Tick if yes	Change in problem 0–6	Success of treatment 0–6
Depression /Feeling low or sad / Weepy			
Anxiety / Nerves			
Stress			
Physical illness			
Work related problem			
Unemployment/redundancy			
Social Problems e.g. housing, financial			
Relationship difficulties			
Family problems			
Problems from childhood			
Bereavement or loss			
Confusion about life or the future			
A feeling of going mad			
Other (please specify)			
Other (please specify)			

If you dealt with these problems by talking them over with somebody else please indicate who (e.g. friend, parent, spouse, GP, etc).

Baseline Interview

Patient ID ☐ **GP ID** ☐ **Date.....**

We would like to gather some information about you and your present circumstances. We would be very grateful if you would complete the following questions. Either tick the appropriate box or write your answer in the space provided. Please remember that all the information given will be confidential.

A1 Marital status

- Single ☐
- Married/cohabiting ☐
- Widowed ☐
- Separated ☐
- Divorced ☐

A2 Education

- COA, RSA or equivalent ☐
- Ordinary GCEs/GCSEs ☐
- Advanced GCEs/GCSEs ☐
- Degree ☐
- Higher degree ☐
- Other ☐
- Please specify .....
- None of the above ☐

A3 Ethnic Origin

- White ☐
- Black Caribbean ☐
- Black African ☐
- Black Other ☐
- Indian ☐
- Pakistani ☐
- Bangladeshi ☐
- Chinese ☐
- Other ☐
- Please specify .....

A4 Accommodation

- Rented from local authority ☐
- Privately rented ☐
- Board and lodging ☐
- Housing association agreement ☐
- Owner/occupier ☐
- Other ☐
- Please specify .....

A5 How many bedrooms are there in your home? .....

A6 How many people live in your home ? Please fill in the boxes below.

- Number of adults living in your home ☐
- Number of children living in your home ☐

A7 Have you received any social security benefits or rent rebates over the last six months (exclude child benefit)?

- Yes ☐
- No ☐

A8 If yes, for how many weeks did you receive these benefits and approximately how much did you receive on each occasion?

(a) ..... weeks of ..... at £ .....
(b) ..... weeks of ..... at £ .....
(c) ..... weeks of ..... at £ .....
(d) ..... weeks of ..... at £ .....

A9 **Work status**

Full time ☐
Part time ☐
Housewife/man ☐
Unemployed ☐
Retired ☐
Long term sick/disabled ☐
Other ☐
Please specify .....

A10 **Type of work** .....

A11 **Work status of partner**

Full time ☐
Part time ☐
Housewife/man ☐
Unemployed ☐
Retired ☐
Long term sick/disabled ☐
Other ☐
Please specify .....

A12 **Type of work of partner** .....

A13 How long have you been in current employment/unemployment?
.....

A14 Work history

Please complete the table below for the last 6 months, noting all job changes in that time and starting with your current status. Please also include all periods of unemployment. Please state gross wage per week (that is before national insurance, superannuation and other deductions).

Job changes in the last six months		**Were you employed?**		**Average number of hours worked per week**		**Please state weekly income (i.e. total pay before tax or other benefits during unemployment**		**Did you change jobs because of your present problem?**	
From month/ year	To month/ year	**(please circle)**		Less than 30	More than 30	Personal	Family	**(please circle)**	
		Yes	No					Yes	No
		Yes	No					Yes	No
		Yes	No					Yes	No

A15 How many days have you had 'off sick' from work in the last six months?

.....

A16 How many of these days off were due to your present problems?

.....

A17 Have you seen the following people for help in the last six months?

Agency	Number of contacts	Duration of contact	Home visit (yes or no)	Cost of travel One way (£) or number of car miles	Child care arrangements
GP					
Psychiatrist					
Social worker					
Doctor/nurse at workplace					
Specialist doctor					
Practice nurse					
District nurse					
Community psychiatric nurse					
Health visitor					
Other, please state					

A18 In the last six months have you seen a counsellor or psychologist?

Yes ☐ Please answer questions A19–A24

No ☐ Please go to question A25

A19 Where was the counsellor or psychologist employed and who was the person involved?

.....

A20 How many times did you see the counsellor/psychologist and for how long each time?

.....

A21 Why did the counselling/psychology end?

.....

A22 Did the counsellor or psychologist charge you for their service? If yes, how much?

.....

A23 How much were the travelling costs to go and see the counsellor/psychologist? (One way (£) or number of car miles)

.....

A24 Did you need to make child care arrangements while seeing the counsellor/psychologist? If yes, what?

.....

A25 In the last six months, have you been:

(a) an inpatient in a general hospital?

Yes ☐

No ☐

If yes, please specify (where, reason, number of days).

.....

.....

(b) an inpatient in a psychiatric hospital?

Yes ☐

No ☐

If yes, please specify (where, reason, number of days).

.....

.....

(c) an outpatient for any reason?

Yes ☐

No ☐

If yes, please specify (where, reason, number of appointments).

.....

.....

A26 Are you taking any medicines at present which have been prescribed by your doctor?

1 .....

2 .....

3 .....

4 .....

5 .....

A27 Are you taking any other tablets or medicines?

1 .....

2 .....

3 .....

4 .....

5 .....

THANK YOU FOR YOUR HELP

Appendix 3

Therapist's process notes

Identification

T1 Therapist number

T2 Patient number

Appointments

T3 Please indicate the dates and lengths of appointments (including the times when the patient did not show up).

(1) .....

(2) .....

(3) .....

(4) .....

(5) .....

(6) .....

(7) .....

(8) .....

(9) .....

(10) .....

(11) .....

(12) .....

T4 Total number of appointments attended: .....

T5 Total number of appointments missed: .....

T6 Total number of appointments booked: .....

Please answer the following questions after the first therapy session.

T7 Please indicate using the list below what you feel to be the client's problem(s). If you feel there is more than one, please underline the main one.

Please indicate in the second column with a tick those problems you aim to address during therapy.

Please indicate in the third column how successful you think the treatment will be for each problem you have indicated. Please use the scale below.

0 1 2 3 4 5 6

Not work at all — Work moderately well — Work extremely well

PROBLEM	✔ if present	✔ if aim to address	Rate success 0–6
Depression / Feeling low or sad /Weepy			
Anxiety / Nerves			
Stress			
Physical illness			
Work related problem			
Unemployment/redundancy			
Social Problems e.g. housing, financial			
Relationship difficulties			
Family problems			
Problems from childhood			
Bereavement or loss			
Confusion about life or the future			
A feeling of going mad			
Other (please specify)			
Other (please specify)			

Please answer the following questions after the first therapy session.

T8 Is the referral to counselling or psychology appropriate? Please rate the appropriateness of the referral on the scale below.

0	1	2	3	4	5	6
Not at all appropriate			Mixed			Highly appropriate

T9 On a scale of 0 to 6, please rate the patient's motivation to be helped.

0	1	2	3	4	5	6
Not at all motivated			Mixed			Highly motivated

Please answer the following questions after the last therapy session.

T10 How did you rate the rapport between the patient and yourself?

0	1	2	3	4	5	6
Very poor			Indifferent			Very good

T11 How did you like the patient?

0	1	2	3	4	5	6
Disliked a lot			Indifferent			Liked a lot

T12 Please indicate using the list below what you **now** feel to have been the patient's problem(s) when they first came. If you feel there is more than one, please underline the main one.

If you think any **new** problem(s) have developed since referral, please indicate this with a tick in the next column.

Please indicate for each problem the change in the patient's condition, using the scale below.

0 1 2 3 4 5 6

Much worse Same Much better

Please indicate your view of the success of the treatment on the scale below.

0 1 2 3 4 5 6

Did not work at all Worked moderately well Worked extremely well

PROBLEM	Present? ✔	New Problem? ✔	Addressed in therapy? ✔	Change 0–6	Success 0–6
Depression /Feeling low or sad/Weepy					
Anxiety / Nerves					
Stress					
Physical illness					
Work related problem					
Unemployment/redundancy					
Social Problems e.g. housing, financial					
Relationship difficulties					
Family problems					
Problems from childhood					
Bereavement or loss					
Confusion about life or the future					
A feeling of going mad					
Other (please specify)					
Other (please specify)					

T13 Why did the sessions end?

(a) Client's request ☐
(b) End of specified time ☐
(c) Client failed to turn up ☐
(d) Agreement between client and you ☐
(e) Your decision ☐
(f) Suggested further referral ☐
(g) Other, please specify .....
.....

T14 Did the patient get any other professional help during the therapy sessions?

.....

.....

.....

.....

.....

THANK YOU VERY MUCH FOR YOUR HELP

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This report was identified as a priority by the Primary and Community Care Panel.

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The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (http://www.ncchta.org) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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