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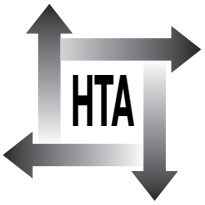

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The research reported in this monograph was commissioned by the HTA Programme as project number 97/43/09. The contractual start date was in May 2000. The draft report began editorial review in May 2004 and was accepted for publication in January 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

A trial of problem-solving by community mental health nurses for anxiety, depression and life difficulties among general practice patients. The CPN-GP study

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Objectives: To compare the effectiveness of community mental health nurse (CMHN) problem-solving and generic CMHN care, against usual general practitioner (GP) care in reducing symptoms, alleviating problems, and improving social functioning and quality of life for people living in the community with common mental disorders; and to undertake a cost comparison of each CMHN treatment compared with usual GP care.
Design: A pragmatic, randomised controlled trial with three arms: CMHN problem-solving, generic CMHN care and usual GP care.
Setting: General practices in two southern English counties were included in the study. CMHNs were employed by local NHS trusts providing community mental health services.
Participants: Participants were GP patients aged 18–65 years with a new episode of anxiety, depression or reaction to life difficulties and had to score at least 3 points on the General Health Questionnaire-12 screening tool. Symptoms had to be present for a minimum of 4 weeks but no longer than 6 months.
Interventions: Patients were randomised to one of three groups: (1) CMHN problem-solving treatment, (2) generic CMHN treatment, or (3) usual GP care. All three groups of patients remained free to consult their GPs throughout the course of the study, and could be prescribed psychotropic drug treatments.
Main outcome measures: Patients were assessed at baseline, and 8 weeks and 26 weeks after randomisation. The primary outcome measure was psychological symptoms measured on the Clinical Interview Schedule – Revised. Other measures included social functioning, health-related quality of life, problem severity and satisfaction. The economic outcomes were evaluated with a cost–utility analysis.
Results: Twenty-four CMHNs were trained to provide problem-solving under supervision, and another 29 were referred patients for generic support. In total, 247 patients were randomised to the three arms of the study, referred by 98 GPs in 62 practices. All three groups of patients were greatly improved by the 8-week follow-up. No significant differences were found between the groups at 8 weeks or 26 weeks in symptoms, social functioning or quality of life. Greater satisfaction with treatment was found in the CMHN groups. CMHN care represented a significant additional health service cost and there were no savings in sickness absence.
Conclusions: The study found that specialist mental health nurse support is no better than support from GPs for patients with anxiety, depression and reactions to life difficulties. The results suggest that healthcare providers could consider adopting policies of restricting referrals of unselected patients with common mental disorders to specialist CMHNs, although there may be other roles in primary care that CMHNs could play effectively. Further research should address the predictors of chronicity in common mental disorders and target extra treatment. More research is also needed into the effectiveness and cost-effectiveness of problem-solving treatment for other disorders, of facilitated self-help treatments for common mental disorders and of CMHN care for people with severe and enduring mental illnesses, as well as the prevention of mental disorders.

Contents

List of abbreviations

A&E	accident and emergency
CBT	cognitive behavioural therapy
CI	confidence interval
CIS-R	Clinical Interview Schedule – Revised
CMHN	community mental health nurse*
CMHT	community mental health team
CONSORT	Consolidated Standards on Reporting Trials
CPA	care programme approach
CPN	community psychiatric nurse
EQ-5D	EuroQol 5 Dimensions
GHQ-12	General Health Questionnaire-12
HADS	Hospital Anxiety and Depression Scale
HADS-A	Hospital Anxiety and Depression Scale – Anxiety subscale
HADS-D	Hospital Anxiety and Depression Scale – Depression subscale
HTA	health technology assessment
ICD-10	International Classification of Diseases (10th revision)
ICER	incremental cost-effectiveness ratio
LOCF	last observation carried forward
NA	not applicable
NSF	National Service Framework
PAS	Problem Appraisal Scale
PCT	primary care trust
PMHW	primary care mental health worker
PS	problem-solving (treatment group)
PSA	problem severity assessment
PST	problem-solving treatment
QALY	quality-adjusted life years
RCT	randomised controlled trial
SAS	Social Adjustment Scale
SD	standard deviation

* Originally we used the term 'community psychiatric nurse (CPN)', but this has been superseded in the NHS by the term 'community mental health nurse', which is used throughout this report.

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Community mental health nurses (CMHNs) care for people living in the community with severe and chronic mental illnesses. They also provide counselling and support for patients with less severe illnesses, who are referred by their GPs. Techniques such as problem-solving treatment may be used to help such patients.

Objectives

The aims of the study were (1) to compare the effectiveness of CMHN problem-solving and generic CMHN care, against usual GP care in reducing symptoms, alleviating problems, and improving social functioning and quality of life; and (2) to undertake a cost–utility, cost-effectiveness or cost-minimisation comparison of each CMHN treatment compared with usual GP care, evaluating not only the direct costs of treatment but also patient costs, including time off work.

Methods

The study was designed as a pragmatic, randomised controlled trial with three arms: CMHN problem-solving, generic CMHN care and usual GP care. General practices in Hampshire and Dorset were included in the study. CMHNs were employed by local NHS trusts providing community mental health services.

Participants were general practice patients aged 18–65 years with a new episode of anxiety, depression or reaction to life difficulties. For inclusion, patients had to score at least 3 points on the General Health Questionnaire-12 screening tool. Symptoms had to be present for a minimum of 4 weeks but no longer than 6 months.

Interventions

Patients were randomised to one of three groups: (1) CMHN problem-solving treatment: a brief structured treatment designed to be given in primary care to help to resolve problems, (2) generic CMHN treatment: nurses were asked to help patients become well as quickly as possible using whatever treatments they were experienced in giving, or (3) usual GP care: GPs were asked to treat the patients as they would normally. All three groups of patients remained free to consult their GPs throughout the course of the study, and could be prescribed psychotropic drug treatments.

Main outcome measures

Patients were assessed at baseline, and 8 weeks and 26 weeks after randomisation. The primary outcome measure was psychological symptoms measured on the Clinical Interview Schedule – Revised. Other measures included social functioning, health-related quality of life, problem severity and satisfaction. The economic outcomes were evaluated with a cost–utility analysis.

Results

Twenty-four CMHNs were trained to provide problem-solving under supervision, and another 29 were referred patients for generic support. In total, 247 patients were randomised to the three arms of the study, referred by 98 GPs in 62 practices. All three groups of patients were greatly improved by the 8-week follow-up. No significant differences were found between the groups at 8 weeks or 26 weeks in symptoms, social functioning or quality of life. Greater satisfaction with treatment was found in the CMHN groups. CMHN care represented a significant additional health service cost and there were no savings in sickness absence.

Conclusions

Specialist mental health nurse support is no better than support from GPs for patients with anxiety, depression and reactions to life difficulties.

Implications for healthcare

The results suggest that primary care trusts could consider adopting policies of restricting referrals of unselected patients with common mental disorders to specialist CMHNs. There may be other roles in primary care that CMHNs could play effectively, for instance consultation and

liaison to support members of the primary healthcare team, or the provision of treatment for patients not responding to self-help or primary care team interventions, in managed stepped care systems, for which there is emerging evidence from the USA. However, this will compete with the need for CMHTs within community mental health teams to deliver the emerging psychosocial therapies for patients with severe and enduring mental illness, such as compliance therapy and cognitive behavioural therapy for moderate to severe depression and psychotic illnesses.

Recommendations for research

The following areas should be considered for future research:

- Research needs to address the predictors of chronicity in common mental disorders, to be able to identify which patients are less likely to recover within a few months with treatment from their GPs alone, and so target extra treatment to those for whom it is needed.
- More research is needed into the effectiveness and cost-effectiveness of problem-solving treatment for other disorders including major depression, deliberate self-harm and personality disorders, and for the prevention of mental disorders.
- More research is needed into the effectiveness and cost-effectiveness of facilitated self-help treatments for common mental disorders.
- More research is needed into the effectiveness and cost-effectiveness of CMHN care for people with severe and enduring mental illnesses.

Chapter 1
Introduction

Background

Community mental health nurses [CMHNs, previously known as community psychiatric nurses (CPNs)] are trained in the care and support of people living in the community who are suffering from severe and enduring mental illnesses, such as schizophrenia. They usually work in community mental health teams (CMHTs) along with other mental health professionals including psychiatrists, psychologists, mental health social workers and occupational therapists. CMHTs may receive referrals of patients from GPs, from inpatient psychiatric units (usually when patients are being considered for discharge), from other inpatient or outpatient facilities [e.g. patients seen by psychiatrists in accident and emergency (A&E)], from social services, from the courts and from other sources.

Whether they work in CMHTs or not, CMHNs will also often take patients referred to them from GPs on an individual basis for specific nurse assessment, and possible treatment, rather than as referrals for assessment by the team as a whole. Given such direct access to CMHNs, GPs like to refer patients to them with non-psychotic, less severe illnesses, including anxiety, depression and life difficulties, for counselling and support.[1–3] For their part, although most CMHNs are not trained in specific therapies for patients with less severe illnesses,[4,5] many report that they consider counselling and potentially preventive work with this group of patients as important parts of their role, especially those CMHNs who have established working patterns that include taking individual referrals directly from GPs as well as referrals via the CMHT.[6]

Potential benefits of direct GP referral to CMHNs

Referral of people with less severe disorders to the CMHN may be beneficial, by saving GP time spent advising and supporting patients, and by reducing GP prescribing of psychotropic medication. CMHN referrals are cheaper than referrals to psychiatric outpatient clinics for this type of help. CMHN treatment can be offered closer to, or in the patient's home and may be less stigmatising for them than attending psychiatric outpatients.[7] Problems may be tackled earlier, preventing significant disability and reducing time spent off work. This may be an important advantage, given the enormous economic burden of anxiety and depression.[8] From the CMHN's viewpoint, taking GP referrals of such patients may give them greater job satisfaction and reduce their risk of 'burnout', since people with less severe illnesses may be more rewarding to treat in some ways than patients with severe mental ill health, substance misuse or personality disorders, who are likely to be much more challenging.[6] However, it has not been established that CMHNs are cost-effective in treating patients with less severe problems, which are often self-limiting.

Potential disadvantages of allowing GPs to refer directly to CMHNs

The main concern is that GP referrals of people with less severe problems divert CMHNs away from the severely mentally ill and are an inappropriate use of a scarce resource. Wooff and colleagues[9] studied CMHN caseloads in Salford and found that, as GP referrals increased over time, the proportions of patients with schizophrenia went down from 39% in 1976 to 23% in 1982, while those with depression went up from 26% to 34%. During the 1990s the quinquennial national CMHN surveys showed that the average nurse's caseload in the UK was around 40 clients, of whom half were described as chronically mentally ill, and just over one-quarter had schizophrenia as a diagnosis.[4,10] This meant that in 1990, extrapolating to the country as a whole, only around 50,000 people with schizophrenia were on the caseload of a CMHN, which was only 20% of the estimated UK total of 250,000 sufferers. In response to these findings, the 1994 Review of Mental Health Nursing in England called for CMHNs to focus on people with severe and enduring mental illness.[11]

This recommendation was in line with the introduction of the care programme approach (CPA),[12] which set out the principles of key workers providing multifaceted care management for patients of the mental health services, prioritised according to the severity of their illnesses. Following the CPA legislation, a greater focus on risk assessment and supervisory roles for mental

health staff with regard to patients with severe mental health problems came with the introduction of discharge guidance and supervision registers.[13] The mid-1990s were therefore characterised by a policy focus on severe and enduring mental health problems, and a shift towards a supervisory culture for mental health nursing.

GP purchasing power

In spite of this, however, the 1996 survey of CMHNs in England and Wales found that the proportion of CMHN referrals received from GPs had increased further to more than 50%, and that the intervention most frequently offered by CMHNs was counselling.[10] A similar picture emerged in Scotland.[14] These increases were probably fuelled by the introduction of the 'internal market' or 'purchaser–provider split' set up by the 1990 National Health Service and Community Care Act,[15] in which GPs became 'purchasers' and secondary care services including CMHTs became 'providers'. GPs could opt to become fundholders and be allocated a budget for purchasing secondary care services directly for their own patients. If they chose not to become fundholders, then the local Family Health Services Authority (later, the Health Authority) purchased secondary care on their behalf. 'Purchasing power' meant that GPs could demand more access to CMHN care for their patients with less severe illnesses, despite the fact that many mental health services were trying to develop policies to prioritise the severely mentally ill. At the same time, CMHNs reported that they were also doing more work with people with severe mental illness, including case management and specific family interventions for schizophrenia.[10] CMHNs were therefore being pulled in different directions and having to take on bigger caseloads.

The need for more research

Only one previous randomised controlled trial (RCT) addressed whether CMHN management of patients with anxiety, depression and life difficulties is more effective than usual GP care.[16] This was a relatively small study, carried out with six general practices in North London, including 36 GPs. Altogether 117 patients were randomised to usual GP care or referral for CMHN care, from 11 nurses in total. Most of the patients recovered within 6 months, no differences were found in psychiatric outcomes between intervention and control groups, and CMHN referral did not save GPs' time. The authors concluded that CMHN referral for such problems was ineffective, and this finding was widely publicised. Less widely quoted, however, was the finding that the economic analysis of the study did show a small but significant difference between the two groups, the CMHN group having fewer days off work.[17] This study suffered from a relatively small sample size and a high dropout rate of more than 25%. Outcome data were reported from only one follow-up point, at 6 months, and so the study may have missed advantages of CMHN referral in the shorter term. Therefore, it did not satisfactorily establish whether it is cost-effective or not for GPs to refer patients with anxiety and depression to CMHNs.

Specific therapy versus non-specific support

It is important also to consider what CMHNs actually do with such patients referred to them. One reason why the earlier trials of psychological interventions such as counselling proved inconclusive was thought to be that therapy was non-specific and poorly defined.[18] Other studies suggested that specific interventions for depression and anxiety in primary care were effective when delivered by psychiatrists and trained primary care physicians, including problem-solving treatment (PST) for life difficulties and behavioural treatment to improve patients' coping strategies.[19,20] Problem-solving is a brief structured treatment that helps patients to resolve problems through seven stages.

Such intervention is too time-consuming to be routinely delivered by GPs, however, and referral to a psychiatrist is relatively expensive. Subsequent research therefore addressed whether PST could be delivered by nurses. Problem-solving by non-mental health community nurses, including four practice nurses, one district nurse and one health visitor, proved less successful than psychiatrist or GP problem-solving, compared with usual GP care.[21] There were at least two possible reasons for this. First, non-mental health nurses are usually employed to help patients with physical health needs, or health promotion, or both. They are not usually trained in mental health nursing, and do not necessarily have the aptitude for working with people with anxiety and depression. Second, the less successful result may have been due to the inclusion in the nurse trial of patients with a range of emotional problems rather than only patients with major depression. Some of the patients had very minor symptoms, and were likely to recover relatively quickly whether or not they received treatment, suggesting that a minimum severity of symptoms may be a predictor of benefit.

Therefore, it was important and timely for this study to address whether CMHN treatment for anxiety, depression and reactions to life difficulties was more effective, and more cost-effective, than usual GP care. If referral proved not to be cost-effective, the Department of Health could then give authoritative advice to GPs not to refer patients with these types of problems to CMHNs. If specific therapy (i.e. problem-solving) was more effective than usual GP care, but non-specific CMHN care was not, then mental health trusts might consider developing services to offer problem-solving, and GPs might be allowed to refer for such specific therapy.

Hypotheses and aims

The study was therefore designed to test two null hypotheses:

- that non-specific ('generic') CMHN care is no more effective for anxiety, depression and reactions to life difficulties than usual GP care (which would serve to confirm the findings of the one previous trial in this area[16])
- that PST given by specially trained CMHNs is no more effective for such problems than usual GP care (which would address whether PST delivered by mental health nurses could be effective for a broad range of emotional problems of relatively mild severity, unlike when it was delivered by non-mental health nurses[21]).

The study had two primary aims:

- to compare the effectiveness of each nurse treatment against usual GP care in reducing symptoms, alleviating problems, and improving social functioning and quality of life (including an assessment immediately after treatment had been given, to determine whether it conferred an early advantage, as well as a later assessment at 6 months, as in the previous trial)
- to undertake a cost–utility, cost-effectiveness or cost-minimisation of each treatment compared with usual care, evaluating not only direct costs of treatment but also patient and employment costs, including time off work.

A secondary aim was to explore whether scores on rapid self-report questionnaires, which are feasible for patients to complete in routine general practice, could help to predict which patients may benefit from referral for CMHN treatment.

Initially, the aim was to include all patients regardless of their level of symptoms. However, in light of the findings of the previous study of PST delivered by community nurses referred to above,[21] together with evidence from counselling studies that active intervention seemed to have an advantage over usual care only for patients with a minimum severity of symptoms,[22] a minimum level of symptoms was set for inclusion in the study, to avoid including patients with very mild problems who were likely to recover quickly without treatment.

Chapter 2
Method

Introduction

The original design will be presented, followed by a section detailing the changes that were made to the protocol in response to problems encountered or other developments during the course of the study. The original design was published in a peer-reviewed journal early in the course of the study.[23]

Design

A pragmatic RCT was set up with three arms: CMHN problem-solving, generic CMHN care and usual GP care.

Setting

General practices in Hampshire and Dorset were recruited to refer patients to the study. The participating CMHNs were employed by local NHS trusts providing community mental health services to the referring practices. The setting was therefore much closer to 'real life' than research studies employing only volunteer therapists, who are likely to be more enthusiastic. However, referrals to the study were kept separate from the trusts' routinely provided services, to avoid having any waiting lists for treatment, and avoid referrals being turned down because patients did not meet any referral criteria that may have applied to the routine service. To maximise the generalisability of the study, the aim was to recruit practices and trusts with catchment areas that included inner city areas of Southampton (with relatively high levels of social deprivation and a significant proportion of people from ethnic minority communities), as well as more suburban areas in Southampton, Bournemouth and Poole, and more rural areas of Hampshire and Dorset.

Ethical approval

Ethical approval for the study was granted by the four local NHS research ethics committees covering the trusts' catchment areas: Southampton and South West Hampshire; East Dorset; North and Mid Hampshire; and Isle of Wight, Portsmouth and South East Hampshire.

Recruitment, randomisation and training of CMHNs

The original plan was to recruit 40 CMHNs from two mental health NHS Trusts: Southampton Community Health Services NHS Trust and Dorset HealthCare NHS Trust, and randomise 20 to each nurse treatment arm. The CMHNs were advised that they could either conduct the work during their contracted hours, with their trust being reimbursed for their time, or conduct the work in their own time and be paid personally for the hours worked. Excess treatment costs for the CMHN interventions were awarded by the Department of Health, through a central subvention, as otherwise the trusts could not have provided the extra treatment needed. All CMHNs who joined the study at the beginning were randomly allocated to one of the two CMHN treatment groups. The random allocation was conducted by the trial statistician (RP) and was stratified by locality to ensure that sufficient nurses in each locality were available for each CMHN treatment arm. As nurses left the study, other nurses were recruited to replace them, and assigned rather than randomised to treatment arm, in order to maintain sufficient nurses to take referrals to the study in each catchment area.

Problem-solving training programme

Those allocated to the problem-solving treatment (PS CMHN) group received training at the start of the study (see the training programme below) and induction in the study procedures. The training of the nurses assigned to the problem-solving group consisted of:

- a 3-day training course
- treatment under supervision of five patients using PST
- a follow-up half-day training session.

Problem-solving supervision continued throughout the study. The three day problem-solving training was led by a consultant psychiatrist (LMW) and a clinical nurse specialist in behavioural psychotherapy

(ID). Both had devised and led previous training courses in problem-solving. They were assisted by three clinical nurse specialists in psychological treatments (DE, AF and JD), who assisted in the training course and provided the supervision for the training patients.

The 3-day training course consisted of the following components:

- a theoretical introduction to problem-solving, setting out the rationale for the treatment and the evidence supporting its use
- information about the morbidity of psychiatric disorders in primary care
- a detailed description of the PST supported by role play and a training videotape
- participant role play, under supervision, of all seven stages of problem-solving
- preparing a videotape of a role-play, problem-solving session
- giving and receiving feedback on videotapes
- review of potential difficulties with PST
- explanation of study procedures.

Following the completion of the 3-day training course, the CMHNs treated five patients each under supervision. Supervision was provided fortnightly in groups of two or three. The nurses were asked to audiotape treatment sessions. These audiotapes were used alongside written notes to facilitate the supervision process.

A follow-up half-day training session was provided before the nurses started to treat patients in the study, to address any continuing concerns that the nurses might have had about the treatment. The session was also used to share good practice and resolve any difficulties that might remain.

Generic CMHN induction

Those allocated to the generic CMHN group were inducted in the study procedures and asked to treat the patients referred to them in whatever way they felt was appropriate. The nurses were advised at recruitment that all those in the generic CMHN group would be offered training in problem-solving at the end of patient recruitment, so they would not be disadvantaged whichever way randomisation turned out for them.

Recruitment of GPs

The previous work on problem-solving[21] and generic CMHN care[16] suggested that, on average, each GP would refer around seven patients in a recruitment period of 21 months. Therefore, the original aim was to recruit 65 GPs to reach a target of 460 patients referred (see sample size section below). Previous experience suggested that an average of two GPs per practice would refer patients, and so the aim was to recruit at least 33 practices in the two participating trusts' catchment areas.

All practices in the two trusts' areas were invited by letter to participate in the study and followed up by telephone contact through their practice managers. If the practice expressed interest a visit was arranged to explain the project in greater detail. The study coordinator (LS) carried out the visit, accompanied where possible by a clinician (TK, LMW or CT). Once GPs agreed that they would refer patients to the study, a further visit was undertaken to induct the GPs in the study protocol. Specific, brief referral documentation was provided, designed to minimise the paperwork for the GPs in referring patients, along with a supply of patient information leaflets (see Appendix 1). In addition, laminated coloured reminder cards of the patient inclusion and exclusion criteria were provided for their offices, to facilitate the referral procedure.

Recruitment of patients

Patients meeting the inclusion criteria (see below) were identified by their GPs in the course of normal surgeries, and referred by fax or telephone to the study coordinator. The GP was responsible only for identifying patients and obtaining permission to make the initial referral, reducing the need for lengthy explanations and obtaining consent during the consultation. Patients were given an information leaflet from the GP and told to expect contact from the research team within the next week.

Eligibility, consent and treatment allocation procedures

After referral from the GP those patients who agreed were visited by a researcher. This was in their home, the GP surgery or any other place convenient to the patient. The researcher asked the patient to reread the information sheet, explained the study procedures and checked the inclusion criteria. Patients were then asked to give written consent. The researcher proceeded to supervise the patient in the completion of the baseline assessment booklet. Once the baseline

assessment was complete the researcher contacted the study office to ask a second member of the research team to carry out the random allocation procedure (see below).

Inclusion and exclusion criteria

The study population consisted of patients aged 18–65 years with a new episode of anxiety, depression or reaction to life difficulties. This age range was chosen because, if treatment was successful, the greatest economic benefits were likely to be seen in patients of working age, so the research efforts were concentrated on this group. In the initial proposal, no minimum severity criterion was planned, but before the trial started a decision was made to include one, as a number of studies of counselling, as well as the previous trial of PST delivered by non-mental health nurses, had suggested that patients with symptoms below a minimum threshold would improve quickly without treatment anyway, and dilute the demonstrable effects of psychological treatment.[21,24] Therefore, for inclusion, patients had to score at least 3 points on the General Health Questionnaire-12 (GHQ-12) screening tool (see below). Symptoms had to be present for a minimum of 4 weeks, as previous research had shown that those with symptoms for at least 4 weeks were likely to remain unwell for some months.[25] A maximum duration of 6 months was set, to avoid the inclusion of patients with more chronic disorders.

Patients already in contact with psychiatric services, or receiving psychological treatments, were excluded, as well as those who would be unable to complete the trial because of spoken and written English that was insufficient to complete the questionnaires, or owing to coexisting severe illnesses or temporary residence.

Inclusion criteria:

- patients aged 18–65 years
- presenting with a new episode of anxiety, depression or reaction to life difficulties
- having a minimum duration of symptoms of 4 weeks
- having a maximum duration of symptoms of 6 months
- scoring 3 or above on the GHQ-12.

Exclusion criteria:

- patients already in current contact with psychiatric services
- patients already receiving psychological treatments from other sources
- patients with severe mental illnesses such as schizophrenia, manic–depressive psychosis, severe substance misuse, dementia or severe depression with active suicidal ideas
- housebound patients
- patients without the spoken and written language skills necessary to take part
- seriously ill and terminally ill patients
- temporary residents.

Randomisation of patients

Remote central randomisation was provided by telephone. The initial plan was to use the Clinical Trials Unit at Oxford, but they were unable to provide the service in the event, so the telephone randomisation service at the University of York was contracted. Randomisation was stratified by referring practitioner. This was because referral rates for psychological treatments vary widely between practitioners, despite relatively similar rates of psychological disorders among their patients,[26] suggesting that GPs vary widely in their selection criteria for referral. Patients referred by one practitioner may therefore differ as a group from another practitioner's referrals, in terms of the type of problem from which they are suffering, or in the severity of their symptoms. A separate schedule was therefore established for each practitioner, to control for possible differences in patient selection. Randomisation sequences were in block sizes of either three or six, to prevent practitioners from guessing to which arm the next referral would be randomised.

Trial arm allocation was given to the second researcher over the telephone immediately. If the patient was allocated to one of the CMHN groups the second researcher would identify and contact the appropriate CMHN to obtain agreement to take the referral. The patient and GP would then be informed of the trial arm allocation, within 1 week of being enrolled.

Blindness

The authors believed, on the basis of experience in the previous trial of nurse problem-solving,[21] that it would be possible in the large majority of cases for the interviewing researcher to remain blind to the patient's allocation to treatment arm. The second researcher who contacted the randomisation service was therefore instructed not to discuss the patient's allocation with the first

researcher who had enrolled the patient and conducted the baseline assessment. The first researcher would then conduct the follow-up assessments, wherever possible, remaining blind to the trial arm allocation. Patients were reminded not to reveal their allocation at the follow-up assessments. Researchers were asked to record incidents of loss of blindness either before or after the assessment, together with the reason for this. This included whether they knew to which trial arm the patient had been allocated or whether they knew that the patient had received CMHN care but were not certain of the specific arm.

Interventions

CMHN problem-solving treatment

Problem-solving is a brief structured treatment that helps patients to resolve problems through seven stages:

1. explanation of the treatment and its rationale
2. clarification and definition of the problems
3. choice of achievable goals
4. generation of alternative solutions
5. selection of a preferred solution
6. clarification of the necessary steps to implement the solution
7. evaluation of progress.

Treatment comprised an initial 1-hour session and five follow-up sessions of 30–45 minutes. Ongoing group supervision of the nurses was carried out by clinical nurse therapists experienced in problem-solving. All CMHNs in this group were asked to record treatment sessions on audiotape to allow for a check on the integrity of treatment.

Generic CMHN treatment

Nurses in the generic CMHN treatment arm were asked to help patients become well as quickly as possible using whatever treatments they were experienced in giving, which could include counselling and support. They were asked to offer patients the same number of therapy sessions as the problem-solving CMHNs: a 1-hour initial assessment followed by five follow-up sessions of 30–45 minutes. The CMHNs in this arm did not receive any supervision over and above the supervision that they usually received in their trust post.

Treatment sessions were offered at a place convenient to the patient. This could be their home, GP surgery or other NHS location, for instance the CMHN base.

Usual GP care

Participating GPs were asked to treat the patients as they would normally in the usual care arm. However, they were asked not to refer patients in the usual GP care arm to a psychological therapist during the study period, unless absolutely necessary.

All three groups of patients remained free to consult their GPs throughout the course of the study, and could be prescribed psychotropic drug treatments.

Assessments

Patients were assessed at baseline and at 8 and 26 weeks after the baseline interview. All patients were asked to a face-to-face interview to complete the follow-up measures. Again, this was at a location convenient to them: their home, the GP surgery or other.

At the baseline interview, patients completed a socio-demographic questionnaire specially designed for the study, including questions on their age, gender, ethnic group, marital status, employment status, occupation (for categorisation of social class), educational attainment, type of accommodation, number of children, past history of mental health problems and treatment received, and family history of mental health problems (see Appendix 2).

Psychiatric symptoms

The Clinical Interview Schedule – Revised (CIS-R) was chosen as the primary outcome because it is a standardised schedule suitable for use by interviewers who are not trained in psychiatry, like the researchers with backgrounds in nursing (LS, JH) or psychology (CG, BP) who assessed the patients in this study. It covers the whole range of symptoms in the area of anxiety, depression and reactions to life difficulties, and it has been shown to be reliable in a primary care setting. The schedule can be used both to provide a total symptom score and to generate a diagnosis according to the International Classification of Diseases (ICD-10)[27] using the algorithm used in the Office of Population Censuses and Surveys (OPCS) national surveys of psychiatric morbidity in Great Britain.[28] The computerised version of the CIS-R (PRQSY3), which is self-complete, was used in the present study.

In addition, the GHQ-12 and Hospital Anxiety and Depression Scale (HADS) questionnaires were completed.[29,30] These questionnaires were used to explore whether scores on rapid self-complete questionnaires could help to predict which

patients might benefit from referral to CMHNs. Patients had to score a minimum of 3 on the GHQ-12 to be included in the study. The HADS gives scores for both depression and anxiety.

Social function

This was measured using the modified Social Adjustment Scale (SAS), a 45-item scale measuring functioning in seven role areas: work outside the home, household tasks, social and leisure activities, the extended family, marriage, children, and the family unit.[31]

Problem Appraisal Scale

The Problem Appraisal Scale (PAS) rates the patient's problems from 1 (none) to 5 (very severe or extreme) in ten areas: parenting, relations with partner, relations with other family members, relations with others, school, employment, housekeeping, social withdrawal, dependency and leisure time. It was used in the previous trial of non-mental health community nurse PST.[21]

The CIS-R, GHQ-12, HADS, SAS and PAS were all to be completed at baseline, and at the 8- and 26-week follow-up assessments.

Patient preference

If patients do not receive the treatment they prefer, their outcome may be adversely affected.[32] Patients' treatment preferences were therefore measured at baseline, after patients had been given a brief description of the treatments being compared, and had given informed consent to be randomised, in order to analyse whether receiving or not receiving their preference for treatment arm was associated with outcome.

Patient satisfaction

This was measured at the 26-week follow-up, using a self-report questionnaire especially designed for the evaluation of PST and used in the previous study of non-mental health community nurses.[21] This 11-item questionnaire asks patients to rate on a five-point scale their agreement with a series of statements about the treatment they have received. To calculate a total satisfaction score from the questionnaire the sum of the scores from ten items was calculated (one item referred only to CMHN treatment and was therefore excluded from the total). Therefore, the lowest satisfaction score could be 10 and the highest 50.

Healthcare resources and other economic data

The healthcare costs of interest to the evaluation were: (1) direct costs associated with usual GP care; (2) costs associated with the interventions (treatment costs for both problem-solving CMHN and generic CMHN care, and the training and supervision costs for the problem-solving nurses); and (3) other NHS costs incurred over the course of 6 months of follow-up.

Patient-related costs such as expenditure on over-the-counter medications or other out-of-pocket health treatments, and employment-related costs arising over the trial period were also investigated.

The volume of healthcare resources [e.g. frequency of professional consultations (except for CMHNs) or visits to a health facility] and patient-related resources (i.e. number of days off paid work or days unable to undertake usual activities) were mostly captured using a resource-use questionnaire administered at baseline, and at the 8- and 26-week follow-ups (see Appendix 2). During the baseline interview patients were asked to recall their contacts with the health service over the previous 4-week period, as it was important to compare the similarity of patients at the start of the trial. Follow-up interviews asked patient to recall contacts for the intervening periods. To help patients to provide valid responses a 'crib sheet' was administered during the baseline interview which explained to patients the type of information they might be expected to provide at future interviews.

Information on the frequency of consultation with the GP, medication prescribed and other referrals made was extracted from the patient's general practice medical records after the 26-week follow-up was completed, to cross-validate data collected from the patient at interview and ensure that they were as complete as possible.

Special attention was paid to the measurement of CMHN contacts. Both groups of CMHNs were required to complete a contact recording sheet for each patient treated; this documented the number of contacts for each patient over the whole course of the study; where they took place (i.e. at the GP surgery, patient's home or elsewhere), and time spent travelling to and from the patient.

The training of CMHNs in problem-solving was also costed. Training costs included the total trainers' time spent at the course, and the preparation and travel and accommodation costs incurred by the trainees. These were presented as a total training cost per nurse. In addition to training costs, a cost per nurse for ongoing supervision of problem-solving CMHNs was

separately identified. To allocate the full costs of problem-solving CMHN intervention costs across the patients randomised to that trial arm, two key assumptions were required. Training was assumed to remain relevant for 4 years before a refresher course was required, and the average caseload of a CMHN was estimated at 20 patients per year. These details enabled costs of training and supervision to be allocated to patients.

Health-related quality of life

A generic health-related quality of life measure extensively used in UK and European-based economic evaluations, the EuroQol 5 Dimensions (EQ-5D) instrument, was used to assess the impact of the trial on quality-adjusted life-years (QALYs).[33] The instrument provides information on five health-related quality of life dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three possible answers: no problems, some problems or severe problems, yielding a combination of 243 possible health state descriptions (see Appendix 3).

Patient-level health states can be converted into a utility level using a published tariff of utility weights for a representative sample of the UK population.[34] In this study mean utility levels were calculated for health states reported at each assessment (baseline, 8-week follow-up and 26-week follow-up), and these points were joined by straight-line interpolation. The resulting area under the utility profile was then calculated and this represented the mean number of QALYs achieved per arm over the trial period. From this it was possible to estimate the QALYs gained for each intervention.

Sample size calculation

The primary outcome measure was the level of psychological symptoms measured using the CIS-R. The mean and standard deviation of the baseline CIS-R score, found in the previous trial of problem-solving by non-mental health community nurses, were approximately 19 and 10 points, respectively.[21] Based on these figures it was originally estimated that 121 evaluable patients would be needed in each group to give 80% power to detect a difference between groups of 4 points on the CIS-R[35] performing treatment comparisons using two-sided tests at the 2.5% level of significance, incorporating a Bonferroni correction to take into account the two planned contrasts between the three groups. Differences that were less than 4 points were considered to be too small to be of clinical importance. To obtain evaluable data on 121 patients in each group at 26 weeks, the plan was to recruit 153 patients per group, making allowance for an anticipated dropout rate of 20%, which was the rate found in the previous nurse PST trial.[21] Therefore, the original plan was to recruit about 460 patients in total. This sample size calculation was subsequently revised during the trial recruitment period (see section 'Recalculation of required sample size', p. 12).

Data entry

Data entry was continuous throughout the study. The researchers were supplied with laptop computers for the completion of the CIS-R with patients and these data were read directly into a database (by SH). Other data collected from patients were entered on questionnaires for scanning directly into databases with the Formic software package. Data were scanned and 20% checked for accuracy (by LS and SH). An error rate ranging from less than 0.1 to 0.3% was found, giving the research team confidence in the accuracy of the scanning process. Data extracted from general practice medical records were entered directly into a database at the surgery via the laptop computer.

Analysis

Descriptive statistics were used to describe the treatment groups at baseline.

Clinical outcomes

Analysis was conducted on an intention-to-treat basis, incorporating patients in their allocated group irrespective of their attendance at sessions. The primary outcome, CIS-R, was compared between each of the two nurse-led groups (generic CMHN care and problem-solving CMHN care) and the usual GP care group, in an analysis of co-variance incorporating patients' baseline CIS-R scores and the GP by whom they were referred. The two contrasts of primary interest were generic CMHN care versus GP care, and problem-solving CMHN care versus GP care, and mean differences with 95% confidence intervals (CIs) were estimated controlling for baseline CIS-R and GP. The other clinical and social outcome measures were analysed in the same way. Separate analyses were carried out for the 8- and 26-week assessments, so that any changes over time could be assessed.

Economic analysis

A cost–utility analysis was undertaken. This compared the incremental NHS and patient costs per QALY gained, per patient, over the 6 months from randomisation for (1) generic CMHN care compared with usual GP care, and (2) problem-solving CMHN care compared with usual GP care.

The total cost of care per patient was calculated by summing the product of each resource-use category and its associated unit costs, and an average was then calculated across all patients in each arm of the study. Mean cost differences and 95% confidence intervals were calculated for the comparisons.[36] Owing to the expected skewness in the distribution of cost data, non-parametric bootstrap confidence intervals were computed.[37] The null hypothesis of no mean difference in costs was also tested using parametric techniques.

Mean QALY differences and associated 95% confidence intervals were computed. The null hypothesis of no mean difference in QALYS was tested using standard parametric techniques. Incremental mean utility levels (with associated standard deviations and 95% confidence intervals) at each follow-up point were also computed. The distribution of EQ-5D responses across the different levels of each dimension was calculated and differences between the relevant trial arms were analysed using a categorical χ^2 test.

Cost results from this analysis were validated by substituting where possible data from the GP case notes in place of imputed values for missing data, and repeating the analysis.

Changes to the original protocol

This section describes the changes made to the planned protocol in response to developments and contingencies encountered in putting it into practice.

Recruitment of CMHNs

The first round of CMHN recruitment did not yield the sufficient number of CMHNs for the study and it became apparent at an early stage that there would be a certain amount of attrition of CMHN numbers. Data on the specific reasons why nurses declined to participate or left the trial were not gathered, but the impressions were that these included the pressured nature of their workload, disinterest in primary care work, commitment to other initiatives or training programmes, and unwillingness to work additional hours. Therefore, two further rounds of recruitment were conducted, each including two more NHS trusts. The second round included Winchester and Eastleigh NHS Trust and Salisbury HealthCare NHS Trust (New Forest area). The third round included Portsmouth HealthCare NHS Trust and Surrey Hampshire Borders NHS Trust (Hampshire area). Because of the attrition of nurse numbers experienced in the first round it was decided that recruitment would not stop at 40 nurses but that all willing CMHNs would be recruited.

Introduction of a pilot stage while the problem-solving nurses were being trained

To recruit a suitable pool of patients for the CMHN training in problem-solving, the participating GPs were initially asked to refer patients meeting the criteria to receive problem-solving from a CMHN in training. This training period afforded the opportunity of piloting all of the research procedures and assessments before the main trial began. These patients were visited by a researcher to obtain consent and complete the baseline assessment, and then allocated to one of the CMHNs in training for up to six sessions of PST, but were not followed up further.

GP recruitment

As the trial expanded with the inclusion of more NHS trusts, further GP recruitment was necessary to ensure that patients were referred as close to participating CMHNs as possible. Therefore, three further rounds of GP recruitment followed the rounds of CMHN recruitment, and again recruitment continued beyond the planned 65 GPs, to include all those willing.

Generic CMHN treatment

Nurses in the generic CMHN group were asked to record their treatment sessions on audiotape. This was introduced to check what type of treatment was actually offered by these nurses.

Usual GP treatment

A change was made to the protocol in this group because many participating GPs had access to counselling services, but often with a waiting list of 8 weeks or more. Asking the GPs not to refer to those services for the whole 26 weeks of follow-up would have meant asking them to withhold a treatment usually available to their patients, which many were unwilling to do. Therefore, as a compromise, GPs were asked and agreed not to refer to counselling within the first 8 weeks of the trial period, which covered the treatment phase,

so that at the first follow-up the CMHN arms could be compared with GP care only.

Assessments

Problem severity assessment

It was decided to assess the severity of patients' problems using a modified version of the Problem Severity Assessment (PSA) scale, an ordered metric scaling technique.[38] This involved asking the patient to identify two important problem areas and rate these at baseline and follow-up, on a seven-point scale. This measure was used instead of the PAS specified in the original protocol, as it allowed for individual identification of problems rather than rating generic problem areas.

Additional satisfaction questions

Feedback questionnaires were given to patients at the 8- and 26-week follow-up points. These included open-ended questions about the patients' views of the treatment that they had received through the study, as follows:

- What do you think has been important in treating your problems?
- Are there any treatments you have not received that you feel would have been useful in treating your problems?
- Do you have further comments?

Questionnaires were left with all patients at the 8- and 26-week follow-up interviews, with a Freepost envelope for returning to the study secretary. This was done to prevent the patient discussing their treatment allocation with the interviewer, who was attempting to remain blind to treatment allocation.

Table 1 summarises the revised schedule of assessments carried out at each time-point.

Recalculation of required sample size

After 12 months of patient recruitment to the main trial, it was apparent that the rate of recruitment was considerably slower than anticipated, even though the study had recruited more than the number of GPs planned. It was necessary to look again at the likely sample size that could be obtained, in the event of this slower than anticipated recruitment rate, to consider whether sufficient power might be obtained for the main comparisons, and whether therefore the study should continue.

In practice the scores obtained on the CIS-R for the first 60 patients completing follow-up were different to those used in the sample size calculation. The standard deviation at baseline was 10.6, close to the value of 10 that had been anticipated, but the mean value was 25, considerably higher than the 19 obtained in the previous community nurse problem-solving study[21] on which the original power calculation was based. This was probably because of the introduction of the minimum severity criterion, which meant that the patient group was more symptomatic than the population of the previous study. It was thought likely therefore that larger differences between the groups might be found, given the higher mean value at baseline. A recalculation of the required sample size using an expected difference of 5 points on the CIS-R, rather than 4, suggested that, for 80% power at the 5% significance level, 65 patients completing follow-up in each arm would be required. To ensure 65 completers in each of the three arms, 246 patients would need to be recruited to the study, allowing for the anticipated 20% dropout rate, to leave a total of around 195 at the 26-week follow-up.

It was concluded that a final sample size of 246 randomised patients, which was achievable in the remaining time, would give sufficient power for

TABLE 1 *Summary of research assessments*

Instrument	Baseline	8-week follow-up	26-week follow-up
Socio-demographic questionnaire	+		
CIS-R	+	+	+
GHQ-12	+	+	+
HADS	+	+	+
SAS	+	+	+
PSA	+	+	+
Patient preference	+		
Patient satisfaction scale			+
Patient views on treatment		+	+
Health service resource use	+	+	+
EQ-5D	+	+	+

the two planned primary comparisons between the groups, and therefore that the study should continue. In this revised calculation it was decided to omit the Bonferroni correction, as a review of significance levels used in other similar studies with more than one prime comparison suggested it was not routinely applied, and so this was judged to be unnecessary. In any event, the authors considered that the robustness of the results could be judged from the 95% confidence intervals around the estimates of differences.

Telephone and postal follow-up

The researchers were advised by Professor Shah Ibrahim, during an HTA programme study monitoring visit, to consider telephone and postal patient assessments, to try to ensure 80% follow-up at 6 months. The follow-up procedure was therefore adapted just over halfway through the trial, to try to maximise follow-up rates for those patients who declined the face-to-face interview. In these cases the patients were asked to complete partial assessments over the telephone, prioritising the GHQ-12 and EQ-5D. If this was declined or the patient did not respond to telephone contact, a postal questionnaire was sent to both the patient and their GP (in case the patient had moved address but continued to consult with the GP), with a Freepost envelope provided.

Chapter 3

Recruitment rates, delivery of interventions and follow-up rates

Recruitment of CMHNs

As explained in Chapter 2, CMHN recruitment to the trial took place in three rounds. *Table 2* details the number of CMHNs recruited in each round. Nurses began to drop out from the study during the training period for round 1, which necessitated the further rounds of recruitment. In total 53 CMHNs joined the study, of whom 21 left before it was completed. Of those who left the study before completion 13 were from the generic CMHN group and eight were from the PS CMHN group. The reasons for leaving across both groups were: moving to new post (12), unable to do further additional work (five), sick leave (two) and dislike of the trial work (two, one from each CMHN group). The higher attrition rate found in the generic CMHN group was believed to be due to the lower commitment to the study these nurses felt without the initial PST training. While taking part in the study three nurses were also participating in the Thorn training course (on psycho-social interventions). None of the nurses was participating in another research study at the same time as this one.

Of the 24 recruited in round 1, 12 were randomised to provide generic care (generic CMHN group) and 12 to provide PST (PS CMHN group). As CMHNs dropped out, newly recruited nurses were allocated arms to maintain sufficient numbers of nurses in each arm, in each geographical area. Overall, by the end of the study, 24 were assigned to the PS CMHN group and 29 to the generic CMHN group.

Most CMHNs were employed at nursing G grade (27), with three at H grade, and the remainder at F (17) or E (six) grade. Six CMHNs had completed the English Nursing Board CMHN course (or equivalent). The most common training courses in which the CMHNs had participated were cognitive behavioural therapy (CBT) (20) and counselling (17). However, these were usually brief courses at an introductory level, with only seven (five in the generic CMHN group and two in the PS CMHN group) nurses having a recognised counselling qualification and none having undergone full CBT training to the level required for national accreditation. Other brief training courses reported by the CMHNs were motivational interviewing, dialectic behavioural therapy, anxiety management, anger management, neurolinguistic programming, psychosocial interventions and brief therapy/problem-solving.

Recruitment of GPs

Altogether, 241 GPs, from 62 general practices across Hampshire and East Dorset, stated that

TABLE 2 *CMHNs, GPs and patients recruited to the trial by trust area (number)*

NHS trust[a]	CMHNs	GPs	Patients referred	Patients recruited
Southampton Community	8	68	91	60
Dorset HealthCare	16	42	122	87
Round 1 total	24	110	213	147
Winchester and Eastleigh	11	39	55	32
Salisbury (New Forest area only)	2	6	11	8
Round 2 total	13	45	66	40
Surrey Hants Border	5	41	53	31
Portsmouth HealthCare	11	45	42	29
Round 3 total	16	86	95	60
Total	53	241	374	247

[a] Owing to NHS trust reconfigurations some of these trusts have since merged or changed names.

TABLE 3 *Characteristics of GP practices (n = 62)*

Practice list size	Mean (range)	8601 (2240–27,239)
Number of principals	Mean (range)	5 (1–15)
Practice location	City	18 (29)
	Suburban	33 (53)
	Rural	11 (18)
Mental health practitioners working on premises	Psychiatrist	11 (18)
	CMHN	15 (24)
	Psychologist	9 (15)
	Social worker	1 (2)
	Counsellor	41 (66)
	Other	4 (7)

Figures are *n* (%) unless otherwise stated.

they would refer patients to the trial. In the event, 143 of these GPs (60%) did not refer any patients to the trial. The remaining 98 GPs referred at least one patient each to the main part of the trial. Of these, 35 GPs referred only one patient to the trial, with the mean number of referrals being 3.8 (range 1–22). *Table 2* details the GPs recruited by trust area and *Table 3* shows the characteristics of the practices in which the GPs were based.

Recruitment of patients

Training and piloting phases

As described in Chapter 2, training and pilot phases were included for the CMHN training in problem-solving. These took place from September 2000 to January 2001, January 2001 to May 2001 and November 2001 to March 2002 for each of the three phases of CMHN recruitment. In total 145 patients were referred to the training phases. Of these, 117 consented to having problem-solving from a CMHN in training, and 22 refused. Of those patients consenting, 100 were seen by a CMHN for an average of four (SD 1.8) sessions each.

Main trial

Recruitment of patients to the main trial took place between February 2001 and April 2003. During this period 374 patients were referred to the trial by their GP, with 247 patients randomised to the trial. See *Figure 1* for details of the referral and randomisation numbers in accordance with the Consolidated Standards on Reporting Trials (CONSORT) statement.[39]

The slight imbalance between numbers in the three arms, with more patients being randomised to the PS CMHN group, arose by chance, owing to the stratification by referring practitioner and the fact that in the event many of the GPs referred only one or two patients each.

Patient characteristics

Table 4 details the socio-demographic characteristics and past history of psychological problems of all randomised patients at baseline. There were no obvious differences apparent between the trial groups on these characteristics.

Table 5 details the baseline diagnoses generated by the CIS-R according to the ICD-10 system. Around 40% of the sample had mixed anxiety and depressive disorder, with around 30% meeting the criteria for a diagnosis of moderate or severe depressive episode. A relatively small number of patients in each group was suffering from primarily anxiety disorders.

Data collection and follow-up rates

Timing of follow-up assessments

The first follow-up was scheduled for 8 weeks (56 days) after baseline and the second at 26 weeks (182 days) after the baseline assessment. Assessments were often delayed, however, owing to the patients' lack of availability at the planned time of follow-up. *Table 6* details the timing of follow-up assessments.

Figure 1 details the follow-up rates for each time point. Overall follow-up rates were 86% at 8 weeks and 76% at 26 weeks. However, as *Figure 1* indicates the follow-up rates were not the same in all groups of the trial. Fewer patients in the GP

TABLE 4 *Patients' socio-demographic characteristics*

		GP (*n* = 78)	Generic CMHN (*n* = 79)	PS CMHN (*n* = 90)
Age (years)	Mean (SD)	34.9 (11.77)	34.2 (11.33)	35.8 (10.92)
	Range	18–64	18–64	18–62
Gender	Male	24 (31)	24 (30)	25 (28)
	Female	54 (69)	55 (70)	65 (72)
Ethnic group	White	75 (96)	76 (96)	90 (100)
	Non-white	3 (4)	3 (4)	0 (0)
Marital status	Married/cohabiting	37 (48)	46 (58)	54 (60)
	Widowed/divorced/separated	14 (18)	7 (9)	10 (10)
	Single	27 (35)	26 (33)	26 (29)
Social class	I	2 (3)	2 (3)	4 (4)
	II	22 (28)	25 (32)	25 (28)
	III (non-manual)	18 (23)	22 (28)	23 (26)
	III (manual)	14 (18)	14 (18)	18 (20)
	IV	12 (15)	10 (13)	12 (13)
	V	5 (6)	1 (1)	6 (7)
	Missing	5 (6)	3 (4)	2 (2)
Employment	Full-time work	36 (46)	40 (51)	34 (38)
	Part-time work	18 (23)	19 (24)	25 (28)
	Permanently sick/disabled	2 (3)	2 (3)	4 (4)
	Unemployed	8 (10)	7 (9)	11 (12)
	Retired	0 (0)	1 (1)	0 (0)
	Student	5 (6)	3 (4)	3 (3)
	Housewife	7 (9)	6 (8)	10 (11)
	Other	2 (3)	1 (1)	3 (3)
Highest examination level	None	7 (9)	11 (14)	9 (10)
	GCSE/'O' level/CSE	45 (58)	37 (47)	42 (47)
	'A' level	11 (14)	10 (13)	13 (14)
	Degree	14 (18)	21 (26)	25 (28)
	Missing	1 (1)	0 (0)	1 (1)
Accommodation status	Owner-occupied	31 (40)	44 (56)	51 (57)
	Rented	34 (44)	23 (29)	31 (35)
	Lives with parents	10 (13)	10 (13)	7 (8)
	Other	3 (4)	2 (3)	1 (1)
No. of children (aged ⩽16 years)	0	42 (54)	47 (60)	50 (56)
	1	13 (17)	12 (15)	15 (17)
	2	15 (19)	13 (17)	19 (21)
	3+	8 (10)	7 (9)	6 (7)
Past history: no. of previous episodes requiring treatment	0	33 (42)	28 (35)	31 (34)
	1	30 (39)	26 (33)	39 (43)
	2	6 (8)	12 (15)	1 (11)
	3+	9 (12)	13 (17)	10 (11)
Previous drug treatment	Yes	42 (54)	43 (54)	50 (56)
	No	3 (4)	8 (10)	9 (10)
	NA	33 (42)	28 (35)	31 (34)
Previous psychological treatment	Yes	21 (27)	36 (46)	33 (37)
	No	24 (31)	15 (19)	26 (29)
	NA	33 (42)	28 (35)	31 (34)
Previous electroconvulsive therapy	Yes	0 (0)	1 (1)	0 (0)
	No	45 (58)	50 (63)	58 (64)
	NA	33 (42)	28 (35)	31 (34)
	Missing	0 (0)	0 (0)	1 (1)
Previous inpatient for an emotional or mental health problem	Yes	2 (3)	4 (5)	4 (4)
	No	43 (55)	47 (60)	55 (61)
	NA	33 (42)	28 (35)	31 (34)
Family history of treatment for emotional or mental health problems	Yes	44 (56)	40 (51)	48 (53)
	No	34 (44)	39 (49)	42 (47)

Figures are *n* (%) unless stated otherwise.
NA, not applicable.

TABLE 5 *Baseline CIS-R-generated primary diagnoses*

	GP (*n* = 78)	Generic CMHN (*n* = 79)	PS CMHN (*n* = 90)
Severe depressive episode	6 (8)	15 (19)	15 (17)
Moderate depressive episode	17 (22)	16 (20)	8 (9)
Mild depressive disorder	2 (3)	2 (2)	1 (1)
Mixed anxiety and depressive disorder	16 (20)	16 (20)	28 (31)
Mixed anxiety and depressive disorder – mild	17 (22)	15 (19)	12 (13)
Social phobia	7 (9)	3 (4)	12 (13)
Agoraphobia	4 (5)	3 (4)	4 (5)
Panic disorder	4 (5)	3 (4)	2 (2)
Specific (isolated) disorder	1 (1)	2 (2)	0 (0)
Obsessive–compulsive disorder	0 (0)	1 (1)	0 (0)
No diagnosis identified	4 (5)	3 (4)	8 (9)

Figures are *n* (%).

TABLE 6 *Timing of research assessments*

	8 weeks (56 days)	26 weeks (182 days)
n	212	190
Mean (SD) days from baseline	61.1 (9.17)	186.3 (10.45)
Range	48–109	161–231

group were followed up, where around 20% refused to take part in follow-up at 8 weeks, compared with 4% and 8% in the generic CMHN and PS CMHN groups, respectively. Slightly higher numbers of patients were untraceable by the research team in the nurse groups at 26 weeks, but higher follow-up was still achieved in those groups.

Health economic data were extracted from GP records in 94% of the patients; nine patients did not consent to their records being checked and seven patients had either incomplete or no records available. *Table 7* specifies the data availability for each measure at each time-point.

Blinding of researchers

Table 8 details whether the researchers were aware of the treatment allocation at each time point. At both time-points researchers were more likely to be aware of treatment allocation in the CMHN groups.

Treatment sessions delivered

In all cases a CMHN was identified to treat each patient after randomisation to a CMHN arm. Of the 53 CMHNs recruited to the study, 37 accepted patient referrals. The number of patients allocated to these CMHNs ranged from one to 16 (mean 3.2).

Of the 169 patients allocated to CMHN treatment, 156 attended for at least one therapy session. In the problem-solving group the range of sessions received by patients was 0–7, mean 4.1 (SD 2.0). In the generic CMHN group the range of sessions received by patients was 0–8, mean 4.4 (SD 2.2). In the generic group 73% of patients received four or more therapy sessions, while in the problem-solving group 62% received four or more sessions.

Audiotaping of treatment sessions

Twenty-three patients did not give written consent for their treatment sessions to be audiotape-recorded, if they were randomised to CMHN treatment. Other patients declined to have sessions recorded later, once the CMHN had visited them. In addition, there was often CMHN reluctance to record sessions, as well as occasional equipment failure. In the event, the treatment sessions of only 30 patients were successfully recorded. Eight PS CMHNs recorded at least one session in 23 patients and six generic CMHNs recorded at least one session in seven patients. All tapes returned were rated by one of the

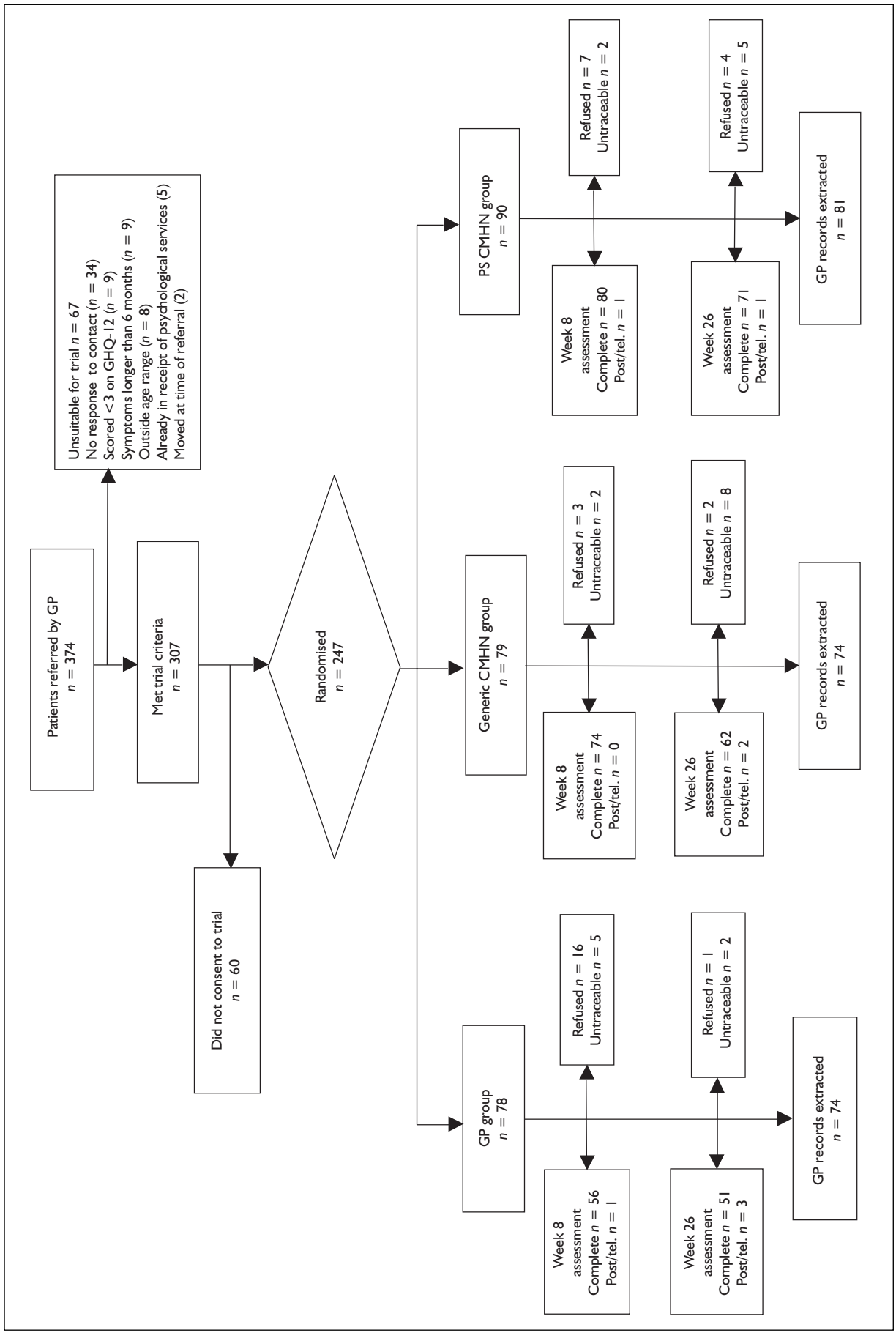


FIGURE 1 *Flow diagram of patient progression through the trial*

TABLE 7 *Data availability at each time-point*

	Baseline	8 weeks	26 weeks
Patient-reported measures			
Socio-demographic questionnaire	247 (100)	NA	NA
CIS-R	247 (100)	210 (85)	184 (74)
GHQ-12	247 (100)	212 (86)	190 (77)
HADS	247 (100)	210 (85)	184 (74)
SAS	247 (100)	210 (85)	184 (74)
PSA	247 (100)	210 (85)	184 (74)
Patient preference	247 (100)	NA	NA
Patient satisfaction scale	NA	NA	184 (74)
Patient views on treatment (postal return)	NA	151 (61)	120 (49)
Health service resource use	247 (100)	210(85)	184 (74)
EQ-5D	247 (100)	212 (86)	190 (77)
Medical record data			
Complete data extraction	NA	NA	231 (93)
Limited data extraction/no records available	NA	NA	7 (3)
No consent to access medical records	NA	NA	9 (4)
CMHN contact record			
Data returned	NA	NA	157 (93)
No data returned	NA	NA	12 (7)

Figures are *n* (%); this record does not account for any missing individual items on assessments.

TABLE 8 *Blinding of researchers*

	GP (*n* = 78)	Generic CMHN (*n* = 79)	PS CMHN (*n* = 90)
8 weeks			
Unblinded: GP	21 (39)	1 (1)	1 (1)
Generic CMHN	0 (0)	21 (30)	0 (0)
PS CMHN	0 (0)	0 (0)	41 (54)
Any nurse	0 (0)	29 (42)	17 (22)
Blind	33 (61)	18 (26)	17 (22)
Unspecified or NA	24	10	6
26 weeks			
Unblinded: GP	20 (37)	2 (3)	1 (2)
Generic CMHN	0 (0)	16 (28)	0 (0)
PS CMHN	0 (0)	0 (0)	35 (54)
Any nurse	1 (2)	18 (31)	14 (22)
Blind	32 (60)	22 (38)	15 (23)
Unspecified or NA	25	21	25

Figures are *n* (% of assessments conducted).

problem-solving trainers (YD) using a rating scale designed for the purpose, assessing both general therapeutic skills and the specific application of PST (see Appendix 2). The assessor was blind to treatment group but asked to record which treatment she thought the nurse was allocated to. As she had been involved in training the nurses for the trial it was thought likely that she would recognise some of the voices of the problem-solving CMHNs in any case. She rated the second or subsequent session where possible, as the first session focuses on assessment rather than actual therapy. The rating scale gave a score between 1 and 4 for each of four general therapeutic skills and for each of six problem-solving skills, a higher score indicating better skills in this area. Overall,

TABLE 9 *Ratings of audiotape-recording of treatment sessions*

	Mean total score	
	General therapeutic skill	**Problem-solving skill**
Generic CMHNs		
GEN1[a]	10	11
GEN2	10	8.5
GEN3[a]	15	8
GEN4[a]	9	10
GEN5[a]	7	6
GEN6[a]	12	8
PS CMHNs		
PST1[a]	10	13
PST2[a]	14	19
PST3[a]	13	16
PST4	14.8	20.6
PST5	8.1	10.6
PST6[a]	11	20
PST7[a]	14	18
PST8	12	13.5
Mean score for each group		
Generic CMHN group	10.4	8.6
PS CMHN group	11.4	15.3

[a] Only one patient episode audiotape-recorded; therefore, scores are for that patient rather than an aggregated mean score.

therefore, general therapeutic skills receive a total of between 4 and 16 and problem-solving skills between 6 and 24. Satisfactory problem-solving is judged to have been delivered when the total score is 12 or above, with a minimum score of 2 for each skill rated.

Ratings were carried out on all 30 patients: for six the first session was rated, for the remainder the second session or later sessions were rated. In all cases the rater correctly identified to which trial arm the CMHN was allocated. *Table 9* shows the total score for general therapeutic skill and application of problem-solving for each individual CMHN and for the two treatment groups. In terms of general therapeutic skills the two CMHN groups were similar. As would be expected, the PS CMHN group was rated more highly in the application of problem-solving skills. The results indicated that seven out of eight CMHNs assessed achieved a satisfactory rating, although some nurses delivered PST with higher fidelity to the treatment than others. Given the small numbers, these data were not subjected to significance testing.

Chapter 4

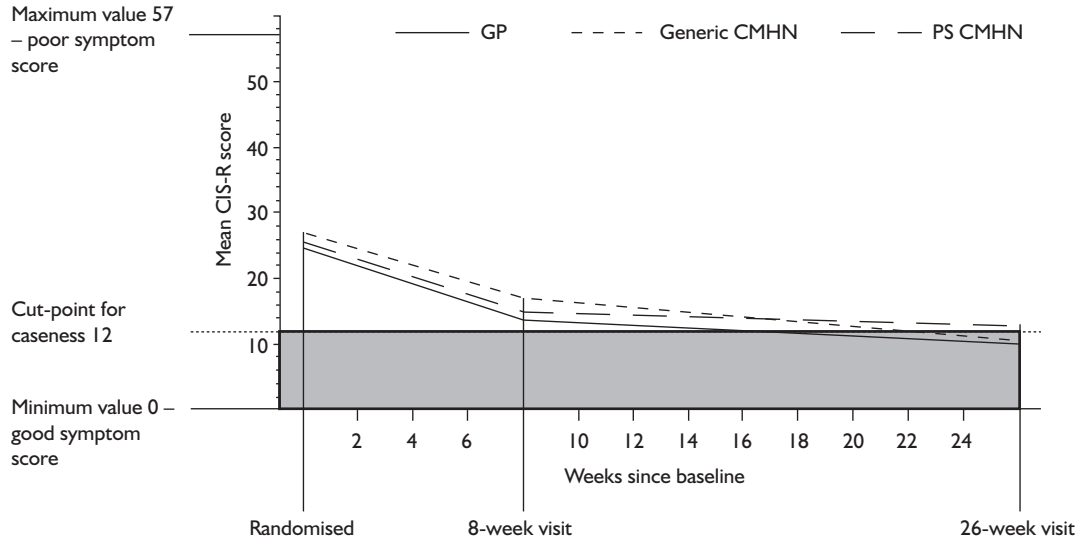
Results: clinical outcomes and patient satisfaction

Clinical outcomes

Table 10 shows the results of the comparisons between groups for the clinical and social function outcome scales used [CIS-R, GHQ-12, HADS – Depression (HADS-D), HADS – Anxiety (HADS-A), SAS and PSA]. None of the comparisons, for any of the scales, at either of the follow-up points, indicates a significant difference in effectiveness between the treatments.

The group randomised to treatment as usual by the GP was slightly less symptomatic at baseline, and this was still evident at 8 weeks. After taking account of baseline CIS-R and referring GP, the PS CMHN group was estimated to have a slightly lower mean CIS-R score at 8 weeks than the GP group, whereas the generic CMHN group was estimated to have a slightly higher mean than the GP group. The 95% confidence intervals show that one can rule out differences between the groups of 6 or more points on the CIS-R scale. At 26 weeks mean CIS-R scores in the three groups remained close to each other. Estimated differences and their 95% confidence intervals were similar to those at 8 weeks.

Mean scores for these scales are shown graphically in *Figures 2–7*. High values for each scale indicate greater symptoms, or poorer social function in the case of the SAS, and so generally the graphs show patients to be improving between randomisation and the 8-week assessment, and improving again, but to a lesser extent, by 26 weeks. Compared with



CIS-R plotted means

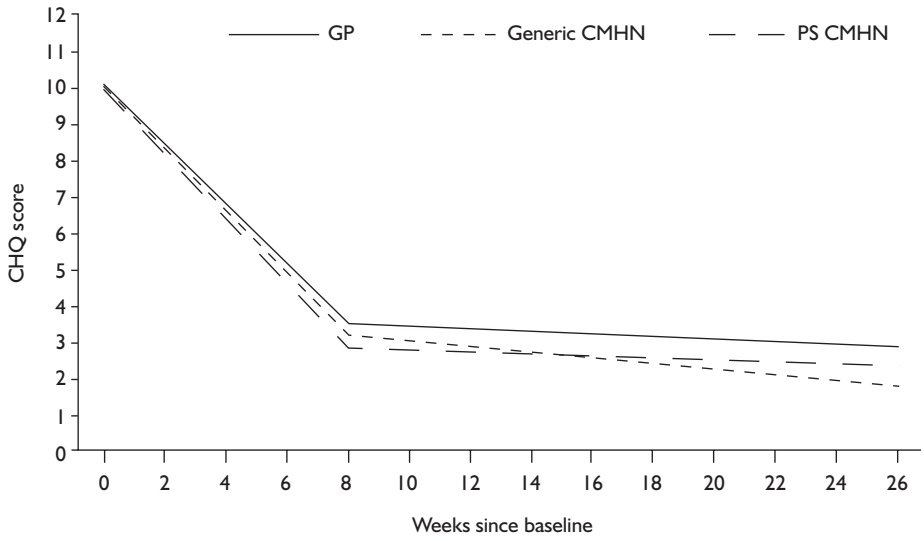
	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	24.68	27.03	25.42
Week 8	13.84	16.88	14.96
Week 26	10.12	10.39	12.75

FIGURE 2 *Graph of CIS-R scores by group*

TABLE 10 *Comparison of CIS-R, GHQ-12, HADS, SAS and PSA between treatment groups*

					Generic CMHN – GP[a]		PS CMHN – GP[a]	
		GP	**Generic CMHN**	**PS CMHN**	**Mean difference (95% CI)**	***p***	**Mean difference (95% CI)**	***p***
CIS-R	Baseline	24.7 (9.8)	27.0 (9.8)	25.4 (10.3)	–	–	–	–
	8 weeks	13.8 (13.9)	16.9 (12.1)	15.0 (11.4)	1.40 (–2.79 to 5.60)	0.509	–1.21 (–5.23 to 2.80)	0.551
	26 weeks	10.1 (10.9)	10.4 (9.4)	12.8 (12.0)	–1.39 (–5.54 to 2.77)	0.510	1.13 (–2.88 to 5.14)	0.579
GHQ-12	Baseline	10.08 (2.26)	9.94 (2.30)	10.03 (2.47)	–	–	–	–
	8 weeks	3.54 (4.29)	3.18 (4.44)	2.79 (4.01)	–0.71 (–2.37 to 0.95)	0.398	–1.24 (–2.84 to 0.37)	0.131
	26 weeks	2.87 (3.93)	1.78 (2.98)	2.32 (3.43)	–1.06 (–2.56 to 0.45)	0.167	–0.81 (–2.25 to 0.63)	0.266
HADS-D	Baseline	9.24 (3.83)	9.96 (3.62)	10.04 (4.23)	–	–	–	–
	8 weeks	5.62 (4.89)	5.99 (4.09)	6.06 (4.50)	–0.62 (–2.20 to 0.96)	0.441	–0.92 (–2.46 to 0.63)	0.243
	26 weeks	4.64 (4.28)	4.32 (3.28)	4.71 (4.47)	–0.89 (–2.39 to 0.60)	0.238	–0.51 (–1.98 to 0.95)	0.489
HADS-A	Baseline	14.01 (3.39)	13.42 (3.74)	13.53 (3.77)	–	–	–	–
	8 weeks	9.23 (3.95)	9.77 (3.67)	9.57 (4.15)	0.67 (–0.75 to 2.09)	0.351	0.07 (–1.31 to 1.44)	0.925
	26 weeks	7.57 (4.28)	8.19 (3.76)	8.68 (4.54)	0.93 (–0.73 to 2.59)	0.269	1.58 (–0.02 to 3.18)	0.053
SAS	Baseline	2.80 (0.39)	2.80 (0.39)	2.84 (0.39)	–	–	–	–
	8 weeks	2.46 (0.48)	2.46 (0.37)	2.50 (0.40)	–0.02 (–0.17 to 0.13)	0.784	0.00 (–0.14 to 0.14)	0.962
	26 weeks	2.34 (0.39)	2.29 (0.38)	2.44 (0.41)	–0.04 (–0.18 to 0.12)	0.659	0.11 (–0.04 to 0.26)	0.137
PSA	Baseline	9.55 (3.57)	9.77 (2.81)	9.66 (3.24)	–	–	–	–
	8 weeks	5.71 (3.92)	5.81 (3.80)	5.93 (3.67)	–0.31 (–1.66 to 1.05)	0.656	0.07 (–1.24 to 1.39)	0.915
	26 weeks	4.53 (3.44)	4.74 (3.32)	5.01 (3.69)	0.66 (–0.74 to 2.06)	0.354	0.71 (–0.66 to 2.07)	0.307

Figures are mean scores (SD).
[a] Adjusted for referring GP and baseline value.



GHQ-12 plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	10.08	9.94	10.03
Week 8	3.54	3.18	2.79
Week 26	2.87	1.76	2.32

FIGURE 3 Graph of GHQ-12 scores by group

the improvements between assessments, differences between the groups are small.

The cut-point 12, shown in *Figure 2*, indicates probable 'caseness' for a specific psychiatric disorder on the CIS-R scale. On average, patients had CIS-R scores above this point at baseline, slightly above it at the 8-week assessment, and on or below it at the 26-week assessment. The same applies to the GHQ-12 scores (cut-point for caseness 3). The cut-points for probable major depression (10) and possible major depression (8) are shown for the HADS-D scores in *Figure 4*. The cut-points for probable (10) and possible anxiety disorders (8) are shown for the HADS-A scores in *Figure 5*. In terms of HADS-D, average scores are in the range of possible major depression at baseline and fall to the normal range by the 8-week assessment. In terms of HADS-A, average scores are in the range of probable anxiety disorder at baseline, and fall to the range of possible anxiety disorder by the 8-week assessment.

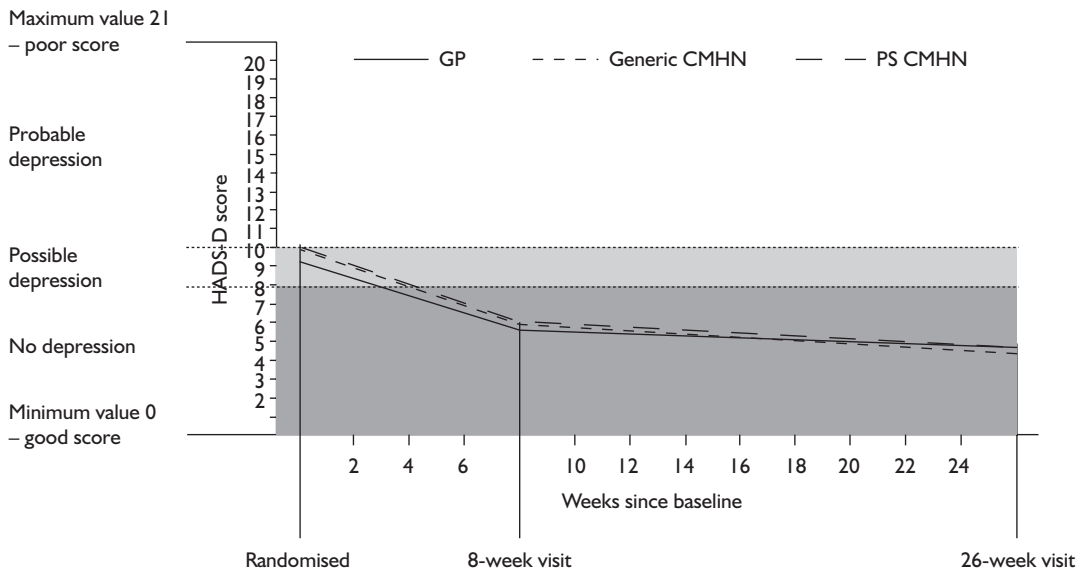
Table 10 and *Figure 6* show the SAS scale to be relatively insensitive to changes between baseline and the 8- and 26-week assessments, compared with the other scales.

Combining the two nurse treatment groups

To check whether a difference in outcome between the nurse treatment groups and the GP group was being missed owing to a smaller sample size than originally planned (a type II error), it was decided to explore whether a difference was found when combining the two nurse groups, to increase the power. *Table 11* shows that combining the two nurse groups actually results in a mean difference closer to zero, compared with the differences between the nurse groups separately and the GP group, which were reported in *Table 10*.

Sensitivity analyses to deal with missing data

Because of the discrepancy in follow-up rates between the GP treatment as usual group and the



HADS-D plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	9.24	9.96	10.04
Week 8	5.62	5.99	6.06
Week 26	4.64	4.32	4.71

FIGURE 4 Graph of HADS-D scores by group

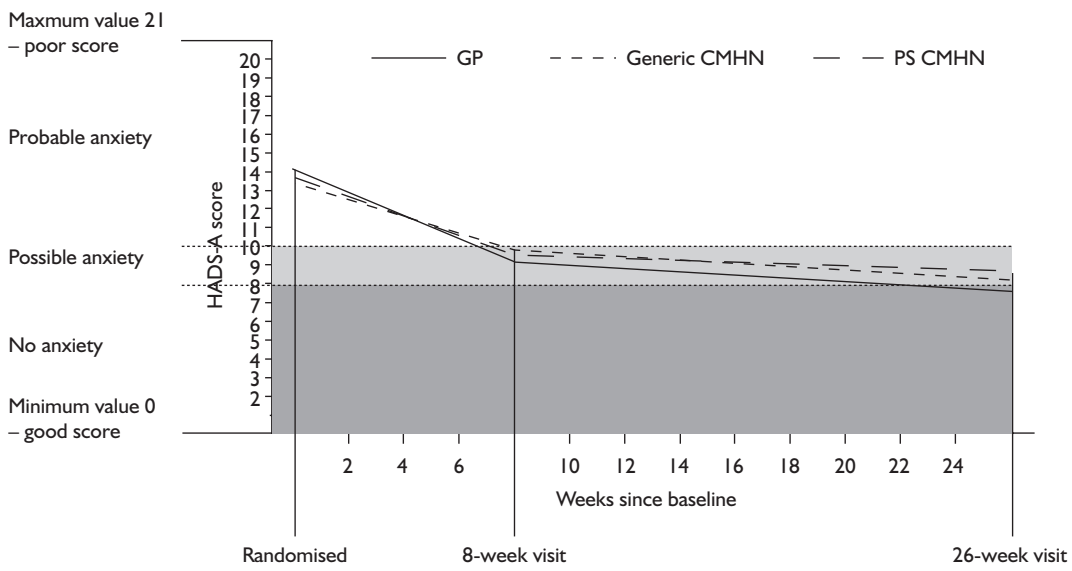
TABLE 11 *Outcome for the two CMHN groups combined versus the GP group*

		GP	Combined nurse group	Mean difference (95% CI)[a]	*p*
CIS-R scores	8 weeks	13.84 (13.91)	15.88 (11.74)	2.04 (–1.76 to 5.84)	0.290
	26 weeks	10.12 (10.87)	11.65 (10.90)	1.53 (–2.01 to 5.07)	0.395

Figures are mean (SD).
[a] Adjusted for referring GP and baseline value.

two nurse treatment groups, sensitivity analyses were conducted to see whether the results changed depending on what assumptions were made about the missing data. The following methods were used to replace the missing values:

- last observation carried forward (LOCF): the last observed value was used for all subsequent missing values
- back to baseline: each missing value was replaced with the patient's observed baseline value (for which complete information was available)
- mean replacement: missing values were replaced with the relevant group mean
- mean difference replacement: the mean difference between the time-point of interest and the baseline value was calculated separately for each treatment group and this change was then applied to the baseline values of those with missing data
- regression on baseline: individual regression lines were fitted in each treatment group taking account of the baseline information; the parameter estimates were then used for the calculation of the missing values.



HADS-A plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	14.01	13.42	13.53
Week 8	9.23	9.77	9.57
Week 26	7.57	8.19	8.68

FIGURE 5 *Graph of HADS-A scores by group*

Table 12 shows that the main findings are not particularly sensitive to the different assumptions about missing data that were investigated. Two comparisons between generic CMHN care and GP care achieve differences of statistical significance at the 5% level. These two comparisons are both of the 26-week CIS-R results and are based on two assumptions about the missing data that would tend to maximise the differences between the groups, given that most patients are improving over time (LOCF, and back to baseline). That is to say, the missing values are assumed to be the same as the 8-week (or baseline) values, whereas for the observed cases there is a strong pattern of scores falling by 26 weeks. Moreover, at the 5% level of significance these results could have arisen by chance, given that the number of tests performed in this analysis was more than 20.

Exploratory subgroup analyses

Given the negative overall outcome, in the context of previous research showing problem-solving to be effective for depression of at least moderate severity, a subgroup analysis was carried out including only those patients with an ICD-10 diagnosis of moderate or severe depressive episode on the CIS-R at baseline. This subgroup analysis was not preplanned and must be regarded as exploratory. *Table 13* shows the results of comparing CIS-R and HADS-D scores between the treatment groups within this subgroup of patients. None of these comparisons shows a significant difference between the groups.

A post hoc, exploratory subgroup analysis was also carried out, splitting the patients into two groups: those with greater or lesser severity of psychiatric problems according to their CIS-R scores at baseline. *Table 14* shows that the outcome on the CIS-R was better in both nurse treatment arms (and significantly so at the 5% level in the PS CMHN arm) at 8-week follow-up in the subgroup with CIS-R scores at baseline greater than or equal to the median, but not in the group with less than median CIS-R scores at baseline. *Table 14* shows that these differences between groups were no longer found by the 26-week follow-up.

TABLE 12 *Sensitivity analyses for dealing with missing CIS-R data*

		GP	Generic CMHN	PS CMHN	Generic CMHN – GP		PS CMHN – GP	
					Mean difference (95% CI)[a]	*p*	Mean difference (95% CI)[a]	*p*
CIS-R (complete cases)	8 weeks	13.84 (13.91)	16.88 (12.06)	14.96 (11.44)	1.40 (–2.79 to 5.60)	0.509	–1.21 (–5.23 to 2.80)	0.551
	26 weeks	10.12 (10.87)	10.39 (9.43)	12.75 (12.01)	–1.39 (–5.54 to 2.77)	0.510	1.13 (–2.88 to 5.14)	0.579
CIS-R (LOCF)	8 weeks	17.45 (13.89)	17.43 (11.98)	16.16 (11.78)	–2.42 (–6.03 to 1.18)	0.186	–3.20 (–6.64 to 0.24)	0.068
	26 weeks	15.15 (12.76)	12.99 (11.14)	14.70 (12.54)	–4.03 (–7.75 to –0.32)	0.033	–1.90 (–5.44 to 1.65)	0.293
CIS-R (back to baseline)	8 weeks	17.45 (13.89)	17.43 (11.98)	16.16 (11.78)	–2.42 (–6.03 to 1.18)	0.186	–3.20 (–6.64 to 0.24)	0.068
	26 weeks	15.74 (12.92)	14.14 (11.85)	15.52 (12.70)	–4.05 (–7.83 to –0.27)	0.036	–1.90 (–5.51 to 1.71)	0.300
CIS-R (mean replacement)	8 weeks	13.84 (11.76)	16.88 (11.67)	14.96 (10.78)	2.03 (–1.36 to 5.42)	0.238	–0.47 (–3.70 to 2.76)	0.774
	26 weeks	10.12 (8.76)	10.39 (8.34)	12.75 (10.65)	–0.26 (–3.29 to 2.78)	0.868	2.44 (–0.46 to 5.33)	0.098
CIS-R (mean difference replacement)	8 weeks	14.61 (12.68)	16.88 (12.06)	15.00 (11.28)	0.39 (–2.98 to 3.77)	0.818	–1.54 (–4.71 to 1.62)	0.337
	26 weeks	11.05 (10.35)	10.62 (9.40)	13.00 (11.32)	–1.84 (–4.78 to 1.10)	0.218	1.06 (–1.75 to 3.86)	0.458
CIS-R (regression on baseline)	8 weeks	14.48 (12.42)	16.82 (11.71)	14.98 (10.97)	0.61 (–2.65 to 3.87)	0.712	–1.35 (–4.46 to 1.76)	0.392
	26 weeks	10.53 (9.11)	10.46 (8.45)	12.86 (11.02)	–1.06 (–3.95 to 1.82)	0.469	1.81 (–0.94 to 4.56)	0.196

Figures are mean (SD).
[a] Adjusted for referring GP and baseline value.

TABLE 13 *Differences in treatment groups for patients with a diagnosis of moderate and severe depressive episode at baseline*

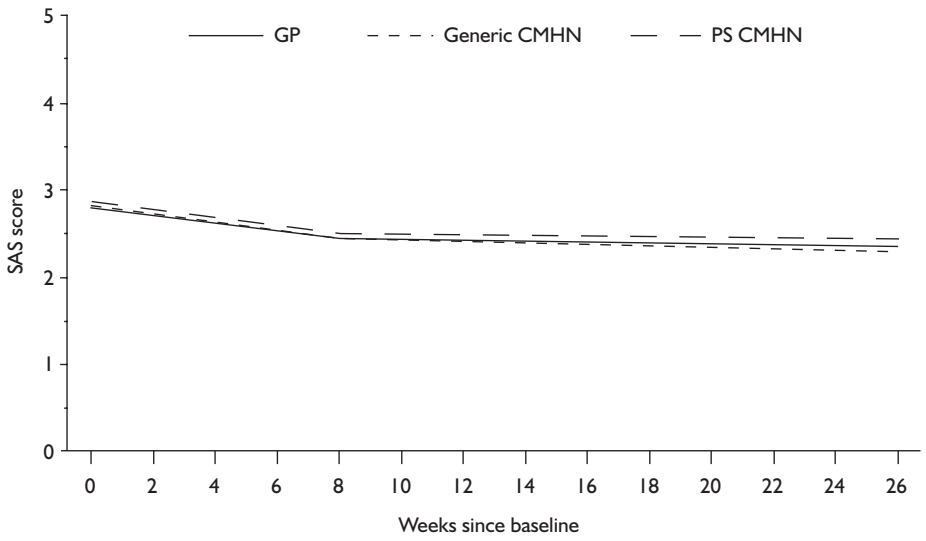
				Unadjusted		Adjusted[a]	
			Mean (SD)	Mean difference (95% CI)	*p*	Mean difference (95% CI)	*p*
CIS-R	Week 8	GP	20.9 (15.7)	0	–	0	–
		Generic CMHN	21.5 (12.0)	0.55 (–7.80 to 8.89)	0.896	–5.37 (–19.03 to 8.28)	0.425
		PS CMHN	23.6 (13.3)	2.68 (–6.21 to 11.57)	0.549	–2.44 (–15.26 to 10.39)	0.698
	Week 26	GP	14.2 (13.0)	0	–	0	–
		Generic CMHN	13.8 (11.3)	–0.45 (–9.26 to 8.36)	0.919	–0.76 (–18.07 to 16.54)	0.928
		PS CMHN	21.9 (15.7)	7.70 (–1.44 to 16.84)	0.097	8.85 (–8.34 to 26.04)	0.295
HADS-D	Week 8	GP	9.1 (5.6)	0	–	0	–
		Generic CMHN	6.6 (4.2)	–2.50 (–5.69 to 0.68)	0.121	–2.89 (–7.11 to 1.33)	0.170
		PS CMHN	8.8 (5.9)	–0.32 (–3.71 to 3.07)	0.853	–1.25 (–6.79 to 4.30)	0.647
	Week 26	GP	6.7 (5.7)	0	–	0	–
		Generic CMHN	4.7 (3.2)	–2.07 (–5.42 to 1.28)	0.221	–2.46 (–6.42 to 1.50)	0.210
		PS CMHN	7.8 (6.3)	1.02 (–2.46 to 4.49)	0.560	0.10 (–4.97 to 5.17)	0.967

[a] Adjusted for referring GP and baseline value.

TABLE 14 *Subgroup analysis according to initial score on the CIS-R*

					Generic CMHN – GP[a]		PS CMHN – GP[a]	
		GP	Generic CMHN	PS CMHN	Mean difference (95% CI)	*p*	Mean difference (95% CI)	*p*
Less than median CIS-R score at baseline	8 weeks	5.9 (5.7)	12.0 (10.0)	9.6 (9.2)	2.72 (–2.00 to 7.45)	0.252	1.51 (–2.73 to 5.78)	0.477
	26 weeks	6.3 (7.0)	7.1 (7.0)	7.4 (5.9)	–2.77 (–7.73 to 2.18)	0.265	–3.00 (–7.45 to 1.44)	0.180
Greater than or equal to median CIS-R score at baseline	8 weeks	22.4 (15.1)	20.8 (12.2)	20.0 (12.5)	–7.65 (–16.18 to 0.88)	0.078	–8.00 (–15.67 to 0.34)	0.041
	26 weeks	14.1 (12.8)	12.8 (10.3)	18.8 (14.2)	–0.14 (–10.03 to 9.74)	0.977	4.10 (–4.74 to 12.95)	0.354

Figures are mean CIS-R scores (SD).
[a] Adjusted for referring GP and baseline value.



SAS plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	2.80	2.80	2.84
Week 8	2.46	2.46	2.50
Week 26	2.34	2.29	2.44

FIGURE 6 *Graph of SAS scores by group*

TABLE 15 *Baseline degree of preference for each of the treatments (total* n = *247)*

	GP	Preference choice Generic CMHN	PS CMHN
Not at all	17 (7)	5 (2)	4 (2)
Not very much	45 (18)	9 (4)	6 (2)
Don't mind	120 (49)	94 (38)	76 (31)
Fairly	37 (15)	68 (28)	64 (26)
Very much	20 (8)	58 (24)	85 (34)
Missing	8 (3)	13 (5)	12 (5)

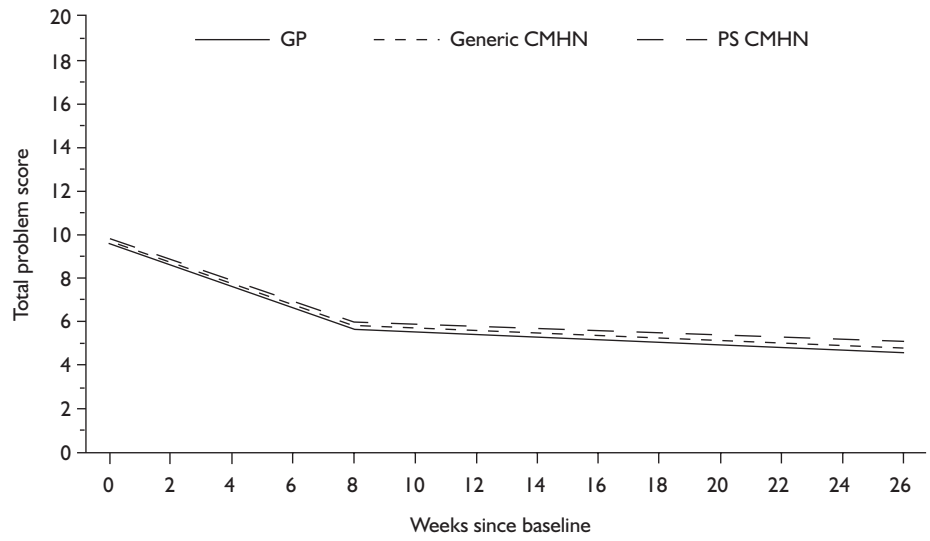
Figures are *n* (%).

A range of subgroup analyses was carried out, splitting the patients into those with greater and lesser symptom scores on the GHQ-12, HADS-D, HADS-A and PSA scales. None of these analyses showed significant differences between the treatment arms at either the 8- or 26-week follow-up assessment point.

All of these subgroup analyses must be treated with caution, as exploratory findings only, given that they were not planned a priori.

Preference for treatment

Two separate approaches were used at baseline to assess the degree of preference for the treatment groups. One question asked patients to rate their degree of preference for each of the three groups and the answers to this question are shown in *Table 15*. This shows that patients had a greater preference at baseline for the two CMHN treatment arms than they did for the GP arm, the proportions of patients 'fairly' or 'very much' preferring the



PSA plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	9.55	9.77	9.66
Week 8	5.71	5.81	5.93
Week 26	4.53	4.74	5.01

FIGURE 7 *Graph of PSA scores by group*

TABLE 16 *Follow-up rates by whether or not patients received their preferred treatment*

	Week 8	Week 26
Patients who received their preferred treatment (n = 50)	46 (92)	40 (80)
Patients who did not receive their preferred treatment (n = 114)	94 (82)	83 (73)
Patients with no reported preference (n = 83)	70 (84)	61 (73)

Figures are *n* (%).

generic CMHN arm (52%) or PS CMHN arm (60%) being significantly higher than the proportion preferring GP treatment as usual (23%).

The other question asked patients to choose their treatment of preference, if they had one. Only 13 (5%) of the 247 patients preferred treatment from their GP, whereas 45 (18%) preferred generic CMHN treatment, and 106 (43%) preferred PS CMHN treatment. No specific preference was reported in 83 cases (33%).

Further analyses were carried out to explore whether follow-up rates or outcome on the CIS-R were affected by whether or not patients received their preferred treatment. *Table 16* shows that the proportions of patients followed up at both the 8- and 26-week assessments were greater among patients who received their treatment of preference.

Table 17 shows adjusted and unadjusted analyses of CIS-R scores for those patients who received their treatment of preference compared with those who did not. Estimated differences in mean CIS-R were similar to those reported in *Table 10* between treatment groups, and none was significant.

TABLE 17 *Comparison of CIS-R scores between those who did and those who did not receive their preferred treatment*

				Unadjusted		Adjusted[a]	
		n	**Mean (SD)**	**Mean difference (95% CI)**	***p***	**Mean difference (95% CI)**	***p***
Week 8	Patients who did not receive their preference	94	16.4 (13.2)	–	–	–	–
	Patients who received their preference	46	13.7 (10.3)	–2.73 (–7.12 to 1.66)	0.221	–1.28 (–6.73 to 4.17)	0.641
Week 26	Patients who did not receive their preference	83	10.6 (10.5)	0	–	0	–
	Patients who received their preference	40	10.4 (10.1)	–0.06 (–4.05 to 3.93)	0.977	0.07 (–5.15 to 5.29)	0.979

[a] Adjusted for referring GP and baseline value.

TABLE 18 *Satisfaction rating at 26 weeks by treatment group*

	n	Mean (SD)	Unadjusted		Adjusted[a]	
			Mean difference (95% CI)	*p*	Mean difference (95% CI)	*p*
GP	48	31.6 (7.6)	–	–	–	–
Generic CMHN	59	37.2 (5.9)	5.59 (3.13 to 8.04)	0.000	5.00 (2.14 to 7.86)	0.001
PS CMHN	66	37.6 (5.8)	6.01 (3.61 to 8.40)	0.000	5.67 (2.89 to 8.45)	0.000

[a] Adjusted for referring GP.

TABLE 19 *Satisfaction items cross-tabulated by treatment group*

	Number agreeing			*p*
	GP *n* = 48	CMHN *n* = 59	PS CMHN *n* = 66	
Statement				
I found the treatment helpful	24	50	50	0.002
I was given help in dealing with problems	20	48	57	0.000
I understand what was wrong with me	33	45	51	NA[a]
I am now fully recovered	16	17	24	0.828
I would have liked to have had more treatment	22	24	28	0.665
I did not feel I got the best treatment possible	21	13	18	0.029
I felt the doctor listened to me	37	48	52	0.48
I felt the nurse listened to me	NA	40	51	NA[b]
I had help in planning what to do between appointments	11	34	54	0.000
My problems were pinpointed	19	42	50	0.000
I would recommend this treatment to a friend	19	49	49	0.000

[a] Counts were too small in some categories to apply the χ^2 test.
[b] Response only in two CMHN groups.

Satisfaction outcome

Satisfaction questionnaire

Table 18 shows that patients in both of the nurse groups reported a higher level of satisfaction than those in the GP treatment group and that these differences were highly statistically significant.

Responses for all 11 items were collapsed into three categories: agree, neither agree nor disagree, and disagree. Each categorised item was then cross-tabulated with the treatment group and the χ^2 test applied (*Table 19*). Taking the individual items, significant differences in satisfaction with treatment were not found on all items. When differences were found between groups these were between the GP and both CMHN treatments, with few differences found between the two nurse groups.

- Patients in the CMHN groups were significantly more likely to agree that they found the treatment helpful and would recommend it to a friend.
- Patients in the CMHN groups were significantly more likely to disagree with the statement that they did not receive the best treatment possible.
- Patients in the CMHN groups were significantly more likely to agree that their problems had been identified and they had help in dealing with them.
- Patients in both CMHN groups were significantly more likely to agree they had help planning what to do between appointments; however, slightly more in the PST group reported this.

Feedback questionnaires

After the 8-week assessment 151 patients (61%) returned the postal questionnaire: 40 in the GP care arm, 53 in the generic CMHN arm and 58 in the PS CMHN arm. After the 26-week assessment 120 (49%) returned the questionnaire: 30 in the

GP care arm, 37 in the generic CMHN arm and 53 in the PS CMHN arm.

Responses to the open-ended questions were analysed using the principles of content analysis. All responses were read and notes were made of the views expressed. An analytical framework was devised from this and data were then coded into this framework. The framework was further adapted and revised in light of any new data that did not fit into the framework.

The three main themes that emerged were: what had been important about treatment in a helpful way, what had been important in an unhelpful way, and what treatment patients thought would have been helpful to them but they had not received. There were few differences between the findings at 8 and 26 weeks, and therefore the findings are presented by theme with the few differences between the time-points noted. The differences between the treatment groups are referred to throughout. Quotes from the questionnaires are identified by patient trial identification number and the treatment group in brackets.

Theme 1: What has been helpful

The opportunity to talk

At both time-points the opportunity to talk and be listened to was identified by many patients as the most important factor in their treatment. While this was commented on much more frequently in the CMHN groups, some patients in the GP group also mentioned this.

> Being able to talk in confidence with someone who understands. (47, PS CMHN)

> Having someone to talk and listen to you without feeling you are being judged. (190, PS CMHN)

> Being able to talk about the way you are feeling, to someone that will listen. (374, PS CMHN)

> Being able to speak to someone with an unbiased viewpoint, who is friendly and patient. (53, Generic CMHN)

> It is nice to jabber on to someone who just listens. (94, Generic CMHN)

> Being listened to and not offered advice or judged. (360, Generic CMHN)

> Talking to a close friend. (129, GP)

> Having the chance to talk through matters with someone outside everything was very important. Having someone to actively hear me and give attention to what I said and give pointers/different perspective, made an all round positive difference. (315, Generic CMHN)

Characteristics of the healthcare professional as a listener

Many patients also identified the characteristics of the person involved in the talking or doing the listening. These were categorised into two themes: those qualities that are associated with good listening skills (e.g. sympathetic, non-judgemental and interested) and those qualities associated with a professional approach (e.g. impartial, objective and unbiased). This characteristic of the professional approach was identified as important for a number of reasons: a fresh perspective, not wanting to burden friends or someone not already involved in their lives.

> The opportunity to talk with someone who, because she did not know me, could give me a totally impartial view/guidance unlike my close friends who are bound to have a tainted opinion of me. (201, PS CMHN)

> The ability to talk to someone who not only understands and listens but can help you to develop thoughts, ideas and action plans to further improvement. (166, Generic CMHN, 26 weeks)

> I found that being able to talk to someone impartial helped a lot and talking to someone knowing it was kept confidential. (306, GP)

The treatment approach

Some patients in the nurse group identified particular aspects of the treatment approach taken by the CMHN as helpful. This was particularly so for the PS CMHN group, where some of the patients mentioned the specific language associated with the model of PST used.

> The fact of ordering the problems, separating them, approaching them in the proposed format and working on that basis. (285, PS CMHN)

> The treatment gave me something to aim for and achieve – taking away the aimless thoughts that I would get. Structuring and planning helped a lot, I could control my life with this method. (173, PS CMHN)

> Talking through problems and setting attainable goals was very beneficial as it became possible to recognise that progress and improvement could be identified. It also helped to break down problems and realise that there were several solutions to the problems and to be able to evaluate the potential pros and cons of various courses of action. (321, PS CMHN, 26 weeks)

Differences between the groups
At 8 weeks the patients in the GP group were much less likely to identify any factors that had been helpful to them, although slightly more in this group identified medication as helpful than in the other groups. At 26 weeks more patients in the GP group were able to say what they thought had been useful in their treatment at this time-point, and this was mainly in relation to having their problems recognised. Some also specifically mentioned the GP as being helpful in their treatment.

> It was good to discuss my problems with my GP and I was pleased that she understood my anxieties. (65, GP)

> I think the support of my doctor has been invaluable in recognition and treatment of my problems. (256, GP)

Helping themselves
A feature of some patients' comments at both time-points was the realisation that self-help was important. This was particularly by being active themselves about addressing their problems.

> Initially I thought the counselling sessions would give me the answers to resolve my problems, but I understand now that it's more my assessing and addressing the issues that concern me. (39, Generic CMHN)

> Figuring out my problems for myself and learning how to overcome them myself. (129, GP)

Knowing they are not alone
It was also helpful for some to understand that the way they were feeling was not unusual or that other people in the same situation would also feel the way they did.

> Knowing my problems are not unusual and that there is help if and when I need it. (208, PS CMHN)

> I have realised I'm not alone and I am experiencing normal feelings. (241, PS CMHN)

> Helping me realise it's OK to have some of the feelings I had. (34, Generic CMHN)

Other factors
A small number of patients in each of the groups identified non-study treatments as being helpful. Likewise, a small number thought that tackling the cause of the symptoms, not just the symptoms, had been helpful.

Some other factors emerged from the comments at 26 weeks. A few patients identified that reaching an understanding about their condition/feelings and a greater awareness of their own needs was important in their improvement. This was commented on more in the PS CMHN group.

> I have actually grown up a lot since having the treatment, I have time for myself and my kids. The negative things in my life are no longer there, and I actually think things through instead of rushing into things. (108, PS CMHN)

A few patients in each group identified taking part in the research process as important in their treatment.

> I feel that the research part of the test (filling in all the forms) made me think a lot about how I was feeling and so made me more aware of what was wrong. (7, GP)

> As each meeting took place with [the researcher], I started to realise by the questions I was answering, that I was actually getting better. You can never remember the questions asked each time, but answering them honestly each time showed me a pattern of recovery. (8, Generic CMHN)

Also a new feature at this time-point was that some of the patients in the CMHN groups felt that the passage of time was important.

> Time has been the major contributory factor in coming to terms with myself and regaining my own confidence in myself. (39, Generic CMHN)

Theme 2: What has been unhelpful
There were fewer comments at both time-points about what had been unhelpful about treatment.

Lack of treatment/medication unhelpful
At 8 weeks an issue for a few of the GP group was that they felt they had not been treated. At both time-points some patients thought that medication had not been helpful.

> I haven't really been treated: I have had antidepressants but they have not made a change in my problems. (48, GP)

> My problems haven't been treated. The antidepressants made me feel ill and I have had no counselling yet. (81, GP)

PST unhelpful
In the PS CMHN group some thought that the particular approach of PST was not helpful for them.

> I didn't realise I would be expected to come up with the problem solving ideas! If I know this already,

> I wouldn't need to go to someone with problem solving skills (I only did what I do already – make lists of pros and cons). I would have liked more ideas and input from the psychiatric nurse, more comments to make me analyse why I think/behave the way I do. (288, PS CMHN)

> [While] the treatment offered would help a lot of people it would not help me. I understand my problems and it will take more than words and numbers to solve things. (299, PS CMHN)

Time constraints
At the 26-week point a few patients in the GP group identified the GP as having limited time in the consultation, or they did not want to burden the GP.

> My GP was excellent, very understanding and helpful, but her time with me was limited due to her workload. (54, GP)

> As yet I haven't been completely satisfied with the treatment that I have received even though my GP is very good and listens well. However I wouldn't like to bother her any more than I had to as there are people that could be cured where as I am not sure the time I spend with my GP would be as constructive as other patients. (299, GP)

Theme 3: What patients would have liked

The themes from the comments about what patients thought would have been useful in their treatment but they did not receive were very similar at both time-points.

Psychological treatments
The main theme was the identification of particular psychological or other therapies that they believed would have been helpful for them. This was found across all the groups, although it is interesting to note that in the GP group most patients identified generic counselling as the treatment that would have been helpful for them, while in the other groups a range of very specific therapies was identified, including: counselling, hypnotherapy, group work/workshops, acupuncture, psychoanalysis, family therapy, cognitive behavioural therapy (CBT), anger management and anxiety management.

Other professionals
A few patients in each of the groups also specified particular health professionals that they thought would have been helpful in their treatment, for instance psychologist or psychiatrist or in the GP group a counsellor.

Informal feedback from the trial CMHNs indicated that many of them suggested to patients that they would benefit from further, alternative treatments or treatments from other mental health professionals. This may explain some of the findings in theme 3.

Other factors
At both time-points some patients in the CMHN groups felt that it would have been helpful if the cause of their symptoms had been addressed and not just the symptoms. A few felt that they would have benefited from longer treatment.

> The CMHN treatment I received was a rather short programme. I feel the course of meetings could have proved even more effective if it had been extended over a 12-month period. (296, Generic CMHN)

At both time-points a few patients across the groups raised issues about future relapse. There were also some comments about the lasting effects of treatment. At 8 weeks this was only commented on by patients in the PS CMHN group; however, by 26 weeks it was across the groups, but only infrequently.

> I think the problem solving approach has helped me – I have been able to find (with the CMHN's help) my own solutions – therefore I feel I have control over the situation. Feeling 'in control' is important because you know you can help yourself in the future when they are no longer there. Also, my CMHN instilled in me the knowledge of how to use the problem-solving strategy in the future. Whether I can draw upon this knowledge and use it effectively in the months to come, will remain to be seen. (373, PS CMHN)

> The treatment has been brilliant – but I do worry about how I will manage in the future if I get depressed or go further down again. (15, Generic CMHN)

> The treatment of my problems that I received was good at the time but obviously there is no help now, or anything that is ongoing when I have bad times and need someone to help. (152, PS CMHN)

Chapter 5

Results: economic outcomes

Resource-use items measured and costed

Table 20 details the items of resources measured, with the exception of prescribed medications which are detailed in *Table 21*.

Unit costs

In *Tables 20* and *21* the costs of each resource item are given for naturally occurring or commonly used units. These units (e.g. an average duration of 9.36 minutes for a GP consultation in the surgery) were applied to the volume of contacts recorded in the trial to estimate a total cost per patient.

Unit costs were obtained from a variety of sources: intervention costs are from the trial, non-hospital-based NHS contacts are from Netten and colleagues,[44] speciality-specific costs per inpatient day and non-inpatient attendance from trust financial returns[41] were used to calculate the cost of each hospital admission and attendance; average earnings data from the New Earnings Survey[42] were used to estimate employment-related costs, and medication costs were obtained from the British National Formulary.[43] All unit costs are expressed in 2002/03 prices.

Handling missing cost data

Pragmatic RCTs frequently have some missing data concerning resource use or outcomes.[45] In the present study the proportion of missing data increased over the 6-month follow-up period. The main cost analysis reported below is based on patients with complete data at all follow-up points on the CIS-R (and EQ-5D), in line with the clinical analysis. For those patients who had complete CIS-R data but some missing resource use data, mean imputation conditional on the trial arm and follow-up point was used.[46]

TABLE 20 *Items of resources measured*

Category	Cost (2002/03 prices)	Unit
Intervention		
CMHN supervision costs	£2000	Per nurse
CMHN training cost	£885.68	Per nurse
CMHN session	£61.00	Per hour of patient contact
Other NHS costs		
GP consultation at surgery	£20.68	Per surgery consultation lasting 9.36 minutes
GP home visit	£63.07	Per home visit lasting 13.2 minutes (plus 12 minutes travel time)
GP telephone consultation	£23.78	Consultation lasting 13.2 minutes
Practice nurse consultation	£10.34	Per consultation
Counsellor consultation	£31.02	Per hour
Social worker consultation	£47.53	Per hour
Psychologist consultation	£28.95	Per hour
Psychiatrist consultation	£89.96	Per hour
Psychiatric day hospital attendance	£113.45	
A&E department visit	£51.70	
Psychiatric inpatient stay (overnight)	£173.55	
Employment-related costs		
Full-time		
Female	£525	Average weekly salary
Male	£396	Average weekly salary
Part-time		
Female	£163.50	Average weekly salary
Male	£150	Average weekly salary

Sources: trial, other studies,[40] Department of Health,[41] National Statistics.[42]

TABLE 21 *Unit costs of medications*

Medication name	Form	Dosage	Unit cost per unit (2002/03 prices)
Acamprosate calcium	Tablet	333 mg	£0.17
Amitriptyline	Tablet	10 mg	£0.03
Amitriptyline	Tablet	25 mg	£0.03
Amitriptyline	Tablet	50 mg	£0.04
Carbamazepine	Tablet	100 mg	£0.05
Chlordiazepoxide	Capsule	5 mg	£0.04
Cipralex	Tablet	10 mg	£0.57
Citalopram	Tablet	10 mg	£0.34
Citalopram	Tablet	20 mg	£0.57
Citalopram	Tablet	40 mg	£0.97
Diazepam	Tablet	2 mg	£0.02
Diazepam	Tablet	5 mg	£0.02
Dothiepin	Tablet	75 mg	£0.10
Dothiepin	Capsule	25 mg	£0.05
Doxepin	Capsule	50 mg	£0.05
Escitalopram	Tablet	10 mg	£0.57
Fluconazole	Capsule	150 mg	£7.12
Fluoxetine	Capsule	20 mg	£0.26
Fluoxetine	Liquid	20 mg/5 ml	£0.19
Prozac	Capsule	20 mg	£0.47
Imipramine	Tablet	25 mg	£0.04
Lofepramine	Tablet	70 mg	£0.18
Mirtazapine	Tablet	30 mg	£0.82
Nortriptyline	Tablet	10 mg	£0.08
Paroxetine	Tablet	20 mg	£0.54
Paroxetine	Tablet	30 mg	£1.04
Paroxetine	Syrup	20 mg/10 ml	£0.14
Seroxat	Tablet	20 mg	£0.59
Propranolol	Tablet	10 mg	£0.02
Propranolol	Tablet	40 mg	£0.02
Propranolol	Tablet	80 mg	£0.02
Propranolol	Capsule	80 mg	£0.20
Sertraline	Tablet	50 mg	£0.58
Sertraline	Tablet	100 mg	£0.95
Temazepam	Tablet	10 mg	£0.03
Temazepam	Tablet	20 mg	£0.05
Thiamine	Tablet	50 mg	£0.03
Trazodone	Capsule	50 mg	£0.21
Trazodone	Tablet	150 mg	£0.42
Venlafaxine	Tablet	37.5 mg	£0.43
Venlafaxine	Tablet	75 mg	£0.71
Venlafaxine	Tablet	50 mg	£0.57
Venlafaxine	Capsule	75 mg	£0.86
Venlafaxine	Capsule	150 mg	£1.43
Zopiclone	Tablet	3.75 mg	£0.11
Zopiclone	Tablet	7.5 mg	£0.16

Source: British National Formulary.[43]

Presentation of results

Cost and effects were jointly compared by calculating incremental cost-effectiveness ratios (ICERs) for (1) care delivered by generic CMHNs compared with usual GP care after 6 months, and (2) care delivered by PS CMHNs compared with usual GP care after 6 months. ICERs are the difference in costs of two alternative treatments divided by the difference in the effects of the treatments. These were plotted on the cost-effectiveness plane (*Figure 8*). This plane has two dimensions: differences in outcome are plotted on the *x*-axis and differences in costs on the *y*-axis, where the origin of the plane represents the comparator (GP care). Positive differences in effects

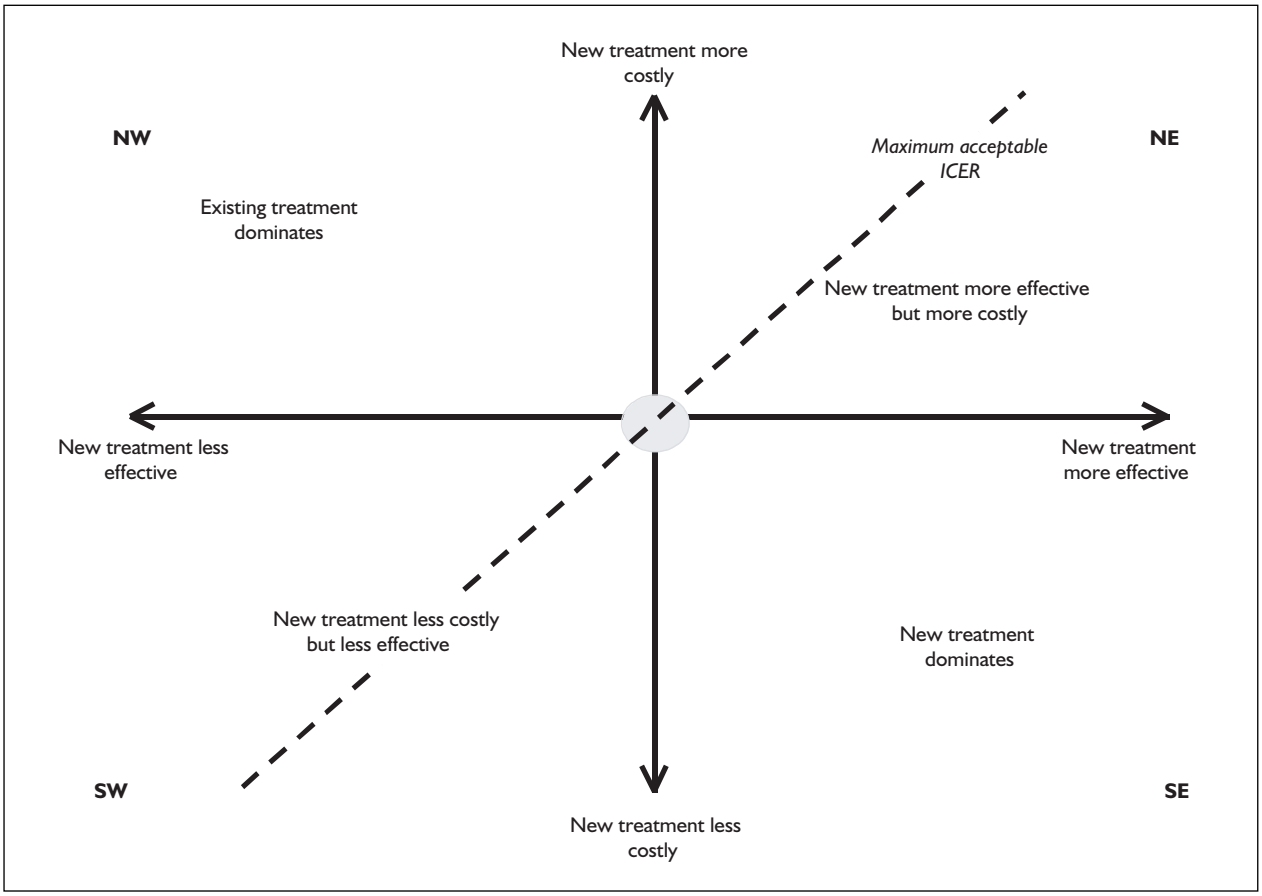


FIGURE 8 *The cost-effectiveness plane*

mean that the new treatment is more effective than the comparator, whereas positive differences in cost mean that the new treatment is more costly than the comparator. The plane is divided into four different quadrants and in each quadrant the interpretation of the cost–utility analysis is different. In the 'south-east' quadrant the new treatment is more effective and less costly than the comparator, hence the new treatment is said to dominate. The interpretation is similar in the 'north-west' quadrant, except that the comparator dominates. The 'north-east' and 'south-west' quadrants pose trade-offs between costs and effects. In the north-east quadrant the new treatment is more effective and also more costly; in the south-west quadrant the new treatment is less effective but also cheaper than the comparator. An external, explicit criterion, is required if results falling into either of these quadrants are to be judged cost-effective or not. This criterion asserts the maximum amount of money that healthcare decision-makers are willing to pay for a health gain. This criterion is represented by the dotted line and divides the plane into halves: below the line a new treatment is judged cost-effective and above the line it is not cost-effective. Expressing the difference in costs and difference in outcomes as a ratio can be problematic, as an intervention that costs more and is less effective could yield the same ratio as an intervention that costs less and is more effective; hence, conventionally, the ICER is only calculated and reported when the intervention is in the north-east quadrant.[47]

If the ICER is represented only as a point estimate on the plane then this provides limited information about the uncertainty surrounding the costs and effects estimates. There are several ways in which uncertainty can be handled. Van Hout and colleagues[48] suggested that if the difference in costs and effects are distributed normally it is possible to draw confidence limits that contain the joint density between costs and effects. Therefore, 95% confidence ellipses are presented on the plane to demonstrate the uncertainty around the point estimate of the ICER.

Economic outcomes

Completeness of data

Eighty-eight patients (36%) had at least one resource use item missing over the 6-month follow-up period. Therefore, complete resource use data were available for 159 (64%) of the patients. The results presented here are based mainly on the 184 patients for whom complete CIS-R data were available over the 6-month period. To achieve this sample, 25 (14%) of the patients who had CIS-R data but not resource-use information had to be imputed. The results were then compared with those obtained using data from GP notes where available instead of imputation, and those obtained using only the 159 patients with complete resource-use data.

After imputing missing values for the 25 patients with missing resource-use data, the numbers of patients included in the economic analysis in each group were as follows: 51 patients in GP care (28%), 62 patients in generic CMHN care (34%) and 71 patients in PS CMHN care (38%).

Socio-economic characteristics of patients and resource use at baseline

There were no obvious differences found between the three groups with respect to the amount of NHS contacts made at baseline (i.e. the 4-week period before treatment). This being the case, any adjustment to baseline costs was unnecessary.

Analysis of costs

The summary results are given in *Table 22*, with the full results of the cost analysis by resource volume and cost category presented in *Table 23*. The data are presented first by trial arm and then incrementally. The first column of data for each trial arm reports the mean volume of resource items consumed per patient. The second column reports mean cost per patient. The final two columns report the mean incremental cost differences, first for generic CMHN care and then for PS CMHN care. These differences were statistically significant with respect to the costs associated with the interventions (i.e. treatment and training costs).

Table 22 reports summary costs related to the intervention, other direct NHS costs, out-of-pocket items and total costs of care by trial arm. With respect to the intervention costs there were mean differences between CMHN care and GP care of £295 (95% CI £259 to 337) and between PS CMHN care and GP care of £303 (95% CI £275 to 327).

In terms of the other direct NHS costs incurred during the study period, the only significant differences were found in the number of GP visits made to the surgery and the number of other hospital contacts. The PS CMHN group made use of fewer consultations than the GP group (2.72 compared with 4.39 visits on average). This translated into a mean cost difference per patient of £35 (95% CI £13 to 56) cost saving for the PS CMHN group. The problem-solving group made use of more 'other' hospital contacts than the GP group (1.22 compared with 0.39 on average). This yields a mean cost difference per patient of £77 (95% CI £10 to 166) favouring the GP group.

Total mean NHS costs per patient were £283 for GP care, £569 for generic CMHN care and £608 for PS CMHN care. Total mean incremental costs of generic CMHN were £286 per patient (95% CI £174 to 411) and for PS CMHN care were £325 (95% CI £204 to 484). This evidence suggests that in both cases GP care was the less costly alternative. The conclusions remained unchanged after accounting for out-of-pocket expenses. Over the study period total costs of care per patient (i.e. intervention costs, direct NHS costs, longer term NHS costs and patient out-of-pocket costs) were £316, £599 and £631 for the GP, generic CMHN and PS CMHN groups, respectively. Incremental mean total costs were £283 (95% CI £154 to 411) for generic CMHN care and £315 (95% CI £183 to 481) for PS CMHN care. The additional costs associated with the two interventions were statistically significant.

Medical record data

The results presented so far were based only on those patients with complete CIS-R data. A full data set was also constructed using information from GP case notes when available and conditional mean imputation for other missing items. Overall, the results did not change significantly from those presented above. For instance, the total mean NHS costs per patient were £248 for GP care, £533 for generic CMHN care and £564 for PS CMHN care, compared with £283, £569 and £608, respectively, for only those with complete CIS-R data. Total mean incremental costs of generic CMHN care were £285 per patient (95% CI £189 to 381) and for PS CMHN care £316 (95% CI £198 to 433). Over the study period total costs of care per patient (i.e. intervention costs, direct NHS costs, longer term NHS costs and patient out-of-pocket costs) were £280, £563 and £586 for the GP, generic CMHN and PS CMHN groups, respectively. Incremental mean total costs were £283 (95% CI £182 to 384) for generic CMHN

TABLE 22 *Summary costings for resource-use items: CIS-R complete cases analysis only (costs expressed in 2002/03 prices)*

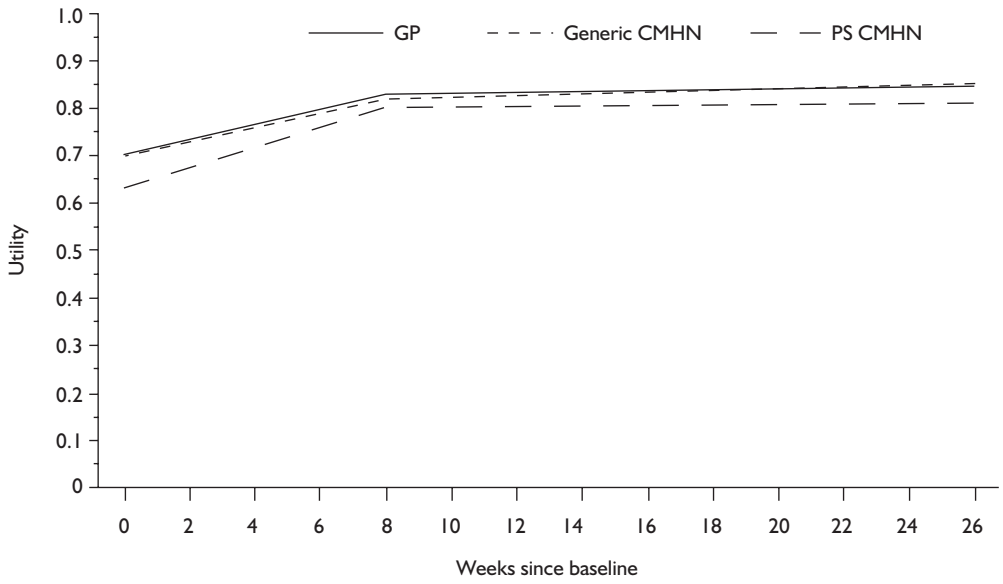
Cost category	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)	Generic CMHN – GP	PS CMHN – GP
	Cost per patient Mean (SD)	Cost per patient Mean (SD)	Cost per patient Mean (SD)	Mean cost difference (95% non-parametric CI)	Mean cost difference (95% non-parametric CI)
Intervention subtotal (1)	£0	£295 (163)	£303 (114)	£295 (£259 to 337)***	£303 (£275 to 327)***
Other direct NHS services subtotal (2)	£283 (300)	£274 (273)	£305 (500)	–£9 (–£120 to 90)	£22 (–£113 to 175)
Total NHS (1)+(2)	£283 (300)	£569 (350)	£608 (501)	£286 (£174 to 411)***	£325 (£204 to 484)***
Over-the-counter items (3)	£33 (82)	£30 (55)	£23 (52)	–£3 (–£32 to 19)	–£10 (–£43 to 12)
Total treatment related (2)+(3)	£316 (327)	£303 (291)	£328 (502)	–£13 (–£133 to 98)	£12 (–£118 to 176)
Total cost of care (1)+(2)+(3)	£316 (327)	£599 (366)	£631 (501)	£283 (£154 to 411)***	£315 (£183 to 481)***
Days off work	£3787 (7540)	£3694 (8464)	£5880 (12,727)	–£93 (–£3304 to 2843)	£2093 (–£1175 to 6013)

*** $p < 0.001$.

TABLE 23 *Detailed costings of resource-use items: CIS-R complete cases analysis only (costs expressed in 2002/03 prices)*

Cost category	GP (*n* = 51)		CMHN (*n* = 62)		PS CMHN (*n* = 71)		CMHN–GP	PS CMHN–GP
	Volume per patient Mean (SD)	Cost per patient Mean (SD)	Volume per patient Mean (SD)	Cost per patient Mean (SD)	Volume per patient Mean (SD)	Cost per patient Mean (SD)	Mean cost difference (95% non-parametric CI)	Mean cost difference (95% non-parametric CI)
Intervention								
Training and supervision costs	0	£0		£0		£36		
Treatment costs	0	£0		£295 (163)		£267 (114)	£295 (£256 to 336)***	£267 (£241 to 294)***
Intervention subtotal (1)	0	£0		£295 (163)		£303 (114)	£295 (£259 to 337)***	£303 (£275 to 327)***
Other direct NHS services								
Medication prescribed		£44 (51)		£36 (53)		£40 (74)	–£8 (–£24 to 18)	–£4 (–£28 to 10)
GP consultations at the surgery	4.39 (3.67)	£91 (76)	3.94 (3.22)	£81 (67)	2.72 (2.14)	£56 (44)	–£9 (–£37 to 17)	–£35 (–£57 to –10)**
GP home visits	0.04 (0.20)	£3 (12)	0.05 (0.28)	£3 (18)	0.11 (0.65)	£7 (41)	£0 (–£5 to 6)	£4 (–£3 to 16)
GP consultation over the telephone	0.27 (0.69)	£7 (16)	0.63 (1.76)	£15 (42)	0.49 (1.58)	£12 (38)	£8 (–£1 to 22)	£5 (–£2 to 17)
Practice nurse consultation at the surgery	0.48 (0.70)	£5 (7)	0.40 (0.73)	£4 (8)	0.56 (1.08)	£6 (11)	–£1 (–£3 to 2)	£1 (–£2 to 4)
Counsellor at the surgery	0.57 (1.8)	£18 (57)	0.11 (0.89)	£4 (29)	0.21 (1.01)	£7 (31)	–£14 (–£34 to 0)	–£11 (–£29 to 3)
Visits to social worker	0.16 (0.99)	£8 (51)	0.18 (1.17)	£9 (58)	0	£0	£1 (–£14 to 22)	–£8 (–£27 to 0)
Home social worker visits	0	£0	0.20 (1.40)	£9 (66)	0.06 (0.38)	£3 (18)	£9 (£0 to 33)	£3 (£0 to 8)
Psychiatrist outpatient attendance	0.14 (0.40)	£12 (36)	0.10 (0.43)	£9 (39)	0.13 (0.51)	£11 (45)	–£4 (–£17 to 10)	–£1 (–£16 to 13)
Psychiatrist home visit	0.06 (0.31)	£5 (28)	0	£0	0.10 (0.72)	£9 (65)	–£5 (–£19 to 0)	£4 (–£10 to 25)
Psychologist attendance	0.69 (4.48)	£20 (130)	0	£0	0.10 (0.61)	£3 (18)	–£20 (–£74 to 2)	–£17 (–£57 to 4)
Outpatient attendance	0	£0	0.05 (0.22)	£6 (26)	0.07 (0.49)	£8 (55)	£6 (£0 to 11)	£8 (£0 to 22)
A&E attendance	0.14 (0.49)	£7 (25)	0.16 (0.45)	£8 (23)	0.06 (0.23)	£3 (12)	£1 (–£9 to 9)	–£4 (–£9 to 9)
Hospital admissions	0.16 (0.99)	£27 (171)	0.08 (0.37)	£14 (65)	0.16 (0.95)	£27 (165)	–£13 (–£78 to 22)	£0 (–£74 to 54)
Other contacts	0.39 (1.22)	£36 (113)	0.82 (1.84)	£76 (171)	1.22 (3.33)	£113 (310)	£40 (–£13 to 96)	£77 (£10 to 166)**
Other direct NHS services subtotal (2)		£283 (300)		£274 (273)		£305 (500)	–£9 (–£120 to 90)	£22 (–£113 to 175)
Total NHS (1)+(2)		£283 (300)		£569 (350)		£608 (501)	£286 (£174 to 411)***	£325 (£204 to 484)***
Out of pocket (3)								
Over-the-counter items		£33 (82)		£30 (55)		£23 (52)	–£3 (–£32 to 19)	–£10 (–£43 to 12)
Total treatment related (2)+(3)		£316 (327)		£303 (291)		£328 (502)	–£13 (–£133 to 98)	£12 (–£118 to 176)
Total cost of care (1)+(2)+(3)		£316 (327)		£599 (366)		£631 (501)	£283 (£154 to 411)***	£315 (£183 to 481)***
Days off work	10.7 (18.18)	£3787 (7540)	10.2 (22.7)	£3694 (8464)	13.8 (27.6)	£5880 (12,727)	–£93 (£–3304 to 2843)	£2093 (–£1175 to 6013)

*** $p < 0.001$, ** $p < 0.01$.



EQ-5D utility levels plotted means

	Group		
Assessment	**GP**	**Generic CMHN**	**PS CMHN**
Baseline	0.70	0.70	0.63
Week 8	0.83	0.82	0.80
Week 26	0.85	0.85	0.81

FIGURE 9 *Graph of mean utility levels by group*

care and £306 (95% CI £186 to 425) for PS CMHN care.

Days off work

Finally, with reference to the number of days off work, no significant differences were found between any of the arms and therefore in the cost per days off work.

Outcomes: EQ-5D utilities and QALYs

The first three columns of *Table 24* show the results of the mean reported utility levels at each point of assessment. In broad terms EQ-5D utilities were estimated to be lowest at the start of treatment (ranging from 0.63 for PS CMHN care to 0.70 for GP and generic CMHN care), showing improvement by 8 weeks (0.80 to 0.83), which was at least maintained by 26 weeks (0.81 to 0.85). In fact there were no statistically significant differences between the arms at any of the EQ-5D assessment points, although there was an imbalance between the PS CMHN and the GP care arms at baseline (mean difference –0.07, 95% CI –0.17 to 0.02).

Table 24 also reports the number of QALYs gained over the study period. Full health maintained over a period of 6 months represents 0.5 QALYs (1.0 utility × 0.5 years). The mean (SD) QALYs achieved for each arm over the 6-month period were 0.40 (0.07) for GP care; 0.40 (0.07) for generic CMHN care and 0.39 (0.09) for PS CMHN care.

Figure 9 shows the mean utility levels at each assessment point for each arm. A straight-line interpolation was assumed between EQ-5D utility levels scored at different time-points. This means that the number of QALYs gained is given by the area below the utility profile. In this instance the three arms achieved similar results: 0.40 (0.07), 0.40 (0.07) and 0.39 (0.09)

TABLE 24 *Utility values obtained from the EQ-5D at each follow-up point and QALYs gained over 26 weeks: CIS-R complete cases analysis only*

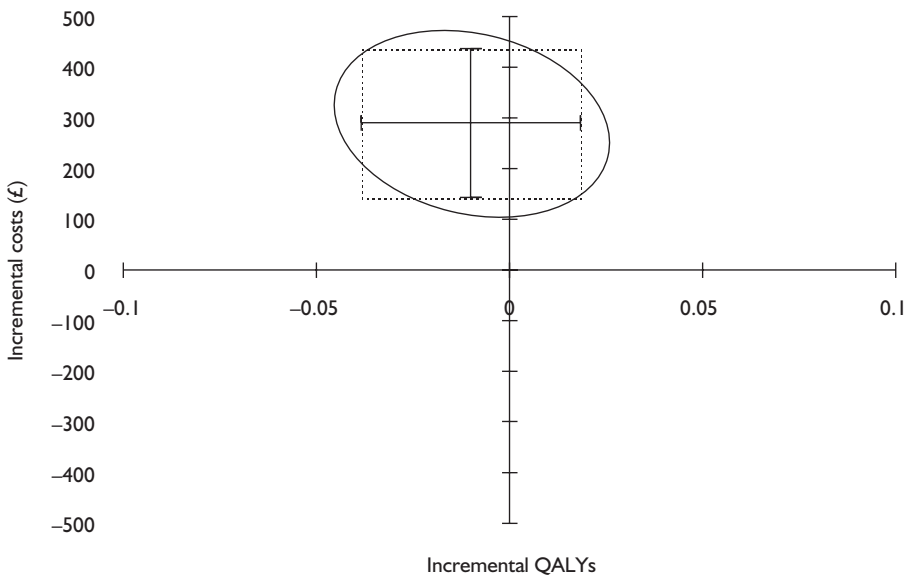
EQ-5D	GP (*n* = 51) Mean (SD)	Generic CMHN (*n* = 62) Mean (SD)	PS CMHN (*n* = 71) Mean (SD)	Mean difference (95% parametric CI) CMHN – GP[a]	Mean difference (95% parametric CI) PS CMHN – GP[a]
Utility level					
Baseline	0.70 (0.23)	0.70 (0.26)	0.63 (0.29)	0 (–0.09 to 0.09)	–0.07 (–0.17 to 0.02)
8-week follow-up	0.83 (0.19)	0.82 (0.19)	0.80 (0.21)	–0.01 (–0.07 to 0.07)	–0.03 (–0.10 to 0.05)
26-week follow-up	0.85 (0.19)	0.85 (0.17)	0.81 (0.24)	0 (–0.06 to 0.07)	–0.04 (–0.12 to 0.04)
QALYs over 6 months	0.40 (0.07)	0.40 (0.07)	0.39 (0.09)	0 (–0.03 to 0.03)	–0.02 (–0.05 to 0.012)

[a] No statistical significant differences.

TABLE 25 *Distribution of EQ-5D answers across the dimensions: CIS-R complete cases analysis only*

	Mobility			Self-care			Usual Activities			Pain			Anxiety		
Follow-up point	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)	GP (*n* = 51)	Generic CMHN (*n* = 62)	PS CMHN (*n* = 71)
Baseline															
1	96%	89%	86%	100%	94%	97%	41%	37%	32%	75%	68%	61%	6%	11%	7%
2	4%	11%	13%	0%	6%	3%	57%	61%	61%	24%	29%	35%	73%	71%	68%
3	0%	0%	1%	0%	0%	0%	2%	2%	7%	2%	3%	4%	22%	18%	25%
8 weeks															
1	96%	94%	87%	100%	97%	97%	65%	56%	66%	71%	76%	70%	47%	40%	32%
2	4%	6%	13%	0%	3%	3%	35%	42%	32%	29%	23%	28%	45%	56%	62%
3	0%	0%	0%	0%	0%	0%	0%	2%	1%	0%	2%	1%	8%	3%	6%
26 weeks															
1	96%	89%	82%	98%	97%	97%	73%	73%	70%	73%	73%	63%	55%	56%	54%
2	4%	11%	18%	2%	3%	3%	25%	27%	27%	25%	27%	32%	41%	40%	42%
3	0%	0%	0%	0%	0%	0%	2%	0%	3%	2%	0%	4%	4%	3%	4%

No significant differences were found on the distribution of the proportions among the three groups at any follow-up point.



CEA plotted means			
		Lower CI	**Upper CI**
ICER	–£29,000	NA	NA
Cost difference	£290	£143	£437
Effect difference	–0.01	–0.04	0.02

FIGURE 10 *Cost–utility analysis of PS CMHN care compared with GP care on the cost-effectiveness plane*

for GP care, generic CMHN care and PS generic CMHN care, respectively. That is, no significant differences in QALYs were found among the arms (the mean difference between generic CMHN care and GP care was 0.0, 95% CI –0.03 to 0.03, and the mean difference between PS CMHN and GP arms was –0.02, 95% CI –0.05 to 0.012).

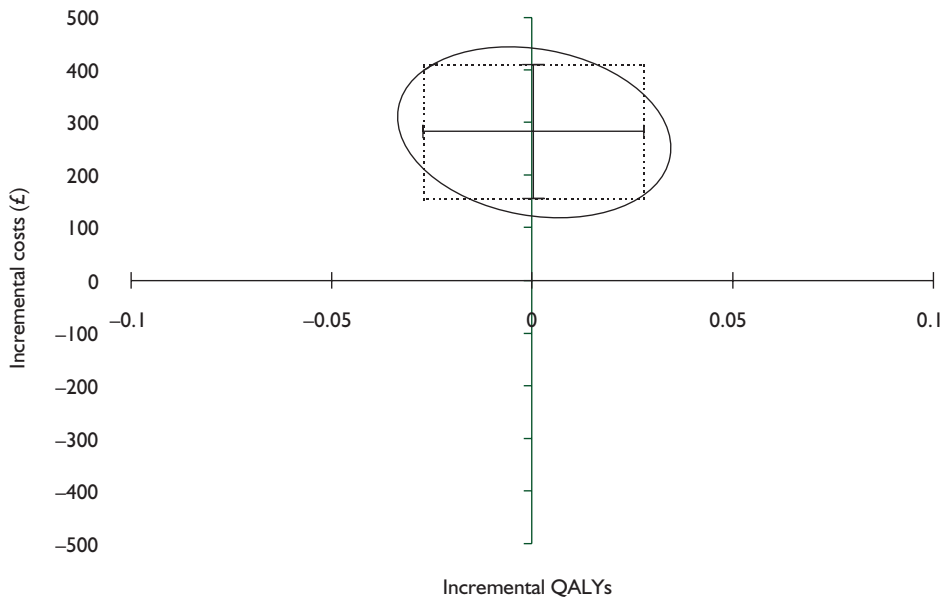
Table 25 shows the distribution of responses to the EQ-5D across different levels of each dimension. The results of the χ^2 test suggested that there were no differences among the groups for any of the dimensions and follow-up points. The table also shows clearly that improvements in the quality of life of patients at 26 weeks were primarily due to movements from level 2 or 3 on the Anxiety dimension to level 1. The proportion of patients who answered level 1 on the Anxiety dimension was 6%, 11% and 7% in the GP, CMHN and PS CMHN groups, respectively, at baseline, but 55%, 56% and 54%, respectively, at the 26-week follow-up point.

Cost-effectiveness

In *Figures 10* and *11*, the vertical bar shows the difference in costs between the intervention and control group, and the horizontal bar the difference in effect, each with associated 95% confidence intervals; the point where the two bars cross represents the point estimate of the ICER. The ellipse represents the 95% confidence interval for the joint density function for costs and effects, and this gives a more accurate representation of the uncertainty surrounding the cost-effectiveness ratio than the 'box' formed by the cost and effect uncertainty bars considered independently.[48]

In *Figure 10* it is clear that PS CMHN is not cost-effective compared with GP care. The point estimate of the ICER is in the north-west quadrant and the confidence ellipse suggests that it is unlikely that PS CMHN represents good value for money.

Similarly, *Figure 11* shows that generic CMHN care is unlikely to be cost-effective compared with GP care.



CEA plotted means			
		Lower CI	**Upper CI**
ICER	£943,333	NA	NA
Cost difference	£283	£155	£411
Effect difference	0.00	–0.03	0.03

FIGURE 11 *Cost–utility analysis of generic CMHN compared with GP care on the cost-effectiveness plane*

Chapter 6
Discussion

Main findings

Clinical outcomes

This study found that referral for CMHN care was no more effective for problems of anxiety, depression and life difficulties than usual care from the GP. This was true both for generic CMHN care and for care from CMHNs specially trained in PST. No significant differences were found in any of the measures of effectiveness examined, including symptoms of mental ill-health on several scales, social functioning or quality of life, either immediately after the treatment had finished or 6 months after referral. All three groups improved to a remarkably similar extent. Therefore, the two null hypotheses could not be rejected.

The ICD-10 diagnoses derived from the CIS-R at baseline showed that a high proportion of patients included in the study had relatively mild anxiety or depressive disorders. This is also reflected in the relatively high baseline quality of life-related utility levels in the GP and generic CMHN arms of 0.70 and in the PS CMHN group of 0.63, compared with a UK population norm of approximately 0.90 in a similar age and gender group. Utility levels improved quickly, approximating to the population norm by 8 and 26 weeks, suggesting, like the other measures, similar patterns of recuperation between arms. It should be noted, however, that relatively few of the patients believed themselves to be fully recovered by the 26-week point. Mean symptom scores at 26 weeks, although improved, were still around 12 on the CIS-R, the level of caseness for psychiatric disorder. A significant proportion of patients therefore remained symptomatic, even though all three groups had improved significantly on average.

Satisfaction

The patients treated by the CMHNs were generally significantly more satisfied with the care they received than those randomised to usual GP care, agreeing that their problems had been better identified and addressed. Comments recorded in the participant feedback questionnaires showed that patients often like to talk to a heathcare professional with good listening skills, at a certain distance from their personal situation, rather than just friends and family. As well as valuing the opportunity to talk, the patients valued more specific interventions such as PST. However, this benefit was gained at some considerable cost.

Economic outcomes

The economic results provide good evidence that CMHN care is significantly more expensive than usual GP care. Health service costs over 6 months were approximately doubled in the two nurse treatment groups compared with the GP care group. On average, generic CMHN care cost an extra £283 per patient, and care from a CMHN trained in problem-solving cost an extra £315 per patient. The main cost driver was the treatment provided by the community psychiatric nurses. PST and supervision was estimated to cost around £36 per patient (assuming training will last for 4 years before a refresher course is required). Consequently, training and supervision did not contribute substantially to the overall additional cost per patient estimated; rather, it was the nurse's time that drove this additional cost. There were no apparent savings in drug costs in either of the CMHN treatment arms. There was a significant reduction in the cost of consultations with their GPs among those patients referred to the PS CMHN arm, but the savings from this were only around 10% of the extra costs of nurse treatment. Conversely, the cost of 'other' hospital contacts was significantly greater for the PS CMHN arm than for the GP care arm, which is difficult to explain. However, because of the large number of comparisons performed across the different costing categories, it is possible that this result was due to chance.

The study by Mynors-Wallis and colleagues[21] suggested that PST for emotional problems provided by non-mental health community nurses could reduce the number of days patients had to take off work compared with usual GP care over 6 months of follow-up. However, this study with a larger sample size could not detect any significant differences in days off work and therefore in employment-related costs.

The lack of any significant advantage in improving symptoms or quality of life in either CMHN

group, coupled to their higher costs as a result of the intervention, shows clearly that referral for CMHN treatment is not cost-effective compared with usual GP care.

Possible explanations for the negative findings

The patients' symptoms were not severe enough

One possible explanation is that the patients included in the study did not have symptoms severe enough to benefit from treatment. A post hoc subgroup analysis suggested that CMHN care was better than GP care, significantly so in the problem-solving arm, for those patients scoring at or above the median on the CIS-R score, at least at the 8-week assessment, although the apparent benefit had disappeared by the 26-week assessment. However, this result must be treated with great caution. It was not a planned subgroup analysis, the study was not powered specifically for it, and the results may have arisen by chance. Other subgroup analyses, dividing the patients into more severe and less severe symptom groups according to the GHQ-12, HADS-D, HADS-A and PSA scales, showed no such advantage for either CMHN arm at either time-point. Neither was any advantage found when restricting the analysis to only those patients with an ICD-10 diagnosis of moderate or severe depressive episode, which is surprising given that PST has been shown in other studies to be beneficial in depression of moderate severity,[19,49] although the sample size for that comparison was limited to 23 patients in each of the GP and PS CMHN arms, and 31 in the generic CMHN arm, which gave very limited power to identify differences between groups.

The original aim was to explore whether scores on brief self-report questionnaires (GHQ-12 and HADS) might help to predict which patients may benefit from referral to CMHN treatment. The lack of benefit shown meant this was not feasible in the event.

The problem-solving treatment was not delivered by the nurses

Another possible explanation for the lack of benefit from PST was that it was not correctly delivered. As far as the audiotaped treatment sessions go, there was evidence that PST was being correctly delivered by almost all of the nurses rated. However, the researchers were able to analyse audiotape-recordings of only a relatively small sample of treatment sessions, due to the apparent discomfort felt by the patients or nurses, or both, at being recorded. The sample for which audiotapes were obtained may be biased in the direction of fulfilling the wish that PST was being delivered properly. However, the PST nurses were trained and supervised as in previous successful studies of PST, and benefited from ongoing feedback from experienced therapists throughout the trial. Informal feedback from the supervisors suggests they believed that, in general, problem-solving was being delivered in accordance with the training the nurses received, just as in previous studies in which they have been involved in training and supervision, which showed PST to be effective. Furthermore, ongoing qualitative work with patients treated in both nurse arms of this study (see below) has shown that patients in the PST group reported that their problems were being addressed and that the nurses were following a structured approach. The PST nurses also stressed in qualitative interviews that they were delivering PST (see below). All the evidence therefore suggests that the PST was indeed delivered as intended.

Strengths of the study

A real-life study

This was a 'real-life' study using NHS community mental health nursing staff. That the study was able to enrol over 50 nurses to the trial overcomes the criticism of bias directed at other studies, for having a smaller number of volunteers self-selected for their interest in research, or interest and expertise in a specific therapy. In addition, the report described fully the 'intervention sample', the CMHNs, and defined in detail the interventions to allow potential replication of the trial, factors that are often under-reported in trials of nursing interventions.[50]

The involvement of a high number of nurses from six trusts, and the inclusion of patients from a range of inner city, urban, and rural general practices across south-central England, suggest that the results are likely to be generalisable to the rest of the UK.

Overcoming problems of recruitment

This was a complex study in terms of recruitment. First, sufficient numbers of nurses to give the treatments had to be enrolled and trained, in repeated rounds of recruitment, partly owing to the relatively high turnover of CMHNs during the study period. In addition, sufficient GPs had to be recruited to the study, and asked to identify,

consent and refer patients during the course of normal surgery consultations, at a time when GPs were reporting an ever increasing workload and showing an ever greater reluctance to spare the time for research. Then, informed consent had to be obtained, and the patients enrolled and followed up for 6 months, a relatively long period for mental health treatment trials. Although the sample size originally planned was not reached (see below), this was a large study, one of the biggest so far of problem-solving, enrolling nearly 250 patients despite the complexities involved. The success of the study is testament to the dedication of the research team.

Good follow-up rates

The follow-up rates were generally good: 86% overall at 8 weeks and 76% at 26 weeks, although it was harder to retain patients in the GP care arm (see below). The study therefore overcame the problems of a small sample size and a high dropout rate affecting the previous trial of GP referral of patients with anxiety and depression to CMHNs.[16]

Limitations of the study

Referral rates and possible referral bias

It is very unlikely that the participating GPs referred all the patients they saw in surgery who would have been eligible for the trial, since many of them referred only one patient each. No information was available on patients who might have been referred but were not, and so it is uncertain whether the patients who were referred are representative of all patients with anxiety, depression and life difficulties presenting to GPs. The study team spent a lot of time maintaining contact with the participating practices, discussing issues affecting referral rates with the GPs, and reminding them at intervals to refer all eligible patients seen in their surgery sessions to the study.

Sample size

The sample size that had originally been planned was not recruited, and the power of the study was reduced as a result. A 4–5-point difference in the CIS-R scores between arms cannot be ruled out with 95% confidence, although a type II error due to lack of power seems very unlikely, given that there was no consistent trend in any of the outcome measures in the direction of benefit from CMHN referral, for either of the two comparisons with GP care, at either follow-up point. In addition, no significant difference was found in the primary outcome when those in the usual GP care group were combined with a combined group formed from the two nurse treatment groups, despite the extra power afforded by that comparison.

The economic analysis used the information obtained on the resource-use questionnaires filled out by the patients, which had gaps in a number of cases. In addition, only patients with complete CIS-R assessments were included in the analysis, further reducing the sample size. However, a secondary source of information, the patients' GP case notes, when used to fill missing data alongside imputed data using the method of mean imputation conditional to the trial arm and follow-up point, did not alter the findings.

Uncertainty about the meaning of the satisfaction scores

Although satisfaction scores were significantly lower in the GP care arm, the actual differences in total satisfaction scores should be treated with some caution, as in calculating the overall scores by adding individual items together the intervals between the points on the five-point scale were treated as being the same for each question and each participant, an assumption that may not hold. It is not known how important an overall 5–6-point difference in the scale is to patients, as the scale has not been validated or calibrated against other measures of satisfaction or patient utilities.

The response rates to the postal questionnaires were lower than the follow-up rate for face-to-face interviews and the responses may reflect a degree of response bias towards receiving more replies from those patients who were satisfied with the treatment they received. The responses to the open-ended questions were subject to a simple content analysis at a descriptive level only, which probably gives less than full insight into their meaning. A qualitative approach is required to explore further patients' attitudes towards talking treatments (see below).

Differential rates for follow-up in the three arms

Although the overall follow-up rates were good, there was a lower follow-up rate in the GP arm. It is difficult to tell whether this biased the findings in a particular direction. Follow-up rates were better among those patients who received the treatment they preferred, so it is likely that there were more disaffected patients in the GP care arm. However, it is not known whether those who dropped out remained more symptomatic than

those who were followed up. Failing to receive their treatment of preference was not associated with a worse outcome on the CIS-R among those who were followed up. The sensitivity analyses suggest that CMHN care, whether generic care or specific PST, is unlikely to be more effective than GP care, unless one believes the LOCF analysis and makes the extreme assumption that all the dropouts remained as symptomatic as they were at the time of last assessment.

Notwithstanding these limitations, the authors believe the results can be presented with a high level of confidence.

Implications for practice

Primary care commissioning of services

The results provide important information for commissioners of services involved in making decisions about whether or not GPs should have direct access to CMHN care for their patients with common mental health problems.

The National Service Framework (NSF) for Mental Health[51] emphasised that less severe mental health problems were very common and that the majority of them should be managed in primary care, with agreed protocols for referral to specialist services, in line with the Mental Health Nursing Review.[11] However, although GP fundholding ended in 1999, GP purchasing power continued to develop through the introduction of primary care groups and subsequently primary care trusts (PCTs), which were charged with the commissioning of services in a 'primary care led NHS'.[52] The lead role of primary care groups in mental health service planning was emphasised in the Department of Health's document *Modernising mental health services*,[53] which suggested that mental health services required a firm base in primary care. The increased power given to primary care organisations to shape the provision of services has meant that GP referrals of people with less severe problems to CMHNs have continued in many areas.

Community mental health team policies

The CMHT policy implementation guide[54] suggests that CMHTs should provide for two groups of patients, stating that "most patients treated by the CMHT will have time limited disorders and be referred back to their GPs after a period of weeks or months (an average of 5–6 contacts) when their condition has improved. A substantial minority, however, will remain with the team for ongoing treatment, care and monitoring for periods of several years". Even where CMHTs have referral policies that restrict ongoing care to people with severe and enduring mental health problems, they often still provide at least one-off assessment for people with less severe problems, which is time-consuming even if patients are then referred straight back to the primary care team for further management. Some community mental health teams have gone further and responded to the demands of primary care by developing specific services for people with mild to moderate symptoms of stress, anxiety and depression. Examples include the Fylde Assessment and Short Term Intervention (ASTI) service,[55] the Community Mental Health Team in Andover, and the Poole and Bournemouth Primary Care Mental Health Teams.

Therefore, best practice in the management of common mental disorders remains an important issue on which PCTs require evidence. So what advice can be provided based on the present results? The findings are in line with the previous study by Gournay and Brooking,[16] who concluded that GP referrals to CMHNs of patients with less severe illnesses were not the best use of a valuable resource. The present findings suggest that PCTs should not purchase individual CMHN care for unselected patients with common mental disorders. There may be other roles in primary care that CMHNs could play effectively, for instance consultation and liaison to support members of the primary healthcare team, or the provision of treatment for patients not responding to self-help or primary care team interventions, in managed stepped care systems, for which there is emerging evidence from the USA.[56,57] However, this will compete with the need for CMHNs within CMHTs to deliver the emerging psychosocial therapies for patients with severe and enduring mental illness, for example compliance therapy[58] and CBT for psychosis.[59–61]

New graduate primary care mental health workers

During the course of this study, primary care mental health policies have continued to develop. Subsequent to the NSF for Mental Health, the NHS Plan recognised that primary care was not well equipped to manage the large number of people with less severe mental health problems, and pledged help through the introduction of graduate primary care mental health workers (PMHWs).[62] It was originally proposed that

PMHWs should be trained in brief therapy techniques of proven effectiveness, and employed to help GPs to manage and treat common mental health problems. It was expected that PMHWs would be mostly psychology graduates, who would have a similar role to that of assistant psychologists in clinical psychology services, but differ by being based in primary care, working alongside the rest of the primary healthcare team. The first wave of these PMHWs was being trained at the time of writing this draft report. It is important that the impact of these new workers is also evaluated, ideally in RCTs (one randomised trial is being conducted in the Heart of Birmingham PCT pilot site).[63]

The results of this study suggest that these new workers should not spend their time treating unselected patients with less severe emotional problems with PST, as this is unlikely to be any more effective than supportive care from the GP. Given the relatively low number of PMHWs (around 1000 nationally initially, i.e. only around three per PCT), they are likely to be better employed in the more extended roles suggested for them in the most recent Department of Health guidance, which include facilitating the delivery of evidence-based interventions for common mental disorders (including self-help), strengthening the information available for patients, supporting the development of practice-based information systems, audit and outcome measurement, improving service users' satisfaction with care, and improving knowledge within general practice teams about the network of community resources for people with mental health problems.[64] A prospective descriptive study of PMHWs, exploring their effectiveness in these roles, is being carried out by the National Primary Care Research and Development Centre in Manchester (Bower P: personal communication, 2005).

The place of problem-solving treatment

The results also suggest that PST should be reserved for patients with depressive disorders of at least moderate severity, for whom it has been shown to be as effective as medication and more effective than placebo and usual GP care.[19,49,65–68] The findings of this study, taken together with the findings of the previous trial of PST delivered by non-mental health community nurses,[21] suggest that it is not cost-effective to use problem-solving as a treatment for the wider range of less severe emotional problems encountered in primary care.

Implications for research

Further work being carried out as part of this study

Two linked studies undertaken alongside the trial will be able to provide additional insights into the trial findings. Members of the research team (CG, LS, JL and LMW) in collaboration with a medical sociologist (KK) are carrying out an in-depth qualitative study with patients receiving CMHN treatment, and are in the process of data analysis at the time of writing this report. The aims of this qualitative study are to explore the patients' experiences and perceptions of the treatment that they received, and to explore, more fully than the questionnaire data reported in Chapter 4 (section 'Satisfaction outcome', p. 33), factors that they found helpful or unhelpful in their treatment. Fourteen patients from the PS CMHN arm and eight patients from the generic CMHN arm have been interviewed, and qualitative analysis is being conducted to identify patterns and themes across the data set. The results will be available in 2005.

Further, a qualitative study with the CMHNs who participated in the trial is being carried out by LS, who is analysing the data at the time of writing this report. The aims are to understand CMHNs' experiences and views of treating patients with common mental health problems, both in general and within the controlled trial setting. Twenty-four of the trial CMHNs (12 from each arm) have participated in individual interviews and 37 trial and non-trial CMHNs have participated in group discussions. This study will give additional perspectives on the issues of RCTs of complex nursing interventions, especially those likely to be influenced by an individual therapist's engagement style, and insight into CMHNs' views on their role in primary care with people with common mental health problems. The results will also be available in 2005.

Future research

The authors' recommendations for future research, in order of priority, are as follows:

1. Research needs to address the predictors of chronicity in common mental disorders, in order to be able to identify which patients are less likely to recover within a few months with treatment from their GPs alone, and so to target extra treatment to those for whom it is needed.

   Common mental health problems are recognised as causing a considerable social and

economic burden. This reflects both the prevalence of the disorders and the fact that although many of the disorders resolve spontaneously, a significant proportion become chronic, with one-third of patients still symptomatic at 1 year.[69] Those patients who remain symptomatic at 1 year often develop illnesses with a chronic course over several years.[70] The challenge in the delivery of care is to target for treatment those patients whose illness will not recover spontaneously before they go on to develop chronic illnesses with long-term disability.

A secondary, exploratory analysis of possible predictors of benefit from treatment across all three groups in this study has indicated that more symptomatic, older and unemployed patients were more likely to remain above the threshold for caseness at 6 months (Price C: personal communication, 2004). It may have been that this study set the threshold for admission too low and that suitable patients for an intervention need to be more symptomatic and have more social impairment. However, these findings must be treated with caution given that the analysis is post hoc and exploratory, and so replication is needed in other studies.

2. More research is needed into the effectiveness and cost-effectiveness of PST for other disorders, including major depression, deliberate self-harm and personality disorders, and for the prevention of mental disorders.

   PST has been shown to be as effective as antidepressants in major depression, but more research is needed to establish its cost-effectiveness compared with other treatments. PST may also be helpful in other disorders, in particular following deliberate self-harm. PST has been identified as being of potential benefit in five studies of deliberate self-harm, summarised in a meta-analysis by Townsend and colleagues, which recommended larger and more definitive studies.[71] Problem-solving skills may also be used in helping patients with personality disorders for whom clear goal-setting might be an advantage. Brief problem-solving techniques are also being evaluated as of possible benefit in preventing mental disorders.

3. More research is needed into the effectiveness and cost-effectiveness of facilitated self-help treatments for common mental disorders.

   These include CBT-based guided bibliotherapy and computerised self-help, exercise and alternative therapies, including St John's wort.[72] More research is needed into the role of the new PMHWs as facilitators of self-help treatment and providers of information on available treatments and resources, with both patients and other members of the primary healthcare team.[73]

4. More research is needed into the effectiveness and cost-effectiveness of CMHN care for people with severe and enduring mental illnesses.

   In addition to more research on the potential value of CMHN consultation and liaison with the primary healthcare team alluded to above, more research is needed into the effectiveness of CMHNs working in CMHTs providing care for people with severe and enduring mental illnesses, including assertive outreach, home-based care, crisis intervention, compliance therapy for antipsychotic treatment and family therapy in preventing relapse.

Chapter 7
Conclusions

Specialist mental health nurse support demonstrated no overall clinical or economic advantage over support from GPs for unselected patients with anxiety, depression and reactions to life difficulties. Primary care trusts could consider adopting policies of restricting referrals of such patients to specialist services. Further, CMHNs within CMHTs could concentrate on delivering the emerging psychosocial therapies for patients with severe mental illness, where there is evidence of benefit.

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Professor Tony Kendrick (Professor of Primary Medical Care) contributed to the design, analysis and report, and Ms Lucy Simons (Research Fellow) to the data collection, analysis and report.
Dr Laurence Mynors-Wallis (Medical Director/Consultant Psychiatrist) and Professor Alastair Gray (Director, Health Economics Unit) contributed to the design, analysis and report.
Professor Judith Lathlean (Professor of Health Research) was responsible for interpretation and contributed to the report, and Dr Ruth Pickering (Senior Lecturer in Medical Statistics) contributed to the design, analysis and report. Mr Scott Harris (Research Assistant, Medical Statistics), Mr Oliver Rivero-Arias (Research Assistant, Health Economics) and Dr Karen Gerard (Senior Lecturer, Health Economics) contributed to the analysis and report, and Professor Chris Thompson (Director of the Priory Health Care Group) to the design and report.

References

1. Briscoe M, Wilkinson G. General practitioners' use of community psychiatric nursing services: a preliminary survey. *Journal of the Royal College of General Practitioners* 1989; **39**:412–14.
2. Sibbald B, Brenneman D, Freeling P, Addington-Hall J. Counsellors in English and Welsh general practices: their nature and distribution. *BMJ* 1993; **306**:29–33.
3. Naji AA, Dow I. *The role of the community psychiatric nurse in community care: a national survey of present practice*. Edinburgh: Chief Scientist's Office, Scottish Office, Department of Health; 1996.
4. White E. *The Third Quinquennial National Community Psychiatric Nursing Survey*. Manchester: Department of Nursing, University of Manchester; 1991.
5. Skidmore D, Friend W. Should CPNs be in the primary health care team? *Nursing Times* 1984; 310–12.
6. Barratt E. Community psychiatric nurses: their self-perceived roles. *J Adv Nurs* 1989;**14**:42–48.
7. Marks I. Controlled trial of psychiatric nurses therapists in primary care. *BMJ* 1985;**290**:1181–4.
8. Moscarelli M, Sartorius N. Costs of anxiety and depression. *Br J Psychiatry* 1995;**166** (Suppl 27):7–9.
9. Wooff K, Goldberg DP, Fryers T. Patients in receipt of community psychiatric nursing care in Salford 1976–82. *Psychol Med* 1986;**16**:407–14.
10. Brooker C, White E. *The 1996 National Community Psychiatric Nursing Survey*. Keele University: Report to the Department of Health, 1997.
11. Mental Health Nursing Review Team. *Working in partnership: a collaborative approach to care*. London: Department of Health; 1994.
12. Department of Health. *The care programme approach for people with mental illness referred to specialist psychiatric services*. HC (90) 22. London: HMSO; 1990.
13. Department of Health. *Discharge guidance and supervision registers*. London: HMSO; 1994.
14. Health Services Research Unit. *The role of the community psychiatric nurse in community care: a national survey of present practice*. Final report submitted to the Chief Scientist's Office, Scottish Office, Department of Health. Aberdeen: University of Aberdeen; 1997.
15. Department of Health. *National Health Service and Community Care Act*. London; HMSO; 1990.
16. Gournay K, Brooking J. Community psychiatric nurses in primary health care. *Br J Psychiatry* 1994;**165**:231–8.
17. Gournay K, Brooking J. The community psychiatric nurse in primary care: an economic analysis. *J Adv Nurs* 1995;**22**:769–78.
18. King M, Broster G, Lloyd M, Horder J. Controlled trials in the evaluation of counselling in general practice. *Br J Gen Pract* 1994;**44**:229–32.
19. Mynors-Wallis L, Gath D, Lloyd-Thomas AR, Tomlinson D. Randomised controlled trial comparing problem solving treatment with amitriptyline and placebo for major depression in primary care. *BMJ* 1995;**310**:441–5.
20. Katon W, Robinson P, Von Korff M, Lin E, Bush T, Ludman E, *et al*. A multifacted intervention to improve treatment of depression in primary care. *Arch Gen Psychiatry* 1996;**53**:924–32.
21. Mynors-Wallis LM, Davies I, Gray A, Barbour F, Gath D. A randomised controlled trial and cost analysis of problem-solving treatment for emotional disorders given by community nurses in primary care. *Br J Psychiatry* 1997;**170**:113–19.
22. Bower P, Rowland N, Hardy R. The clinical effectiveness of counselling in primary care: a systematic review and meta-analysis. *Psychol Med* 2003;**33**:203–15.
23. Simons L, Mynors-Wallis L, Pickering R, Gray A, Brooking J, Thompson C, *et al*. A randomized controlled trial of problem solving for anxiety, depression and life difficulties by community psychiatric nurses among general practice patients: background and method. *Primary Care Psychiatry* 2001;**7**:129–35.
24. King M, Sibbald B, Ward E, Bower P, Lloyd M, Gabbay M, *et al*. 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. *Health Technol Assess* 2000;**4**(19):1–83.
25. Catalan J, Gath D, Edmonds G, Ennis J. The effects of non-prescribing of anxiolytics in general practice I: Controlled evaluation of psychiatric and social outcome. *Br J Psychiatry* 1984;**144**:593–602.
26. Goldberg D, Huxley P. *Mental illness in the community: the pathway to psychiatric care*. London: Tavistock; 1980.

27. World Health Organization. *The ICD-10 classification of mental and behavioural disorders: diagnostic criteria for research*. Geneva: WHO; 1993.

28. Meltzer H, Gill B, Petticrew M. *The prevalence of psychiatric morbidity among adults aged 16–64, living in private households, in Great Britain*. London: OPCS; 1994.

29. Goldberg D, Blackwell B. Psychiatric illness in general practice. A detailed study using a new method of case identification. *BMJ* 1970;**ii**:429–43.

30. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Rating Scale. *Acta Psychiatr Scand* 1983; **67**:361–70.

31. Cooper P, Osborn M, Gath D, Feggetter G. Evaluation of a modified self-report measure of social adjustment. *Br J Psychiatry* 1982;**141**:68–75.

32. Torgerson DJ, Klaber-Moffett J, Russell IT. Patient preferences in randomised trials: threat or opportunity? *J Health Services* 1996;**1**:194–7.

33. Brooks R. EuroQol: The current state of play. *Health Policy* 1996;**37**:53–72.

34. Dolan P, Gudex C, Kind P, Williams A. The time trade-off method: results from a general population study. *Health Econ* 1996;**5**:141–54.

35. Altman DG. Statistics and ethics in medical research. III: How large a sample? *BMJ* 1980; **281**:1336–8.

36. Altman DG. *Practical statistics for medical research*. London: Chapman and Hall; 1991.

37. Briggs A, Gray A. Handling uncertainty when performing economic evaluation of health care interventions. *Health Technol Assess* 1999;**3**(2).

38. Chalkley AJ, Mulhall DJ. The PQRSTUV: The personal questionnaire rapid scaling technique – 'Ultimate version'. *Br J Clin Psychol* 1991;**30**:181–3.

39. Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ* 1996;**281**:1336–8.

40. Simpson S, Corney R, Fitzgerald P, Beecham J. A randomised controlled trial to evaluate the effectiveness and cost-effectiveness of counselling patients with chronic depression. *Health Technol Assess* 2000;**4**(36):1–83.

41. Department of Health. *NHS trust financial returns*. London: Department of Health Publications; 2000.

42. National Statistics. *New earnings survey 2003*. London; Office of National Statistics. 2000.

43. *British National Formulary*. London: British Medical Association/Royal Pharmaceutical Society of Great Britain; 2003.

44. Netten A, Dennett J, Knight J. *Unit costs of health and social care 2002*. University of Kent at Canterbury: Personal Social Services Research Unit; 2002.

45. Lin DY, Feuer EJ, Etzioni R, Wax Y. Estimating medical costs from incomplete follow-up data. *Biometrics* 1997;**53**:419–34.

46. Little RJ, Rubin DB. *Statistical analysis with missing data*. New York: John Wiley; 1987.

47. Stinnett AA, Mullahy J. The negative side of cost-effectiveness analysis. *JAMA* 1997;**277**:1931–2.

48. van Hout B, Al MJ, Gordon GS, Rutten FF. Costs, effects and C/E-ratios alongside a clinical trial. *Health Econ* 1994;**3**:309–19.

49. Mynors-Wallis LM, Gath DH, Day A, Baker F. Randomised controlled trial of problem solving treatment, antidepressant medication, and combined treatment for major depression in primary care. *BMJ* 2000;**320**:26–30.

50. Lindsay B. Randomized controlled trials of socially complex nursing interventions: creating bias and unreliability? *J Ad Nurs* 2004;**45**:84–94.

51. Department of Health. *National Service Framework for Mental Health*. London; Department of Health Publications; 1999.

52. Department of Health. *The new NHS: modern, dependable*. London: HMSO; 1997.

53. Department of Health. *Modernising mental health services: safe, sound and supportive*. London: Department of Health Publications; 1998.

54. Department of Health. *Mental health policy implementation guide: community mental health teams*. London: Department of Health Publications; 2002.

55. Department of Health. *Fast forwarding primary care mental health: gateway workers*. London: HMSO; 2002.

56. Katon W, Robinson P, von Korff M, Lin E, Bush T, Ludman E, *et al*. A multifaceted intervention to improve treatment of depression in primary care. *Arch Gen Psychiatry* 1996;**53**:924–32.

57. Wells KB, Sherbourne C, Schoenbaum M, Duan M, Meredith L, Unutzer J, *et al*. Impact of disseminating quality improvement programs for depression in managed primary care. *JAMA* 2000; **283**:212–20.

58. Kemp R, Hayward P, Applewhaite G, Everitt B, David A. Compliance therapy in psychotic patients: randomised controlled trial. *BMJ* 1996;**312**:345–9.

59. Sensky T, Turkington D, Kingdon D, Scott JL, Scott J, Siddle R, *et al*. A randomized controlled trial of cognitive-behavioral therapy for persistent symptoms in schizophrenia resistant to medication. *Arch Gen Psychiatry* 2000;**57**:165–72.

60. Pilling S, Bebbington P, Kuipers E, Garety P, Geddes J, Orbach G, *et al*. Psychological treatments in schizophrenia. I: Meta-analysis of family intervention and cognitive behaviour therapy. *Psychol Med* 2002;**32**:763–82.

61. Turkington D, Kingdon D, Turner T. Effectiveness of a brief cognitive-behavioural therapy intervention in the treatment of schizophrenia. *Br J Psychiatry* 2002;**180**:523–7.

62. Department of Health. *The NHS plan*. London: HMSO; 2000.

63. Cooper H, Lester H, Freemantle N, Wilson S. A cluster randomised controlled trial of the effect of primary care mental health workers on satisfaction, mental health symptoms and use of services: background and methodology. *Primary Care Psychiatry* 2003;**14**:475–83.

64. Department of Health. *Graduate primary care mental health workers: best practice guidance*. London: HMSO; 2003.

65. Barrett JE, Williams JW Jr, Oxman TE, Frank E, Katon W, Sullivan M, *et al*. Treatment of dysthymia and minor depression in primary care: a randomized trial in patients aged 18 to 59 years. *J Fam Pract* 2001;**50**:405–12.

66. Dowrick C, Dunn G, Ayuso-Mateos JL, Dalgard OS, Page H, Lehtinen V, *et al*. Problem solving treatment and group psychoeducation for depression: multicentre randomised controlled trial. *BMJ* 2000;**321**:1450–4.

67. Williams J, Barrett JE, Oxman TE. Treatment of dysthymia and minor depression in primary care: a randomized controlled trial in older adults. *JAMA* 2000;**284**:1519–29.

68. Dowrick C, Casey P, Dalgard O. Outcomes of Depression International Network (ODIN). *Br J Psychiatry* 1998;**172**:359–63.

69. Mann AH, Jenkins R, Belsey E. The twelve-month outcome of patients with neurotic illness in general practice. *Psychol Med* 1981;**11**:535–50.

70. Lloyd KR, Jenkins R, Mann AH. Long term outcome of patients with neurotic illness in general practice. *BMJ* 1996;**313**:26–8.

71. Townsend E, Hawton K, Altman DG, Arensman E, Gunnell D, Hazell P, *et al*. The efficacy of problem-solving treatments after deliberate self-harm: meta-analysis of randomized controlled trials with respect to depression, hopelessness and improvement in problems. *Psychol Med* 2001;**31**:979–88.

72. National Institute for Clinical Excellence. Depression: the management of depression in primary and secondary care. London: NICE; 2004.

73. Lester H, Glasby J, Tylee A. Integrated primary mental health care: threat or opportunity in the new NHS? *Br J Gen Pract* 2004;**54**:285–91.

Appendix 1

Information sheet for patients

A study of the usefulness of two types of therapy, given by community mental health nurses, compared with usual treatment by the family doctor.

Introduction

This study is assessing three types of treatment for people with emotional or social difficulties. The three types of treatment being compared are:

i. Problem-solving therapy given by a mental health nurse. This involves listing your problems and listing the steps needed to solve each problem and helping you to overcome the barriers to solving them.
ii. Treatment from a mental health nurse. The nurse will meet with you and offer you whatever treatment he or she thinks is appropriate. This may include talking about your symptoms and problems.
iii. Treatment from your GP. The doctor will offer you treatment he or she thinks is appropriate. This may include meeting with you, talking about your problems or medication.

Both the first two treatments would be carried out in up to six appointments with a community mental health nurse, either at your doctor's surgery or in your home.

The decision about which of these treatments you will receive is made at random. Whichever treatment you receive you will be able to continue to see your own family doctor. If you are allocated to a mental health nurse, we would like to tape-record (audiotape) the therapy sessions with your permission, in order to check on the exact type of therapy given. Around one in forty of these tapes will be selected at random to be checked by a doctor or therapist working on the study. All the tapes will be kept anonymously and destroyed at the end of the three-year study.

What will I have to do if I take part?

If you take part in the study, you will be offered one of the treatments listed above, and you will also be asked to see a research worker on three occasions for a confidential interview about your symptoms. These interviews last about 1 to $1^1/_2$ hours and will be arranged at a time convenient to you. You will also be asked to fill in some questionnaires about how you are feeling, what your treatment preferences are and what views you have of other treatments.

What are the possible risks of taking part?

There should be no risk to you. You will be encouraged to talk through your problems with the mental health nurse or your doctor, but anything you tell them will be confidential. If you feel unable to talk through any problem, they will not press you on this.

Are there any possible benefits?

If you agree to take part in this study, you will be helping us decide which is the best way to help people with emotional symptoms in the future.

Do I have to take part?

You are free not to take part in this study, or to withdraw from the study at any time without your care being affected. If you do withdraw from the study we will liaise with your family doctor to arrange whatever further treatment is appropriate.

What do I do now?

The research worker will advise you about further treatment. If you have any questions or worries about the study, please telephone one of us at the numbers given below. Please discuss this information with your family or friends, as well as your GP, if you wish.

Appendix 2

Unpublished assessments

Idno ☐☐☐

CPN-GP Study

Patient preference – (baseline)

In this study we are comparing three types of treatment. Please could you look at the information booklet about these treatments.

Q1 Please tick the box that corresponds to your preference for which type of treatment should be used to treat your current problems.

Treatment from your general practitioner ☐

Treatment by a mental health nurse ☐

Problem-solving treatment by a mental health nurse ☐

Don't know ☐

Q2 How much do you prefer each of the alternatives?

	Not at all	*Not very much*	*Don't mind*	*Fairly*	*Very much*
Treatment from GP	☐	☐	☐	☐	☐
Treatment by a mental health nurse	☐	☐	☐	☐	☐
Problem-solving by a mental health nurse	☐	☐	☐	☐	☐

Q3 How strongly do you agree or disagree that people suffering from depression should be treated with medication?

Strongly agree ☐

Tend to agree ☐

Neither agree nor disagree ☐

Tend to disagree ☐

Strongly disagree ☐

☐☐☐

Q4 How addictive would you say the following drugs are?

	Not addictive at all	*Not very addictive*	*Fairly addictive*	*Very addictive*
Tranquillisers (for example sleeping tablets) or Valium (diazepam)	☐	☐	☐	☐
Antidepressants (depression tablets)	☐	☐	☐	☐
Aspirin	☐	☐	☐	☐

Q5 How effective would you say the following are in the treatment of depression?

	Very effective	*Fairly effective*	*Not very effective*	*Not at all effective*
Antidepressants (depression tablets)	☐	☐	☐	☐
Tranquillisers (for example sleeping tablets) or Valium (diazepam)	☐	☐	☐	☐
Counselling and/or talking about the problem	☐	☐	☐	☐

Q6 Have you any other comments you would like to make? Please continue on a separate sheet if necessary

Idno

CPN-GP Study

Socio-demographic interview

Date of interview

D D M M Y Y

Interviewer Initials

Location of interview

1. Home
2. GP Surgery
3. Other

Postcode

Sex

Male ☐ Female ☐

Date of birth

D D / M M / Y Y Y Y

Q1 Ethnic group

☐ White ☐ Black Caribbean ☐ Black African

☐ Black Other ☐ Indian ☐ Pakistani

☐ Bangladeshi ☐ Chinese ☐ Other Asian group

☐ None of these – other, please say

Q2 Marital status

☐ Married ☐ Widowed ☐ Divorced

☐ Cohabiting ☐ Separated ☐ Single

Q3 a) Number of dependants in the home (not children)

Q3 b) Number of children under 5 years

Q3 c) Number of children aged 5 to 16 years inclusive

Q4 **a) Patient's occupation**

Economic position

☐ Full-time work ☐ Part-time work ☐ Permanently sick/disabled

☐ Unemployed ☐ Retired ☐ Student

☐ Housewife ☐ Other

Economic other

If 'other' please say

Q4 **b) Current/main employment (write housewife if appropriate)**

Patient occupation

Q4 **c) If currently unemployed, last full-time occupation**

Patient social class

Organisation function/nature of business

Number of people supervised

Q5 **a) Partner's occupation – Economic position**

☐ Full-time work ☐ Part-time work ☐ Permanently sick/disabled

☐ Unemployed ☐ Retired ☐ Student

☐ Housewife ☐ Other

Economic other

If 'other' please say

Q5 **b) Current/main employment (write housewife if appropriate)**

Partner's occupation

Q5 **c) If currently unemployed, last full-time occupation**

Partner's social class

Number of people supervised

Organisation function/nature of business

Q6 **a) Age left full-time education**

Q6 b) Age left part-time education

Q6 **c) Highest exam level**

☐ None ☐ CSE ☐ GCSE/'O' Level ☐ 'A' Level ☐ HND ☐ Degree ☐ Other

If 'other', please specify

Exam level other

Q6 **d) Still in education**

☐ Yes – FT ☐ Yes – PT ☐ No

If still in PT or FT education, title of course

Course title

Q7 **a) Accommodation status**

☐ Owner-occupied ☐ Council/housing association ☐ Private rental

☐ Other rented ☐ Lives with parents ☐ Other

If other please specify

Q7 **b) Type of accommodation**

☐ Detached ☐ Semi-detached ☐ End-terrace

☐ Mid-terrace ☐ Flat/maisonette ☐ Bedsitter

☐ Hostel ☐ Halls of residence ☐ NFA

☐ Other please specify

Other accommodation

Floor of main accommodation

Past illness history

Past history of emotional or mental health problems (depression, anxiety, etc.)

Q8 **Have you had any emotional or mental health problems in the past? If none go to Q19.**

Number of previous episodes requiring treatment: ☐☐

Q9 **How old were you when you first had this type of problem?**

Age at first episode: ☐☐

Q10 **What do you understand was your previous diagnosis? What were you told was wrong with you?**

☐☐ ☐☐ ☐☐ ☐☐ ☐☐

1 – depressive disorder
2 – anxiety disorder (OCD, panic, agoraphobia, etc.)
3 – mixed anxiety/depression
4 – schizophrenia/other psychotic disorders
5 – eating disorders
6 – substance abuse (drugs/alcohol/solvents, etc.)
7 – other

Q11 **What was the longest time you had emotional or mental health problems?**

Longest duration of episode (in weeks) ☐☐☐

Q12 **Have you been given any drugs in the past for emotional/mental health problems?**
Previous drug treatment(s): ☐ Yes ☐ No

Q13 **If yes, please specify drug name**
What were the names of the drugs you were given?

☐ ☐ ☐ ☐

1 – Hypnotics & anxiolytics
2 – Antipsychotics
3 – Antidepressants
4 – Other

☐☐☐

Q14 Previous psychological treatment(s)

Yes ☐ No ☐

Q15 If yes, please specify treatment type

☐☐☐☐

1 – psychiatrist
2 – counsellor
3 – psychologist
4 – mental health nurse
5 – social worker
6 – other
7 – uncertain

Q16 Previous ECT?

Yes ☐ No ☐

Q17 Have you seen a psychiatrist for any emotional or mental health problem?

Yes ☐ No ☐

Q18 Have you been an inpatient for any emotional or mental health problem?

Yes ☐ No ☐

Q19 Has anyone in your immediate family (parent, brother or sister, child) had treatment for emotional or mental health problems?

Yes ☐ No ☐

Idno

CPN-GP Study

Health resource use (baseline)

We would like to know the number of contacts you have had with the following services over the last 4 weeks.
Please answer each of the following questions by writing in the appropriate boxes. If there has been no contact place a zero in the appropriate box.

Q1 General Practice and Community Nursing Services

Number of times you saw a GP at the Surgery?

Number of times you saw a GP at your home?

Number of times you spoke to a GP on the telephone?

Number of times you saw a practice nurse at the Surgery?

Number of times you saw a counsellor at the Surgery?

Q2 Social Services

Number of times you saw a social worker?

How many of these visits were in your home?

Q3 Psychiatric Hospital and Community Services

Number of times you saw a psychiatrist at the hospital clinic?

At which hospital?

Number of times you saw a psychiatrist at home?

Number of times you saw a psychologist?

Q4 a) Other Hospital and Specialist Services

Number of times you attended a Day Hospital?

At which hospital?

Q4 b) Number of times you went to Accident & Emergency Department?

At which hospital?

Q4 **c) Number of nights you spent in a hospital ward?**

At which hospital?

Q4 **d) Number of contacts with anyone else from the hospital?**

Which health professional did you see?

At which hospital?

Q5 **Out of pocket expenses**

Over the last 4 weeks have you paid from your own pocket for any over the counter medications or for visits to aromatherapists, acupuncturists, or other non-NHS health professionals?

Please tick appropriate box yes ☐ no ☐

If 'yes' what was the approximate total cost?

Q6 **Employment**

Are you in paid employment? Full time ☐ Part time ☐ No ☐ (if no omit next question only)

If yes, how many days off work have you had over the last **4 weeks**?

Have any friends or family had to take time off work in the last **4 weeks** to help you?

How many days over the last **4 weeks** have you been unable to follow your usual daily activities?

Idno

Problem severity assessment

This questionnaire asks you about two main problems that you have been experiencing in your life in recent weeks.

You should think about the most important problem you have and write it in the box marked Main Problem. Then look carefully at the pairs of words listed underneath the box. Choose the word from each pair that most closely describes the nature of that problem. You must choose one word from each pair even if you think the words seem odd or inappropriate.

Please tick the box for each word chosen.

Main Problem

problem code

Absent	
Mild	
Absent	
Moderate	
Mild	
Moderate	
Mild	
Severe	
Moderate	
Severe	
Moderate	
Very severe	
Severe	
Very severe	

Please repeat the same process for your second problem.

Second Problem	problem code

Absent	
Mild	
Absent	
Moderate	
Mild	
Moderate	
Mild	
Severe	
Moderate	
Severe	
Moderate	
Very severe	
Severe	
Very severe	

Patient satisfaction questionnaire

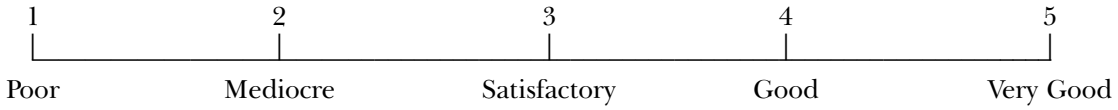
Please indicate by ticking the boxes your views on any treatment you have received from the CPN-GP Study. You should not include any other treatments arranged by your GP or from anywhere else.

	Strongly agree	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
1. I found the treatment helpful					
2. I was given help in dealing with problems					

3. I understand what was wrong with me	☐	☐	☐	☐	☐
4. I am now fully recovered	☐	☐	☐	☐	☐
5. I would like to have had more treatment	☐	☐	☐	☐	☐
6. I did not feel that I got the best treatment possible	☐	☐	☐	☐	☐
7. I felt that the doctor listened to me	☐	☐	☐	☐	☐
8. I felt that the nurse listened to me (please ignore this question if you have not seen a nurse)	☐	☐	☐	☐	☐
9. I had help in planning what to do between appointments	☐	☐	☐	☐	☐
10. My problems were pinpointed	☐	☐	☐	☐	☐
11. I would recommend this treatment to a friend	☐	☐	☐	☐	☐

Problem-solving competency checklist

For each item, assess the student on a scale of 1–5 and record the rating on the line next to the item number. If the descriptions for a given item occasionally do not seem to apply to the session you are rating, feel free to disregard them and use the more general scale below.



Please do not leave any items blank. For all items, focus on the skill of the student, taking into account how difficult the patient seems to be and the stage in therapy.

Patient ID Number _____ **CPN ID number** _____

Session number _____

PART 1: GENERAL THERAPEUTIC SKILLS

1. Clarity of Communications

1. Student overused jargon and was muddled in his/her presentation of information.
2. Student presented information in a generally coherent fashion but was overly technical.
3. Student presented information in a generally clear way.
4. Student presented information in a clear and well ordered fashion and checked patients' understanding.

2. Pacing and Efficient Use of Time

1. Student made no attempt to structure therapy time. Session seemed aimless.
2. Session had some direction, but the student had significant problems with structuring or pacing (e.g. too little structure, inflexible about structure, too slowly paced, too rapidly paced, unable to deal with over-talkativeness).
3. Student was reasonably successful at using time efficiently. Student maintained appropriate control over flow of discussion and pacing.
4. Student used time very efficiently by tactfully limiting peripheral and unproductive discussion and by pacing the session as rapidly as was appropriate for the patient.

3. Facilitates Communication

1. No attempt to facilitate patient communication.
2. Some use of facilitating skills but overuse of closed questions with little encouragement for patient to be open about problems.
3. Student made reasonable efforts to facilitate communication.
4. Every effort made to facilitate communication – relaxed, open posture; made and maintained eye contact with the patient; made facilitative noises while listening; made supportive comments.

4. Interpersonal Effectiveness

1. Student had poor interpersonal skills. Seemed hostile, demeaning, or in some other way destructive to the patient.
2. Student did not seem destructive, but had significant interpersonal problems. At times, student appeared unnecessarily impatient, aloof, insincere or had difficulty conveying confidence and competence.
3. Student displayed a satisfactory degree of warmth, concern, confidence, genuineness and professionalism. No significant interpersonal problems.
4. Student displayed optimal levels of warmth, concern, confidence, genuineness and professionalism, appropriate for this particular patient and in this session.

PART 2: APPLICATION OF PROBLEM-SOLVING TECHNIQUES

5. Explanation and Rationale

1. Student used procedures without adequate and explicit rationale.
2. Student tended to give incomplete and/or unclear rationale for procedures used.
3. Acceptable explanation of problem-solving treatment
4. Student gave complete rationale and established patient comprehension.

6. Clearly Defining the Problem

1. No attempt to define problem.
2. Some attempt to clarify problem but problem remains somewhat woolly and indefinite. Complex problems not broken down.
3. Satisfactory attempt to clarify problem.
4. Excellent definition of problem, patient and student both clear about problem.

7. Setting Achievable Goals

1. No goals set.
2. Goals set but by student not patients, or goals not achievable during therapy, or goals remain vague and non-specific.
3. Reasonable attempt to set clear SMART goals.
4. SMART goals set by the patient and patient understands the goals set.

8. Looking at Solutions

1. No attempt made to consider different solutions.
2. Inadequate consideration of alternative solutions, or too many ideas from student, or no decision making guidelines given.
3. Satisfactory attempt to consider alternative solutions and made a decision.
4. Good structured approach to consider alternative solutions, involving brainstorming patient's ideas; deferring judgement until as many solutions as possible considered. Clear decision making guidelines spelt out.

9. Homework

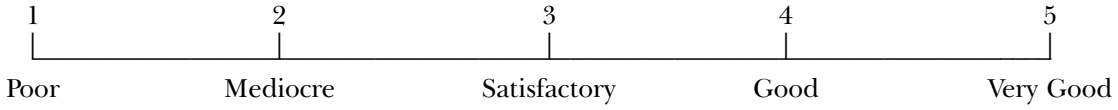
1. Student did not set homework.
2. Homework tasks set but not clearly defined.
3. Homework tasks set with satisfactory detail.
4. Clear homework tasks set out in precise terms with times and frequency of activities where appropriate. Patient seen to understand the relevance of tasks set.

10. Reviewing Previously Set Homework

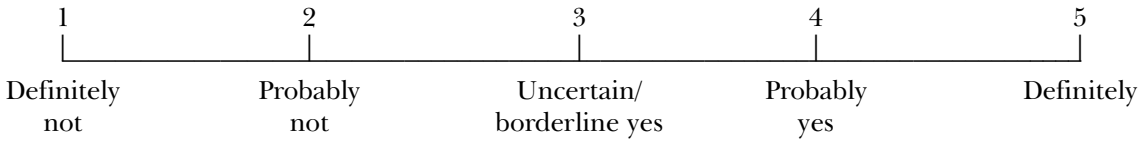
1. Student did not review previous homework.
2. Student reviewed previous homework poorly and in a cursory fashion.
3. Student reviewed previous homework competently.
4. Student reviewed previous homework very well, praising success and making helpful positive comments about failure, using homework then as platform for session.

OVERALL RATINGS AND COMMENTS

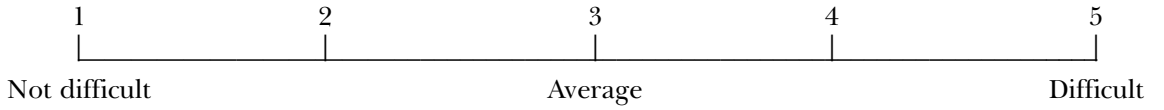
1. How well would you rate the clinician overall in this session as a student using problem-solving for emotional disorders?



2. If you were conducting an outcome study of problem-solving, do you think you would select this student to participate at this time (assuming this session is typical)?



3. How difficult did you feel this patient was to work with?



BLIND TO TREATMENT GROUP
Which treatment group was this CPN in? (please circle)

PST Generic CPN Don't know

Appendix 3

The EQ-5D classification system

1 Mobility
1 I have no problems in walking about
2 I have some problems in walking about
3 I am confined to bed

2 Self-care
1 I have no problems with self-care
2 I have some problems washing or dressing myself
3 I am unable to wash or dress myself

3 Usual Activities (e.g. work, study, housework, family or leisure activities)
1 I have no problems with performing my usual activities
2 I have some problems with performing my usual activities
3 I am unable to perform my usual activities

4 Pain/Discomfort
1 I have no pain or discomfort
2 I have moderate pain or discomfort
3 I have extreme pain or discomfort

5 Anxiety/Depression
1 I am not anxious or depressed
2 I am moderately anxious or depressed
3 I am extremely anxious or depressed

Appendix 4

CMHN process notes and PST paperwork

Patient case notes

GP Name

First name

Surname

Surgery address

Date of Birth

Study Number

Telephone number

Date of contact

Ethnicity

Room available in surgery?

NHS number

Address

Notes

Telephone number

Patient case notes

Presenting problems/symptoms

Please note: if the patient is at risk of suicide, the GP should be informed and the patient may be withdrawn from the study. If the patient is a risk to others you may take action to inform the appropriate authority.

Plan for treatment

Patient case notes

Details of follow-up contacts

Date	Evaluation/progress of plan	Review date

Patient case notes

Progress continued

Date	Evaluation/progress of plan	Review date

Nurse's Signature Date

CPN treatment summary report

(to be completed at the end of treatment)

Patient name	Start of treatment
GP name	End of treatment
CPN name	Number of sessions

Presenting symptoms

Summary of treatment

Outcome of treatment

CPN/patient contact recording sheet
Usual treatment

CPN name/number _____ ☐☐☐

Patient name/number _____ ☐☐☐

Please complete table after each contact with the patient. The location box should have a code in for each arranged visit, even if patient was not seen, e.g. M or DNA

Patient contact	Date	Location (see key below)	Time with patient (to the nearest 15 mins)	Approx travelling time from CPN base (one way)
Assessment visit				
Follow-up 1				
Follow-up 2				
Follow-up 3				
Follow-up 4				
Follow-up 5				
Follow-up 6 (in case of DNA)				
Follow-up 7 (in case of DNA)				

Over the treatment period, please estimate the amount of contact with your usual supervisor for this patient (please tick one box)

None	15 mins	30 mins	45 mins	1 hour	$1\frac{1}{4}$ hours	$1\frac{1}{2}$ hours
☐	☐	☐	☐	☐	☐	☐

Was the patient seen within your usual catchment area? (Y/N) ☐

How many sessions were tape recorded? ☐

Key to location code
H = patient's home
S = GP surgery or other NHS location
B = CPN base
M = missed appointment (patient failed to attend without notice)
DNA = did not attend for other reasons (cancelled appointment with notice)

CPN/patient contact recording sheet
Problem solving

CPN name/number _____ | | | |

Patient name/number _____ | | | |

Please complete table after each contact with the patient. The location box should have a code in for each arranged visit, even if patient was not seen, e.g. M or DNA

Patient contact	Date	Location (see key below)	Time with patient (to the nearest 15 mins)	Approx travelling time from CPN base (one way)
Assessment visit				
Follow-up 1				
Follow-up 2				
Follow-up 3				
Follow-up 4				
Follow-up 5				
Follow-up 6 (in case of DNA)				
Follow-up 7 (in case of DNA)				

How many supervision sessions did you attend for this patient? | | |

How many sessions were tape recorded? | | |

Was the patient seen within your usual catchment area? (Y/N) | | |

Key to location code
H = patient's home
S = GP surgery or other NHS location
B = CPN base
M = missed appointment (patient failed to attend without notice)
DNA = did not attend for other reasons (cancelled appointment with notice)

Problem-solving worksheet

Problem:

Goal(s):

Solutions:

a)	a) Pros (+)	a) Cons (–)
b)	b) Pros (+)	b) Cons (–)
c)	c) Pros (+)	c) Cons (–)
d)	d) Pros (+)	d) Cons (–)

Choice of solution:

Steps to achieve solution (homework):

a)

b)

c)

d)

Next appointment ……

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Feedback

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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