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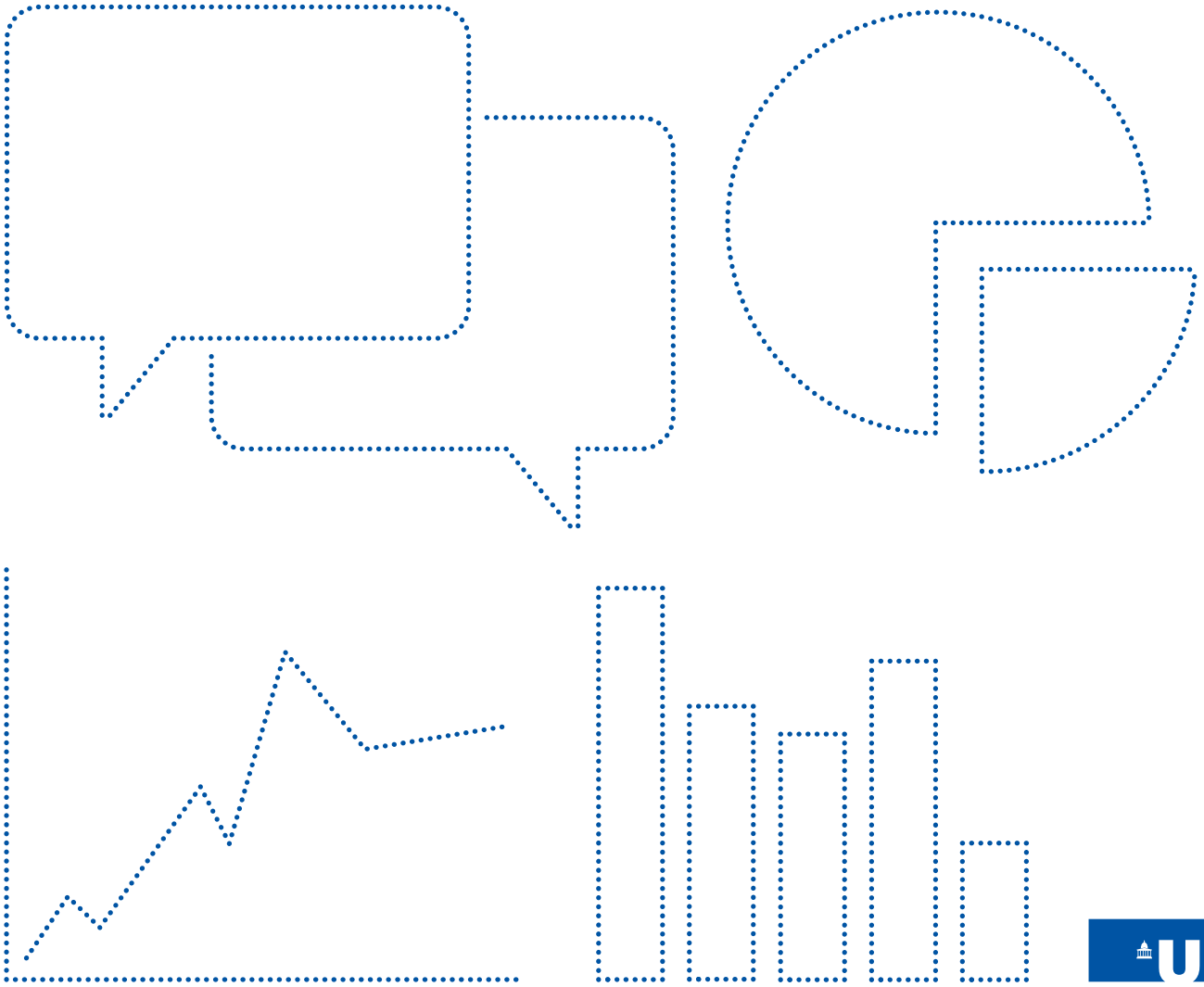
ProCEED

Report of a study of proactive care by practice nurses for people with depression and anxiety



UCL

This report presents the findings of a three year study which explored whether regular proactive reviews delivered by nurses in GP practices resulted in better mental health and social outcomes for people living with depression.

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Foreword

Primary care professionals see people experiencing depression every day. Many people also have one or more long-term physical conditions and often a range of social problems. For some, the term 'depression' doesn't do justice to describing their lives and William Styron, in his autobiographical account *Darkness Visible*, called depression a 'wimp of a word' preferring the term melancholia.

It seems amazing but people with chronic recurrent depression still do not routinely get the same quality of systematic nurse-led chronic disease management that a person with diabetes or a person with asthma will have been receiving for decades. The very nature of depression often means that people drop out of care, disappear from view and get forgotten in a way that would rarely happen to someone with type 2 diabetes. Historically, practice nurses have received relatively little training in organising and providing depression care, traditionally seeing it more as the remit of the GP.

This gap is being addressed particularly since the introduction of depression indicators in the Quality and Outcomes Framework (QOF). The existing indicators have never however gone so far as to reward systematised chronic disease management for people with chronic recurrent depression. There has been much debate about the existing indicators and currently there is an opportunity to make them more relevant. One improvement could be to reward practices for having nurse-led systems of chronic depression management in place.

The ProCEED study is therefore very timely and the findings will add to the debate about how best to monitor and achieve high quality depression care in general practice. A large component of this involves ongoing practice-based chronic disease management for people with chronic and recurrent depression led by well trained and confident practice nurses.

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Section 1
Executive summary

Executive summary

"This report will be of interest to GPs and practice managers looking for new ways to meet the need for services designed to help those with chronic and recurrent depression."

This report will be of interest to GPs and practice managers looking for new ways to meet the need for services designed to help those with chronic and recurrent depression. It will also be of interest to practice-based nurses, looking to improve their confidence and skills in helping those with depression, and people with depression who are interested in new approaches to help manage their condition. In addition a training pack (Supporting people with depression and anxiety: A guide for practice nurses) has been produced for practice nurses building on the findings of this study.

The majority of people who seek support from the NHS for depression are treated within general practice, it being the third most common reason for consultations. There is evidence that over half of all people who experience a significant episode of depression will have a second episode, and that the risk of further recurrences increases greatly with each episode. However, there appears to be little consistency in the longer-term care and support offered to people in primary care, despite the significant psychological, physical and social difficulties they face.

The rationale behind this trial was to evaluate the treatment of depression as a potentially chronic or recurring problem, using regular proactive contact and follow-up of at risk people by practice nurses, supported by general practitioners (GPs) in their practices. There is evidence in favour of such strategies from the USA, but they have not previously been formally researched in the UK. Work from the USA has shown that organised, enhanced care can have a beneficial effect both on the outcomes of participants with a new episode of major depression and also those with a high risk of recurrence. The form of organised or enhanced care suggested in this proposal has elements in common with management of other chronic diseases in general practice such as asthma, diabetes and hypertension. Practice nurses are in an excellent position to provide such an approach and there is evidence that they can do this very well, often communicating particularly effectively with participants in the management of chronic problems.

In addition to the main randomised controlled trial which evaluated the impact of structured care provided by practice nurses using standard outcome measures, we conducted two qualitative studies which were separately funded by the research team at University College London.

Aims

The main objective was to establish whether structured, proactive care provided by practice nurses for participants with chronic depression in primary care can lead to a cost effective improvement in medical and social outcomes when compared with usual GP care.

A secondary objective of the original study was to assess whether training general practice nurses can lead to improved assessment and follow-up of participants with chronic depression and provide ongoing skills in this area.

A further aim of the qualitative study was to explore the impact of receiving or delivering nurse-led proactive care on both the intervention participants and the practice nurses, and to establish which components of the intervention are likely to be associated with a positive outcome, from both the participant and practice nurse perspective.

Methods

This was a randomised controlled trial. The comparison was between 'GP usual care' (control arm) and 'structured care' involving regular follow-up by practice nurses in addition to 'GP usual care' (intervention arm), for participants with a history of recurrent or chronic depression. Participants were recruited from 42 general practices throughout the UK. The main trial evaluated the intervention overall, analysing the data collected from all participants using standard outcome measurement scales, while the qualitative study collected in-depth interview data from a sub-set of the individual participants and practice nurses who had been involved in the trial.

Intervention

For all intervention participants the practice nurse undertook a baseline assessment, asking about current mood, social circumstances, current treatment (medication and/or psychological therapy) and any side-effects or queries about their disorder or its management. Participants were given an educational booklet about depression and its treatment at this initial appointment. The nurses answered any questions about current or past treatments and checked whether participants were taking any treatments currently prescribed and clarifying any problems identified. If there were current symptoms of depression, alternative or additional treatments were discussed. These could be in the form of medication, psychological therapies or social interventions. The rationale and evidence for any of these was made clear, both in the background literature given to participants and in their discussions with the nurses. Social factors, which could be contributing to the ongoing nature of participants' depression, were explored (for example social isolation, low physical activity, unemployment, finance, housing) and appropriate advice given or referrals to other agencies made. The importance of participant choice and their active participation in this process and in deciding the treatments selected was emphasised. A joint management plan was formulated between the nurses and each of their participants and reviewed during subsequent appointments, together with a review of how the participant was feeling and any progress made against previous goals set.

The intervention consisted of 10 appointments with the practice nurse over a two year period. If participants were keeping well and if requested by the participant and considered appropriate, this review could be conducted over the telephone. If nurses were concerned about a trial participant, they were asked to discuss them with the relevant GP, who might also see the participant if indicated. During the 24 month study period the participants in the control arm had 'treatment as usual' and continued to see their GP on request, with no restrictions placed on any interventions which the GP might recommend.

All the participating practice nurses received three full days of training. Each nurse was also assigned a member of the research team as a 'clinical supervisor' and had regular telephone contact (generally every three to four months) with them throughout the trial period.

Outcome measures

The impact of the intervention was evaluated using several standard tools to measure symptoms of depression and their impact. The key outcome was the severity of the symptoms the participant experienced, measured using a questionnaire called the Beck Depression Inventory (BDI-II). A range of other outcome measures were used to collect data on social functioning, quality of life, the costs of medical and informal care for these participants and their health service use. All of these measures collected numerical data, which was analysed using statistical techniques to look for evidence of whether the intervention had led to a positive change overall.

The qualitative study collected information from a sub-set of the practice nurses and participants who had received practice nurse input through semi-structured interviews. Those interviewed were selected to cover a whole range of important characteristics within the two groups and the interviews were continued until no new themes emerged. This qualitative data gave us additional information and useful insights into some of the main trial findings.

Main findings

558 people were recruited to participate in this study, with 282 in the intervention group, and 276 in the control group. The baseline data indicated that the intervention and control groups were broadly similar and that this was a severely affected group, with just over 60 per cent of participants scoring in the severely depressed and moderately/severely functionally impaired ranges on the relevant outcome measures.

Severity of depression

— There was a trend towards a decrease in severity of depression in both intervention and control groups.

— Overall the intervention led to a small improvement in severity of depression above that found in the control group, but the evidence was not strong enough to conclude that this was caused by the intervention, rather than chance.

Social functioning

— There was an improvement in social functioning between baseline and follow-up in both the intervention and control groups.

— There was a greater improvement in the reported social functioning of the group that received the nurse intervention compared to the control group. This effect was found to be statistically significant and therefore it can be said that the intervention improved social functioning.

Health status

— There was an improvement in participant reported health status between baseline and follow-up in both the intervention and control groups.

— The intervention had a small impact on perceived health status leading to a greater improvement in this group compared to the control group, but the evidence was not strong enough to conclude that this was not a chance finding.

Session attendance

— Relating the improvements seen in severity of depression, social functioning and general health to the number of sessions attended found statistically significant improvements, per session, in severity of depression and social functioning in the intervention group.

— Attending all 10 sessions can lead to significant improvement in the severity of depression and a significant increase in social functioning.

Service usage

— The intervention appears to have led to a significant increase in the number of nurse/counsellor sessions attended by participants in the intervention group and also a significantly greater number of months people spent on antidepressants, during the study period, compared to the control group. It does not appear to have led to a difference in the number of GP appointments.

Cost effectiveness

— Looking at the clinical measures, if commissioners were willing to pay £300 in public sector costs per point of improvement in depression and social functioning, the likelihood of the intervention being more cost effective than treatment as usual was greater than 50 per cent.

— The cost effectiveness analysis indicated that the intervention was not more cost effective than treatment as usual in terms of quality adjusted life years (QALYs).

Qualitative results

A sub group of people with chronic depression valued this intervention and perceived that they benefited from it. The characteristics of this sub-group included those who reported feeling open to the intervention in the first instance and those who reported having significant life events immediately before or during the intervention.

Participants and the nurses perceived that benefits came from developing a working rapport, aided by a focused format to the review sessions and continuity in the nurse providing the intervention.

Many participants said that they saw the nurses as an appropriate professional to consult for this type of intervention; often perceiving their general practitioners as being focused on prescribing medication and not having enough time to address their other concerns fully.

"I have huge faith in my doctor and if I go with a medical problem that's fine but I think depression isn't an acute medical problem. I think it's more something that you need to have time with somebody. And the time to me is more important than the prescription. That time to me [with the nurse] was worth 100 prescriptions." Participant 22

It was clear from the interviews that, prior to taking part in the study, many of the practice nurses were apprehensive about broaching mental health problems in the clinical consultation and felt inadequately prepared to respond to participant with low mood.

Many practice nurses reported that receiving appropriate training and having contact with participants with depression through the trial, improved their confidence and clinical skills.

"I'm more confident about talking to people about how they feel and not so worried about, you know, what they're gonna throw at me and say back." Nurse 10

Nurses who reported a previous experience and a positive attitude to mental health issues prior to the trial also seemed to find providing this care more acceptable and positive than those who felt they had been encouraged to take part by other members of the primary care team.

Discussion

It was possible to recruit a large number of primary care participants to this trial (558 nationally) over a relatively short time period of nine months, indicating a perceived need amongst the participants for some form of additional intervention for their depression. This was supported by the qualitative interviews, which indicated that many of the participants interviewed had found their regular care from the practice lacking.

The main results of this trial indicate that practice nurse-led proactive care was beneficial for some participants, with all measures showing positive trends. However, the outcomes for the intervention group as a whole were borderline significant, suggesting that the intervention was not successful for everyone.

Nurse involvement

Other trials which have used a similar proactive care model, most notably from the USA, have reported slightly more significant findings. However, most of these studies have involved mental health professionals as case-managers for long-term depression, rather than nurses. This study involved nurses in a role similar to case managers which could have been a factor in the overall results. Mental health training for practice nurses in the UK is severely under-resourced, as demonstrated in participant and nurse observations from the qualitative data where it was clear that some nurses had found the intervention challenging. This study included a fairly brief training element for the nurses involved. If the intervention were to be rolled out more widely, additional training and support would be required to ensure that those nurses who wished to provide this form of intervention had sufficient skills and felt empowered to deliver proactive care for depression. In addition, the study highlighted an urgent need to improve the basic level of training given to all practice nurses in working with people with anxiety and depression, as this appears to currently be very limited and of poor quality.

Severity of symptoms

The severity of depressive symptoms (assessed using the BDI-II) was the primary outcome measure for this trial. Measures were taken at regular time intervals throughout the trial and a positive trend was observed in both control and intervention groups which could possibly be explained by regression to the mean. However, although the results were not statistically significant, the intervention group did show an improvement in the severity of their reported depression which was greater than that found in the control group. Two years is a relatively short period of time in the illness trajectory of many of these participants and it would be interesting to see whether this trend continued and reached significance after the trial ended.

Social functioning

The intervention led to a significant improvement in social functioning, assessed using the Work and Social Activity Scale (WSAS), which is a very important finding. Although the severity of symptoms was the main outcome measure, this result may be more promising. If an intervention can improve social functioning it has more practical benefits for the individual and society, and might possibly lead to a reduction in the severity of symptoms of depression over time as the individual is able to play a fuller role in society. Many people in the mental health field consider that assessing how people function in society is more important than measures of symptom severity which, given the nature of the condition, are more likely to fluctuate at different points in time. In the qualitative interviews participants reported becoming engaged in a wide range of activities, and feeling that the intervention had had a positive impact on their confidence and self-esteem.

Number of sessions attended

When the outcomes were analysed by sessions attended, rather than for the study overall, it appeared that attending all the sessions offered could lead to a significant improvement in both symptoms and functioning. This means that the more sessions someone was able to attend, the more likely they were to benefit. However, many participants did not attend every session, and there are likely to be several different reasons for this. The qualitative data suggests that participants and nurses varied in their engagement and motivation, which had an impact on session attendance. Decisions about rolling out an intervention like this would need to consider this and explore alternative solutions for participants who expressed low levels of engagement and motivation. It is unlikely to be something which all practice nurses would wish to provide.

Cost effectiveness

The intervention was found to be relatively cost effective for achieving positive changes in severity of depression and functioning. However, the intervention was not judged to be cost effective in terms of quality adjusted life years (QALYs). The National Institute for Clinical Excellence (NICE) prefers the QALY measure but there is currently much debate about whether the scale is sensitive enough to assess changes in mental health. Given this debate, it seems that the intervention has shown promising results for cost effectiveness, suggesting that if commissioners were willing to invest in proactive care in this way, they could expect a return for their investment in terms of people's levels of depression and social function.

Service usage

When considering the health service data collected over the two 24 month periods there was no significant difference between the two groups in terms of GP attendances. This is not surprising given that the qualitative data indicates that those participants interviewed did not find seeing their GP about their depression particularly helpful. The number of nurse attendances increased significantly more in the intervention group over the study time-frame, but this is accounted for by the fact that the nurses were providing the intervention. Interestingly, the average number of months on antidepressants fell in both groups. However, the average number of months on antidepressants was significantly higher in the intervention group in the 24 months study period, compared to the control group. This is likely to be associated with the nurses having addressed participants' concerns about their medication and arranging reviews and changes of formulation when the current treatment was reported to be ineffective. It is surprising that there weren't more documented referrals to psychological therapies in the intervention group, as the nurses had been encouraged to actively consider such strategies in their discussions with the participants. This could be connected to limited availability of talking treatments through the NHS, despite the Improving Access to Psychological Therapies (IAPT) initiative.

Conclusion

Overall, the ProCEED intervention has shown some positive findings and leaves a number of areas open for further investigation. The significant improvement in social functioning is a very important result, and one that is difficult to achieve for this group. There was a trend towards a reduction in the severity of people's depression that would benefit from further study, and there was a significant positive impact from attending all the sessions. The economic analysis has shown that the intervention has a good chance of being likely to be cost effective in terms of reducing symptoms and improving function, and there are some interesting findings about the impact on service usage. The qualitative interviews offered some interesting insights into possible reasons for some of these results, with levels of motivation and engagement appearing to be crucial. Many respondents felt the practice nurse was a more suitable professional than the GP to deliver ongoing proactive care, and the model of focused appointments with a clear but holistic approach worked for many participants and nurses.

Recommendations

— Current Primary Care Trusts and future Clinical Commissioning Groups should ensure adequate primary care services are commissioned for anyone with recurrent or chronic depression. The Department of Health should also consider this within the context of the delivery of its cross-Government mental health strategy.

— GP practices should offer anyone with recurrent or chronic depression the choice of accessing a system of proactive care. This could and should involve practice nurses, GPs with a specialist interest in mental health and mental health professionals working in a primary care setting.

— Research bodies should fund and/or carry out further research into proactive care for people with recurrent or chronic depression in a primary setting. This is in order to better predict who is most likely to benefit from this form of intervention and who is likely to not respond and will need some other form of intervention. One model will not suit all.

— Researchers and health professionals should work together to further refine and test interventions for people with recurrent or chronic depression. Examples may include computer based interventions, behavioural activation or motivational interviewing techniques.

— The Royal College of Nursing and local NHS Trusts should ensure mental health is prioritised for all practice nurses through structured peer group training and support. This is particularly pertinent as practice nurses are often expected to broach the topic of depression as part of their standard workload.

— The Royal College of Nursing and other appropriate bodies should make available appropriate training for practice nurses in order for them to be able to provide long-term, proactive interventions for people with depression.

— The Royal College of General Practitioners should improve GP communication skills training, taking into account feedback from participants regarding the difficulties they had in discussing issues apart from medication with their general practitioners.

— The Royal College of Nursing and Mind should continue working together on training and support for practice nurses in managing depression, building on the training pack developed from this project.

Section 2
Introduction

Introduction

People with long-term depression are frequently lost from effective care provision, with resulting psychological, physical and social problems, and at a great financial and social cost to society.

This report presents the findings of a three year study which explored whether structured, proactive care delivered by nurses in GP practices resulted in better mental health and social outcomes for people living with depression.

Proactive care in this context refers to regular, structured review meetings involving the same health professional. This is likely to be a more consistent approach than many of these participants currently receive within the primary care setting.

We included a cost effectiveness component to establish whether any benefits demonstrated in this trial were associated with a reduction in other health care or social costs.

Report remit

This report covers the background, methods and results from the main randomised controlled trial funded by the Big Lottery Fund. We are also reporting the main results from a qualitative study involving in-depth interviews with both trial participants receiving the intervention and practice nurses involved in delivering this, as these give useful additional detail to the main trial results. The qualitative arm was self-funded by the research team, with external peer review and full ethical approval.

This report should be of interest to GPs and practice-managers looking for new ways to meet the need for services designed to help anyone with chronic and recurrent depression. It will also be of interest to practice-based nurses, looking to improve their confidence and skills in helping those with depression, and people with depression who are interested in new approaches to help manage their condition.

In addition a training pack (Supporting people with depression and anxiety: A guide for practice nurses) has been produced aimed at practice nurses which includes the practical learning from this study.

Aims of the study

The main objective was to establish whether structured, proactive care of participants with chronic depression in primary care leads to a cost effective improvement in medical and social outcomes when compared with usual GP care.

A secondary objective of the original study was to assess whether training general practice nurses can lead to improved assessment and follow-up of participants with chronic depression and provide ongoing skills in this area.

A further aim of the qualitative study was to explore the impact of receiving or delivering nurse-led proactive care on both the intervention participants and the practice nurses, and to establish which components of the intervention are likely to be associated with a positive outcome, from both the participant and practice nurse perspective.

Section 3
Background

Background

"Major depression is very common, affecting around 1 in 10 of the general population of the UK at any time."

Major depression is very common, affecting around 1 in 10 of the general population of the UK at any time.[1] The majority of people with depression in the UK who seek medical help are treated within general practice, it being the third most common reason for consultations.[2]

Symptoms of depression are varied, but most commonly include low mood and tearfulness, loss of interest and enjoyment in activities and changes to concentration, eating and sleeping patterns. Most people experience these symptoms occasionally, but if they last for more than two weeks and impact on a person's ability to live their normal life then a diagnosis of depression might be given. Often depression will be experienced over a particular time period, called an episode, which can be mild, moderate or severe. If these episodes pass but then return at the same level of intensity, the depression can be said to be recurrent. If a person experiences constant symptoms this is called chronic depression, which may be chronic low level depression (chronic dysthymia) or the persistence of a significant level of depression (chronic major depression).

There appears to be little consistency in the longer-term management of this condition in primary care despite the significant psychological, physical and social difficulties experienced by this group.[3,4] People living with recurring and chronic depression may be socially disadvantaged and marginalised because of the effects of the condition on their health and social functioning, and the lack of services targeting their needs.

There is evidence that over half of all people who have an acute or severe episode of depression will have a recurrence, and that the risk of further recurrences increases greatly with further episodes.[3] In addition, a significant minority of people (around 18 to 25 per cent) will experience chronic depression.[4] This may be associated with an earlier death and considerable health and social costs.[5] If people do not make a full recovery from an episode of major depression they face a greater risk of relapse and partial recovery from an episode may result in poorer long-term outcomes.[6,7]

Evidence also shows that the earlier a recurrence is detected, the better and speedier the recovery, but currently many patients who experience recurring depression are inadequately treated and have little or no specific follow-up in primary care.[8, 9]

"The tradition within primary care in the UK has been to recognise and manage depression when it is acute or very severe (i.e. a reactive rather than proactive model of care)."

These findings would suggest that recurring or chronic depression could benefit from more proactive treatment, where regular contact with a health professional is encouraged and supported. There is evidence in favour of such strategies from the USA, but they have not been formally researched in the UK.[10,11] Work from the USA has shown that organised, enhanced care can have a beneficial effect both on the outcomes of people with acute major depression and those with a high risk of recurrence.[12,13] However, there are significant differences between the UK and US models. Managed care in the US setting was developed to provide a structure for the provision of care for costly conditions such as depression within the constraints of a private insurance based system. The models developed and studied involved a range of health professionals as the case managers, including mental health professionals such as psychologists and social workers, as well as a nurse practitioner. The aim of this study was to develop a model suitable for a UK primary care context.

In the UK, practice nurses are involved in the regular review of many patients with long-term physical health problems, which often co-exist with depression and anxiety. If effective, a practice nurse intervention would be easier to generalise across UK general practices, as the availability of even low intensity mental health professionals (such as primary care graduate mental health workers) is still quite variable and they frequently change posts. Using more experienced mental health personnel would impact on the assessment of cost effectiveness, so for all these reasons it was decided to work with practice nurses for this initiative. We conducted a small local feasibility study involving practice nurses in the coordinated care of people with long-term depression[14] and, as the results were encouraging, applied for funding for this national clinical trial.

The tradition within primary care in the UK has been to recognise and manage depression when it is acute or very severe (i.e. a reactive rather than proactive model of care). Increasingly, particularly with an ageing population, more proactive management strategies for chronic conditions are being recognised as required. Organised or enhanced care of this type has elements in common with the management of other chronic conditions in UK general practice, such as asthma, diabetes and hypertension.[15] Models for managed or proactive care identify similar elements for a range of chronic conditions, including a well-defined care plan, patient education, scheduled follow-ups, review of outcome and concordance, and targeted use of specialist consultation or referral.[16]

Practice nurses are involved in the regular review of many primary care patients with long-term health problems such as asthma, diabetes, respiratory and cardiovascular problems and there is evidence that they can do this very well, often communicating particularly effectively with patients in the management of chronic problems.[17] Given the evidence for the recurring or long-term nature of many cases of depression and the fact that depression and anxiety often co-exist with long-term physical health problems, involving practice nurses in the coordinated care of both would seem to be a good way forward.

Stigma and perceived lack of appropriate treatments often make people with depression reluctant to present to their doctors, apprehensive that their concerns and preferences will not be taken into account,[18] and uncertain about the effectiveness of the treatment.[19] A positive and optimistic attitude from professionals is often valued by people living with depression,[20,21] and there is also evidence that a sense of active participation, empowerment and self-control over health can improve health outcomes.[22,23] Such active participation necessitates patients being given sufficient information and time to be able to make informed choices about their treatment.[24]

Section 4
Methodology

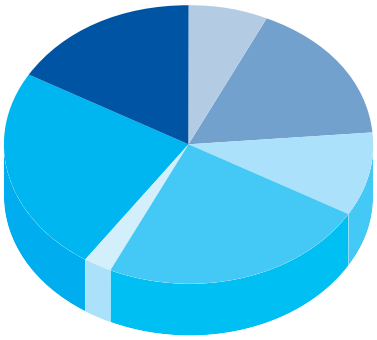
Methodology

This research was conducted through a randomised controlled trial. This is a study design used to evaluate the effectiveness of a treatment by comparing two groups of people who all have the condition being studied. One group receives the treatment, and the other group does not. Because the allocation of participants to the groups is done at random (by chance) it is likely that any of the participant characteristics which may affect the outcome are evenly distributed between the two groups. The participants in this trial were allocated to their study groups using an independent computerised service run by the Medical Research Council to ensure that the allocation was not biased.

In this study the comparison was between 'GP usual care' (control group), and a 'structured care' approach involving regular follow-up by practice nurses in addition to GP usual care (intervention group), for participants with a history of recurrent or chronic depression.

Participants were recruited from 42 general practices throughout the United Kingdom, 38 of which were members of the Medical Research Council's General Practice Research Framework (MRC GPRF), a framework of over 1,000 general practices throughout the UK.

Figure 1: Location of participating practices in ProCEED



Greater London	3
Midlands	7
Northern Ireland	4
North of England	10
Scotland	1
South East England	10
South West England	7

The criteria which were used to decide whether or not to include potential participants were:

Inclusion criteria

(i) Men and women aged 18 and over.

(ii) Two or more documented episodes of depression within the previous three years.

(iii) Evidence of recurrent and/or chronic depression (measured with a scale called the Composite International Diagnostic Interview explained on page 23).[25]

(iv) A score of 14 indicating mild depression on a scale called the Beck Depression Inventory-II (BDI-II) (explained on page 22).[26]

(v) Sufficient English to be able to complete self-report questionnaires.

Exclusion criteria

(i) Current psychotic symptoms (such as hearing voices or having delusional thoughts).

(ii) Impaired cognitive function.

(iii) Incapacitating alcohol or drug dependence.

This was a practical general practice-based trial and we wanted those included to reflect normal general practice as far as possible, so we aimed to keep the exclusion criteria to a minimum. Participants who expressed suicidal ideas were not excluded, but the practice nurses were given clear guidelines about their management and at what point it would be appropriate to communicate with the GP if they were concerned about a participant.

What the trial involved

Clinical review appointments

For all intervention participants the practice nurse undertook a baseline assessment at the first appointment, asking about current mood, social circumstances, current treatment (medication and/or psychological therapy), and any side-effects or queries about their disorder or its management.

The intervention participants were given a specially written educational booklet about depression and its treatment at this initial appointment, as appropriate participant education materials can be helpful as part of an integrated approach.[11]

The nurses answered participants' questions about current or past treatments and checked whether they were taking the treatment, clarifying reasons for any difficulties. If there were current symptoms of depression, alternative or additional treatments were discussed. These could be in the form of psychological therapies, medication or social interventions. The rationale and evidence for any of these were made clear in the background literature given to participants and in their discussion with the nurses.

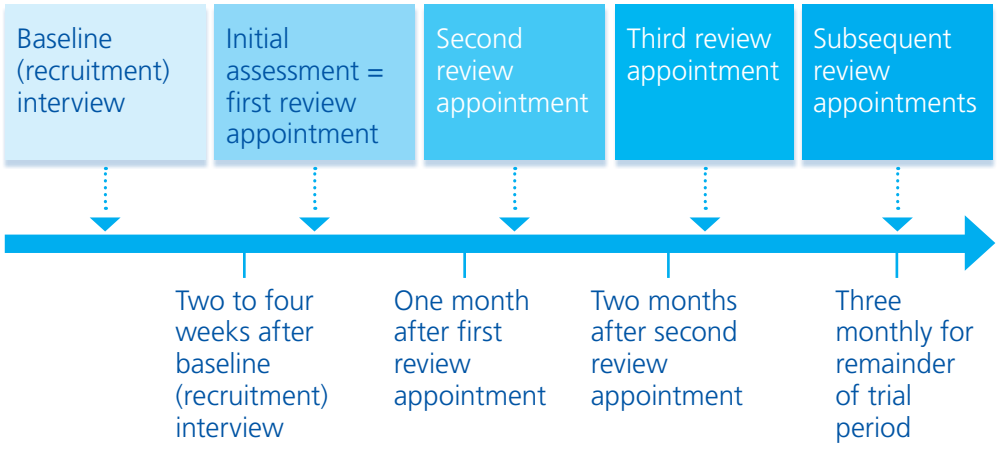
Social factors which could be contributing to the participants' depression were explored (for example social isolation, family or relationship responsibilities or difficulties, low physical activity, unemployment, finance, housing) and appropriate advice given or referrals to other agencies made. The importance of participant choice and active participation in this process and in the treatments selected was emphasised.

A joint management plan was then formulated between the nurses and each of their participants. This covered a possible range of topics, with the participants deciding which areas were of particular relevance for them and how they would like to address these. This plan was reviewed during subsequent appointments, alongside a review of how the participant was feeling and any progress made towards goals set. Participants were given support to monitor their own mental state and to have a sense of their own individual likely predictors of relapse.

Timing of intervention appointments

Intervention participants were seen for a baseline assessment, after one month and then two months later. After this, the reviews for intervention participants took place every three months for the remainder of the 24 month trial period, but could be more frequent if there were any significant clinical concerns about the participant's mood. If the participant felt they were keeping well they could request to conduct this review over the telephone.[27]

ProCEED Timeline for Intervention group participants



Control group

During the 24 month study period the participants in the control group had 'treatment as usual' and continued to see their GP on request, with no restrictions placed on any interventions which the GP might recommend. It was stipulated that the control group participants should not see the practice nurse for any mental health intervention, although they might see the nurse for physical health problems.

Practice nurse training sessions

All the practice nurses involved in delivering the intervention received three full days of training and received a comprehensive set of training materials. There was a separate fourth training day for the nurses involved in conducting the follow-up assessments. To maintain blindness this was a different group of individuals.

Day 1: This covered the procedures required to recruit participants to the trial, checking their eligibility and conducting the computerised randomisation. The nurses were given training using case vignettes and role play to help them assess participants for recurrent major depression and chronic depression at the start of the process.

Day 2: This covered the procedures and information required for the intervention appointments, including assessment of a participant's level of depression at follow-up, details of evidence based pharmacological and psychological treatments for depression and the importance of considering relevant social factors, as well as training in completing the relevant forms for the study. The nurses were also given some basic training in the use of simple problem solving techniques.[28]

Day 3: A further day's training was arranged after six months for the nurses to discuss some of their clinical cases, focusing in particular on ways of working with people who had more complex problems. Brief training was given in the use of simple motivational interviewing techniques to use with participants finding it difficult to make any changes in their lives.[29] The nurses worked in small groups with a clinical supervisor to discuss cases which they had found challenging for a variety of reasons and the results of the small group discussions were presented to the whole group.

Apart from the two training manuals, the nurses were regularly updated with information about potentially useful resources available on the internet. They were also encouraged to ensure that they maintained access to up to date information about appropriate local voluntary and other organisations which they could encourage participants to contact where appropriate.

Day 4: This training session was for the procedures required for the final assessment at 24 months. As we wanted those assessing the final outcomes to have no knowledge about which group participants had been allocated to, this involved training a new cohort of nurses using the same case vignettes and role play techniques as in the initial training on Day 1. They were also trained in the paperwork to complete for the final assessment.

Nurse supervision sessions

Each nurse was assigned a member of the research team as a 'clinical supervisor'. Nurses had regular telephone contact (generally every three to four months) with their supervisors throughout the trial period.

Data collection – Quantitative outcome measures

Mental health problems are often more difficult to measure and assess than physical health problems, there is no blood test or x-ray to show the severity of depression.

In order to measure the presence and severity of depression, questionnaires that ask about a person's mood and other symptoms are therefore used.

Primary outcome

The Beck Depression Inventory (BDI-II) was the primary measure used in this study. The BDI-II is a reliable and well validated measure for measurement of the severity of depression and monitoring its clinical outcome, which has been used in many primary care studies.[26] It was also used in the assessment of cost effectiveness as part of the health economic analysis. It asks 21 questions, and participants give a score for each on a scale of 0 to 3. The sum of all the answers is added together at the end, and the higher the score, the more severe the symptoms.

Example: Question Number 1. from the Beck Depression Inventory-II
Pick the statement that best describes the way you have been feeling during the past two weeks including today.

Score
0 I do not feel sad
1 I feel sad much of the time
2 I am sad all the time
3 I am so sad or unhappy that I can't stand it

Secondary outcomes

The impact that depression has on an individual's life is about more than just the severity and duration of the symptoms. It can also significantly affect their social functioning and quality of life. Depression is also very costly. This includes the costs incurred by the individual themselves and people involved in their care, the direct costs of health care, the social costs associated with issues such as unemployment, and the costs associated with people being unable to contribute to their full potential. A number of other measures were therefore used to collect this information.

(i) Social functioning: This was assessed using the Work and Social Activity Scale (WSAS). This is a well-established, brief questionnaire, which assessed participants' perceived difficulties with physical and social functioning associated with their depression.[30]

(ii) Clinical outcome of depression: Collected using the Composite International Diagnostic Instrument (CIDI).[25] This instrument is frequently used in mental health studies and was modified to allow collection of diagnostic data for the three groups of participants being recruited – those with recurrent or chronic major depression and chronic dysthymia. This information was collected both at baseline and the end of the trial via participant interviews with the practice nurses.

(iii) Quality of life: This was assessed using the Euroquol.[31] Participants rated their overall health state (termed health status) using a visual analogue scale with points between 0 and 100 called the EQ-VAS, where the higher the score the better the respondents rated their perceived health status. The other component of the Euroquol, the EQ-5D was used to provide information for the cost effectiveness evaluation.

(iv) Resource use and costs: Participants were asked to complete a modified version of the Client Service Receipt Inventory (CSRI)[32] at baseline and the 24 month follow-up. This asked about contacts over the previous three months with primary care (for example GP, GP nurse), hospital (for example inpatient admissions, outpatient appointments), mental health services (for example psychiatrist, counsellor) and community services (for example social work, self-help, complementary therapies) as well as medication use. A unit cost drawn from nationally applicable sources[33] or estimated using an equivalent approach[34] was attached to each item of service use to calculate the costs to the public purse. In addition participants were asked about socio-demographic details, and information about receipt of informal care and the impact of depression on participant's ability to work and carry out usual tasks.

(v) Practice service data: The practice nurses were asked to count the number of GP attendances and home visits, practice nurse contacts, referrals for psychological therapy and prescriptions for psychotropic medication for all participants for the 24 months before recruitment and the 24 months of the trial. This provided a different set of information to the service data collected for economic analysis.

The questionnaires listed were self-completed, apart from the CIDI which was administered via an interview and the service usage data which was collected from the GP records by the nurses involved in the study.

Timing of collection of outcome measures

Outcome	Baseline (completed at the surgery)	3 months (completed by post)	6 months (completed by post)	12 months (completed by post)	18 months (completed by post)	24 months (completed at the surgery)
BDI-II	X	X	X	X	X	X
WSAS	X					X
CIDI	X					X
Euroquol	X					X
CSRI	X					X
Practice service data	X					X

Sample size

If there is a difference in the outcomes of the intervention and control groups, it is important to be able to conclude that this difference has been caused by the intervention, and not by chance. Part of the way this is done is to ensure there are enough people taking part in the study.

A detailed power calculation was carried out which showed that between 420 and 630 participants in total would be needed to:

— show a clinically meaningful change on the main outcome measure, the BDI-II

— provide sufficient power for the cost effectiveness analysis

— allow for other factors such as up to a quarter of the participants dropping out from the trial because of moving away from the practice area or deciding to withdraw from the study.

For further details of the power calculations and planned statistical and health economic analyses please see the protocol paper.[35]

Data collection – Qualitative study

The qualitative study involved in-depth interviews with a sample of participants from the intervention group from the main trial and a sample of the practice nurses delivering the intervention.

In a qualitative study it is not possible to interview all the potential participants, but the aim is to obtain a sample which is as representative as possible of all the characteristics likely to be important. All the practice nurses who had taken part in the study were approached and asked whether they would agree to take part in the qualitative interviews. From those who agreed, data collected (at the point when they started working on the ProCEED trial) was used to select both nurses who had described themselves as confident and nurses who reported themselves to be unconfident in working with people with depression. A broad distribution of other factors, such as the number of trial participants the nurses had recruited and their prior experience were also considered.

All the intervention participants who had been recruited by nurses involved in the qualitative arm of the study were approached. Those who agreed to be interviewed were purposively selected to get adequate representation from:

— people with the three different types of depression (chronic major depression, chronic dysthmia (milder depression) or recurrent major depression)

— those who had regularly attended the intervention sessions with the nurse

— those who were poorer attendees.

Age, gender and employment status were also monitored within the sample in order to achieve maximum diversity.

The interviews were conducted using a topic guide developed by the research team. This was reviewed and refined after four or five interviews with each group had been carried out. Both sets of interviews were conducted until data saturation was reached i.e. no new themes were emerging in the interviews. All the interviews were conducted by the same person, tape-recorded and transcribed by an independent transcriber.

Data was analysed using the framework analytical process.[36] This approach involves the systematic process of five key stages; familiarisation, developing a thematic framework, indexing, charting and interpretation. The data from both the nurse and participant interviews was analysed comparatively to explore different perspectives of the nature of proactive structured care and its effectiveness and acceptability in the primary care setting.

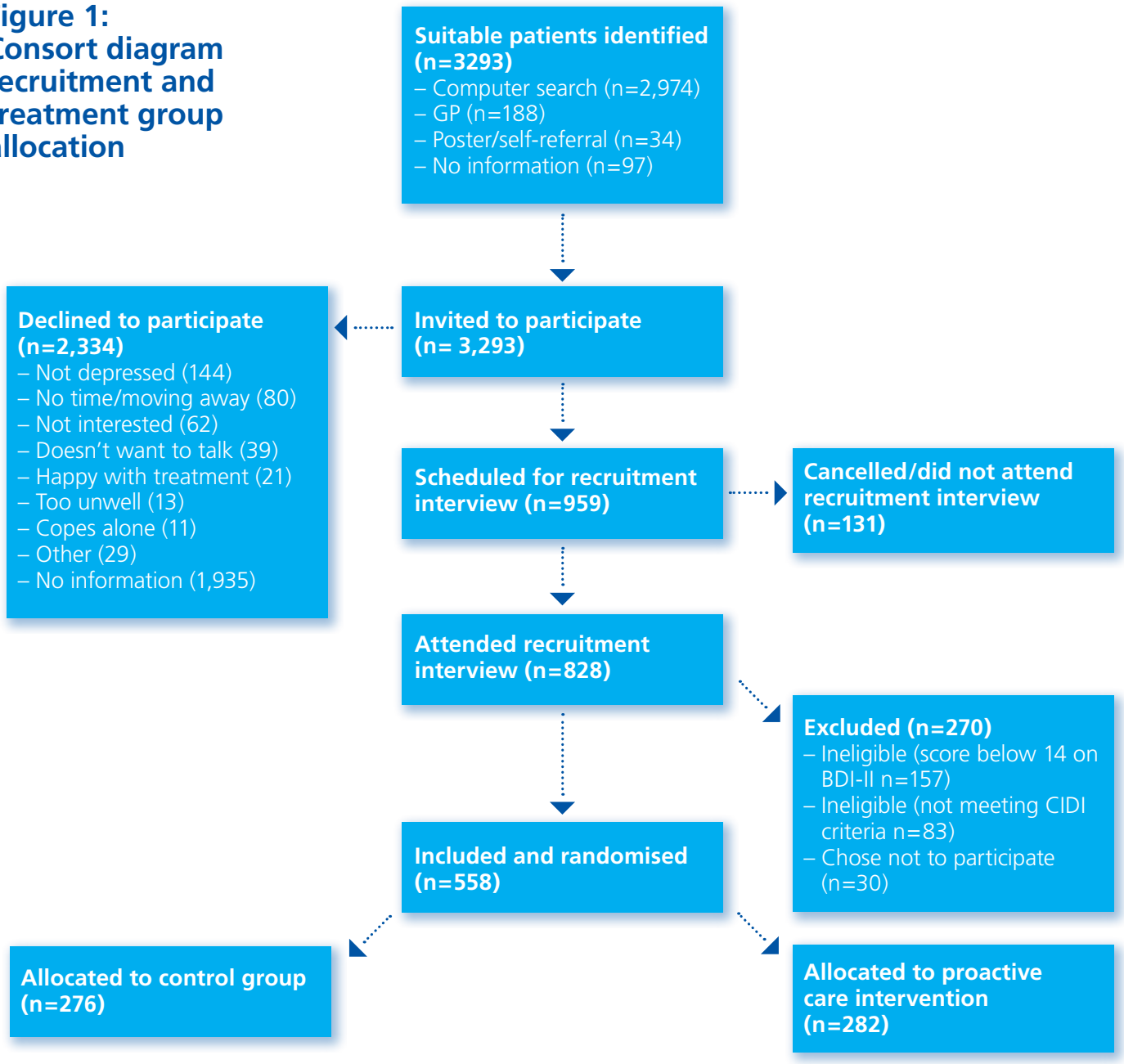
Section 5
Results

Results

Participants

3,293 people in the 42 participating practices were identified as potentially suitable to take part in the trial using the methods described in the previous section. Figure 1 shows how the final 558 study participants ended up in the trial.

Figure 1: Consort diagram recruitment and treatment group allocation



Response rates

The initial study design involved asking participants to complete and return BDI-II questionnaires at three monthly intervals. However, because the response rate (percentage of participants who returned the questionnaires) went down from 72 to 66 per cent between the three months and six months review appointments there was a concern that this would persist or get worse at later time points and impair the validity of the study results.

The frequency of completion for the BDI-II questionnaires was therefore reduced to six monthly (see table for collection of outcome measures on page 24) and ethical approval was granted to incentivise their completion using £10 vouchers which could be used at many stores nationally. The response rate at 12 months was 67 per cent, and at 18 months was 63 per cent.

Extra effort was made to maximise the response rate for the final assessments, as this was such an important outcome point. The final response rate for the BDI-II at 24 months was 77 per cent.

Main findings

This section gives the results from the outcome measures designed to assess the severity of participants' depression, and the impact it had on their functioning. It also provides information about whether or not the intervention had an impact on the amount of health services that participants accessed. All data was entered twice to minimise data entry errors and was analysed using software called SPSS (version 15.0) and STATA (version 10).

Key findings

— There was a trend towards a decrease in severity of depression (according to the BDI-II) in both intervention and control groups.

— Overall the intervention was associated with a reduction in the severity of depression above that found in the control group, but the evidence was not strong enough to conclude that this was not a chance finding.

— There was an improvement in social functioning (according to the WSAS) between baseline and follow-up in both the intervention and control groups.

— The intervention had a moderate impact on social functioning leading to a greater improvement in this group compared to the control group. This effect was found to be statistically significant.

— There was an improvement in participants' perceived health state (according to the EQ-VAS) between baseline and follow-up in both the intervention and control groups.

— The intervention had a small impact on health state leading to a greater improvement in this group compared to the control group, but the evidence was not strong enough to conclude that this was not a chance finding.

— Relating the improvements seen in severity of depression, social functioning and general health to the number of sessions attended found statistically significant improvements, per session, in severity of depression and social functioning.

— Attending all 10 sessions could lead to significant improvement in the severity of depression and a significant improvement in social functioning.

How did the characteristics of the two groups compare at baseline?
558 individuals were included in the study with 282 (50.5 per cent) being randomised to the intervention group and 276 (49.5 per cent) to the control group.

Table 1 presents the socio-demographic variables by randomisation group. Also included are the baseline mental health diagnostic categories according to the Composite International Diagnostic Interview (CIDI). Continuous variables are presented as means (the average across participants) with standard deviations (the average variation between participants). Categorical variables are presented as numbers and percentages.

Table 1: Baseline characteristics

		Intervention	Control
Age (years)	Mean (S.D.)	48.3 (12.3)	48.4 (13.4)
Gender	Female	217 (77.0%)	201 (72.8%)
Marital Status	Married	133 (47.7%)	127 (46.9%)
Living with	Partner/children	212 (76.3%)	188 (69.1%)
Accommodation	Owner-occupied	188 (68.6%)	179 (66.1%)
Ethnicity	White UK	251 (90.6%)	241 (89.3%)
Employment	Paid	137 (48.9%)	121 (44.8%)
Diagnosis (CIDI)	Chronic major depression	78 (28.1%)	86 (31.6%)
	Recurrent depression	155 (55.8%)	142 (52.2%)
	Dysthymia	45 (16.2%)	44 (16.2%)

From this table we can see that the two groups were fairly well balanced with respect to baseline characteristics. There was a slightly higher percentage of females in the intervention compared to the control group, likewise those living with a partner/child and those in paid employment.

How did the outcome measurements compare at baseline?

The outcomes of importance were those measuring the severity of depression (BDI-II) and the levels of social functioning (WSAS). Of secondary importance was the EQ-VAS, measuring general health. Baseline scores for these outcomes are summarised in Table 2 as means and standard deviations, with the number of participants who had completed the measures at baseline also shown.

Table 2: Baseline outcome scores

		Randomisation Group		All participants
		Intervention	Control	Total
BDI -II	Mean	31.90	33.14	32.51
	S.D.	9.79	10.60	10.21
	Number of participants with score available	278	272	550
WSAS	Mean	22.09	22.40	22.24
	S.D.	9.55	9.36	9.45
	Number of participants with score available	280	272	552
EQ-VAS	Mean	54.54	52.76	53.67
	S.D.	19.49	20.12	19.80
	Number of participants with score available	281	269	550

The baseline outcome scores for the BDI-II and WSAS indicate that the participants were quite severely affected on both measures, with 60 per cent being severely depressed or moderately to severely functionally impaired.

Table 3: Severity of depression and level of impairment at baseline

Baseline Depression – BDI-II	% of participants
Mild depression (score of 14 to 20)	11
Moderate depression (20 to 29)	27
Severe depression (29 to 63)	62

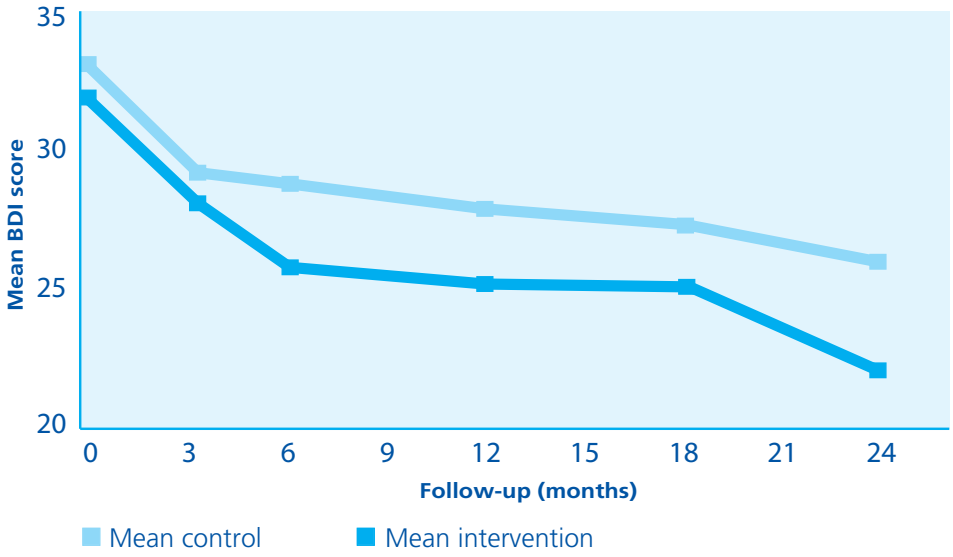
Functional Impairment – WSAS	% of participants
Sub-clinical impairment (score of 0 to 10)	11
Significant impairment (10 to 20)	28
Moderate/severe impairment (20 to 40)	61

Analysis of outcome scores

Did the intervention lead to a reduction in the severity of depression?

The BDI-II was used to measure the severity of depression. The mean BDI-II scores at each follow-up, for the intervention and control groups, are shown graphically in Figure 2.

Figure 2: Mean BDI-II scores by follow-up time for each group



Initial analysis looks for the crude differences in mean BDI-II score between intervention and control groups at baseline and each of the five follow-ups. The mean scores in each group, along with the numbers of individuals are presented in Table 4.

Table 4: BDI-II scores

	0 months	3 months	6 months	12 months	18 months	24 months
Intervention (Number)	31.9 (278)	28.1 (221)	25.8 (201)	25.2 (201)	25.1 (196)	22.1 (224)
Control (Number)	33.1 (272)	29.2 (180)	28.8 (167)	27.9 (166)	27.3 (152)	26.0 (206)
Difference in means	1.2	1.1	3.0	2.7	2.2	3.9
95 per cent confidence interval	(-0.5,3.0)	(-1.3,3.6)	(0.2,5.7)	(0.2,5.7)	(-0.8,5.2)	(1.1,6.7)
p-value	0.153	0.368	0.033	0.055	0.150	0.006

The differences in means (control minus intervention) along with the 95 per cent confidence intervals (the likely true range for this difference we would expect to find in the population) are also presented.

P-values assessing how likely it is that the observed differences are due to chance, rather than a true effect of the intervention, are also given. If the p-value is small (conventionally less than 0.05) then the findings are said to be 'statistically significant', meaning the difference is unlikely to be due to chance alone.

From this crude analysis, the general pattern is that of an increasing difference between the intervention group and the control group over time, with the suggestion that the intervention has some effect. However, a number of other factors need to be taken into account to make the analysis more robust.

- The mean BDI-II score at baseline (0 months) is higher in the control group by 1.2 so this difference needs to be taken into account
- Individuals included in the study were recruited from 42 general practices. Values from participants within the same practice are more likely to be similar than values from participants from different practices. Despite the use of individual randomisation within practice, the analysis needs to take account of this natural clustering inherent in the study design.
- Finally because the measurements were repeated over time the analysis needs to be adjusted to account for the fact that these measurements were not independent.

Multi-level (hierarchical) modelling adjusting for the baseline difference and accounting for the repeated measurements over time and the clustering by practice was therefore undertaken.

Following this more detailed analysis, which included 486 individuals who had a baseline and at least one follow-up measure, the estimate of group effect was 1.2 with 95 per cent confidence interval (-0.3, 2.7), p=0.125.

This indicates that the average effect over time of the intervention is to decrease the mean BDI-II score by 1.2 points. This effect has a p-value of 0.125 which means it is not statistically significant.

BDI-II scores reduced for the intervention and control group. However, because the difference between the two groups was not statistically significant, it is not possible to say that the intervention led to a greater reduction in symptoms or severity of depression.

Did the number of sessions attended lead to a reduction in the severity of depression?

Not all participants in the intervention group attended the same number of sessions with the practice nurse. This could impact on how effective the treatment was. To look at the effect of the intervention "per session" a method of analysis, often known as contamination adjusted intention to treat (CAITT), was used. This allows the 'per session' effect of the treatment to be summarised whilst still analysing participants as they were randomised.

This CAITT analysis found a per session effect of -0.37 with 95 per cent CI (-0.68,-0.07), p=0.017.

This indicates that the average improvement in BDI-II score per session attended was -0.37. This result had a p-value of 0.017 indicating a statistically significant decrease. From this we can expect that attending all 10 sessions could lead to significant improvement in a participant's BDI-II score of around -3.7.

Did the intervention lead to improved social functioning?

The WSAS questionnaire was used to measure difficulties that participants had with physical and social functioning as a result of their depression. It was only completed twice, at the start and end of the study.

The mean scores in each group, along with the numbers of individuals are presented in Table 5. The differences in means (control minus intervention) along with the 95 per cent confidence intervals for these differences are also presented. Finally the p-values are provided as a way of assessing the statistical significance of the differences.

Table 5: WSAS scores

	0 months	24 months
Intervention (number)	22.1 (280)	16.2 (224)
Control (number)	22.4 (272)	18.8 (205)
Difference in means	0.3	2.6
95 per cent confidence interval	(-1.3,1.9)	(0.3,4.9)
p-value	0.704	0.027

Similarly to the BDI-II, the crude analysis suggests that the difference between the intervention group and the control group had increased over the course of the study, with the intervention group becoming less impaired.

However, the analysis needs to be made more robust, and take into account the difference in means at baseline, and the clustering effect of the different practices. Multi-level modelling adjusting for the baseline difference and accounting for the clustering by practice was therefore undertaken.

From the above analysis, which included 425 individuals for whom a baseline and follow-up measure were available, the estimate of group effect is 2.5 with 95 per cent confidence interval (0.6,4.3), p=0.010. This indicates that the effect of the intervention is to decrease the mean WSAS score at 24 months by 2.5 points. This effect is statistically significant at the conventional 5 per cent level (p=0.010).

As this effect is statistically significant we can say that the intervention may have led to a greater reduction in the perceived social and physical impairment associated with being depressed.

Did the number of sessions attended lead to greater social functioning?

As for the BDI-II, a CAITT analysis was undertaken to assess the effect of the intervention 'per session'. This CAITT analysis found a per session effect of -0.33 with 95 per cent CI (-0.55,-0.10), p=0.004.

This indicates that the average improvement in WSAS score per session attended was -0.33. This result had a p-value of 0.004 indicating a statistically significant decrease. From this we can expect that attending all 10 sessions could lead to a significant improvement in WSAS score of around -3.3.

Did the intervention improve general health?

The Euroquol visual analogue scale health thermometer (EQ-VAS) was used to measure participant perceived health status. It was only completed twice, at the start and end of the study.

The mean scores in each group, along with the numbers of individuals are presented in Table 6. The differences in means (control minus intervention) along with the 95 per cent confidence intervals for these differences are also presented. Finally the p-values are provided as a way of assessing the statistical significance of the differences.

Table 6: EQ-VAS scores

	0 months	24 months
Intervention (number)	54.5 (281)	61.7 (214)
Control (number)	52.8 (269)	58.0 (201)
Difference in means	-1.8	-3.7
95 per cent confidence interval	(-5.1,1.5)	(-7.9,0.4)
p-value	0.293	0.077

The crude analysis suggests that the difference between the intervention group and the control group had increased over the course of the study, with the intervention group becoming less impaired.

The analysis needs to be made more robust, and take into account the difference in means at baseline, and the clustering effect of the different practices. Multi-level modelling adjusting for the baseline difference and accounting for the clustering by practice was therefore undertaken.

From the above analysis, which included 410 individuals for whom a baseline and follow-up measure were available, the estimate of group effect is -2.9 with 95 per cent confidence interval (-6.5,0.8), p=0.127.

This indicates that the effect of the intervention is to increase the mean EQ-VAS score at 24 months by 2.9 points. This effect has a p-value of 0.127 which means it is not statistically significant.

Perceived healthy status improved for both the intervention and control groups. However, because the difference between the two groups was not statistically significant, it is not possible to say that the intervention led to this improvement.

Did the number of sessions attended lead to greater general health?
As for the previous two outcomes, a CAITT analysis was undertaken to assess the effect of the intervention "per session".

This CAITT analysis found a per session effect of 0.38 with 95 per cent CI (-0.13, 0.88), p=0.142.

Although this indicates an average improvement in EQ-VAS score (per session attended) of 0.38, this result had a p-value of 0.142 indicating that we cannot conclude that this increase was not down to chance.

Did the intervention have an impact on final diagnosis?

The diagnostic category according to the CIDI was recorded at 24 months. The numbers and percentages of participants in each category, by group, are presented in Table 7. A comparison of the percentage of participants in each of the diagnostic categories between the intervention and control groups found that these did not vary other than can be expected by chance p=0.368.

There was, however, an improvement in diagnosis from baseline (see Table 1). Overall 30.4 per cent of participants experienced no episodes of depression. Also the percentage classified as chronic major depression fell from around 30 to 15 per cent, and those with recurrent major depression from around 53 to 40 per cent.

Table 7: Baseline characteristics

Diagnosis (CIDI)	Intervention	Control	All participants
Chronic major depression	27 (13.8%)	28 (16.6%)	55 (15.1%)
Recurrent depression	87 (44.4%)	60 (35.5%)	147 (40.3%)
Dysthymia	25 (12.8%)	27 (16.0%)	52 (14.2%)
No episodes of depression	57 (29.1%)	54 (32.0%)	111 (30.4%)
Total	196	169	365

There was an improvement in the diagnostic categories across both groups at 24 months, with a trend towards less severe diagnose being recorded, but as this did not differ significantly between the two groups it cannot be said to have been due to the intervention.

Did the intervention have an impact on the services that the participants accessed?

Information was collected from the GP notes about the services that were accessed by participants in the 24 months before the study and for the 24 months study period. The services covered were:

— Visits to the GP

— GP home visits

— Nurse/counsellor visits

— Number of referrals to psychological therapy/psychotherapy

— Number of referrals to psychiatrist or community mental health team

— Number of months on antidepressant medication.

Table 8 presents descriptive statistics, by randomisation group, for these outcomes for both the pre-study and study periods.

Table 8: Services used

		Control		Intervention	
		Mean (S.D.)	Number	Mean (S.D.)	Number
GP visits	Pre-study	15.8 (9.7)	271	15.5 (9.9)	270
	Study period	13.4 (9.1)	226	13.7 (9.5)	234
GP home visits	Pre-study	0.2 (0.9)	224	0.2 (1.2)	236
	Study period	0.1 (0.5)	190	0.1 (0.6)	193
Nurse/counsellor visits	Pre-study	5.0 (5.4)	249	4.6 (5.5)	248
	Study period	5.3 (6.8)	218	6.3 (6.9)	226
Referrals to psychological therapy/psychotherapy	Pre-study	0.3 (0.6)	145	0.4 (0.9)	155
	Study period	0.3 (0.6)	119	0.4 (0.8)	126
Referrals to psychiatrist or community mental health team	Pre-study	0.6 (1.8)	154	0.4 (0.7)	154
	Study period	0.4 (0.8)	126	0.6 (1.4)	117
Number of months on antidepressant medication	Pre-study	12.7 (8.3)	269	14.1 (8.8)	267
	Study period	11.7 (9.6)	250	13.6 (9.7)	261

The effect of the intervention on these services was investigated. The statistical methods took into account the baseline differences in means and clustering effect of the different practices.

Results from this analysis are presented in Table 9. The numbers included in each analysis, the difference in means (control minus intervention) along with the 95 per cent confidence intervals for these differences are presented. Finally the p-values are provided as a way of assessing the statistical significance of the differences.

Table 9: Comparison of services used

	Number in analysis	Difference in means	95% Confidence Interval	p-value
GP visits	448	-0.1	(-1.7,1.5)	0.898
GP home visits	338	0.1	(-0.0,0.1)	0.060
Nurse/counsellor visits	397	-1.8	(-3.2,-0.3)	0.017
Referrals to psychological therapy/psychotherapy	174	-0.2	(-0.5,0.1)	0.135
Referrals to psychiatrist or community mental health team	174	-0.2	(-0.7,0.2)	0.317
Number of months on antidepressant medication	490	-1.4	(-2.8,-0.02)	0.047

Access rate for only two of the services were found to differ significantly between the randomisation groups:

— The total number of nurse/counsellor visits – this was found to be lower by 1.8 in the control group with 95 per cent confidence interval (-3.2,-0.3), p=0.017. This would be expected as the intervention required more nurse visits than is usual.

— After adjusting for any baseline differences the mean number of months on antidepressant medication was found to be lower by 1.4 in the control group with 95 per cent confidence interval (-2.8,-0.02), p=0.047.

The number of nurse/counsellor visits and the number of months on antidepressant medication were significantly higher in the intervention group at follow up.

Economic analysis

In parallel with the outcomes evaluation, an assessment was carried out to see whether the intervention was more cost effective than usual care.

The cost effectiveness analysis looked at differences between the intervention and control group in terms of both outcomes and costs over the two year trial period. If an intervention improves people's health and welfare (better outcomes) and also saves money, it is clearly the more cost effective option. Often, though, interventions may help people to recover but require an additional investment. In this case, additional information about the probability of the intervention being cost effective at different monetary values that the decision-maker may be 'willing to pay' (WTP) for better outcomes could be helpful.

The sample includes 209 people in the intervention and 195 in the control group who completed all information necessary for the cost effectiveness analysis.

Key findings

— The intervention led to an increase in the number of people seeing practice nurses for depression. This is likely to be due to contacts associated with the ProCEED intervention. Consequently, the costs of practice nurse contacts increased in the intervention group.

— The intervention group received significantly more support from friends and family at follow-up, while this decreased for the control group.

— Productivity losses decreased for both groups and formed a smaller proportion of total costs at follow-up.

— For the control group, total societal costs decreased, while they remained the same for the intervention group, resulting in higher costs for the intervention group at follow-up.

— The probability that ProCEED was cost effective in terms of QALY gain is low, even at high values for willingness-to-pay.

— The results are more encouraging for the BDI-II and WSAS, but are also harder to interpret.

Use of services and support

What support and services did participants use during the three months prior to the start of the intervention?

Participants were asked to record any contacts with services over the three months before the intervention started using the CSRI measure. This established a baseline to see if the intervention would have an impact on service use.

— People used a broad range of services, from hospital to complementary therapies and from social care to self-help, but (with the exception of primary care) only a few people used each service.

— Over 80 per cent of people saw their GP, and about 60 per cent saw them specifically about depression.

— Practice nurses were seen by a third of people, but only five per cent of the intervention and nine per cent of the control group saw them about depression.

— Except for counsellors, few people reported contacts with mental health services.

— There were no group differences in the proportions of people using services, except for counsellors who were seen by 20 per cent of the intervention and 10 per cent of the control group.

Did ProCEED generate differences in service use at follow-up?

Participants were asked to complete the CSRI again at the 24 month follow-up point. The overall picture of service use remained roughly the same as at the baseline, but there were some important changes.

— There was a significant drop in the proportion reporting GP contacts for depression – from 56 to 45 per cent in the intervention group, and from 62 to 39 per cent in the control group.

— Almost 10 times as many people in the intervention group reported contacts with a practice nurse for depression as in the control group (three per cent vs. 29 per cent). This significant difference was almost certainly because of recommended contacts with the practice nurse due to the intervention.

— Use of any hospital services (such as inpatient stays) and mental health services (for example psychiatrists) remained similar to the baseline and there were no significant differences between the groups.

How much informal care did people receive?

While formal services are important in supporting people and their costs are of great interest to policy makers and service planners, another key source of support is through family and friends (informal care). Participants reported the number of times people came to help them and the average length of time they stayed. The monetary value of informal care has been based on the minimum wage rate.[37] These results are displayed in Table 10.

Table 10: Informal care contacts and cost at baseline and follow-up (24 months)

	Baseline		Follow-up	
	Control	Intervention	Control	Intervention
% receiving informal care	36%	35%	32%	34%
Mean number visits (range)	9.9 (0-182)*	6.1 (0-90)	6.0 (0-90)*	7.2 (0-180)
Mean duration (hours) per visit (range)	2.3 (0-140)	2.4 (0-112)	1.9 (0-112)	1.7 (0-56)
Mean total hours of informal care (range)	27.2 (0-720)*	16.9 (0-360)	15.6 (0-325)*	23.1 (0-630)
Mean total value of care (range)	£149 (0-3,974)*	£93 (0-1,987)*	£86 (0-1,794)*	£128 (0-3,478)*

*Significant change over time

The mean costs of informal care decreased between baseline and follow-up for the control group but increased for the intervention group.

Productivity losses

What were the productivity losses in our sample and did ProCEED make a difference?

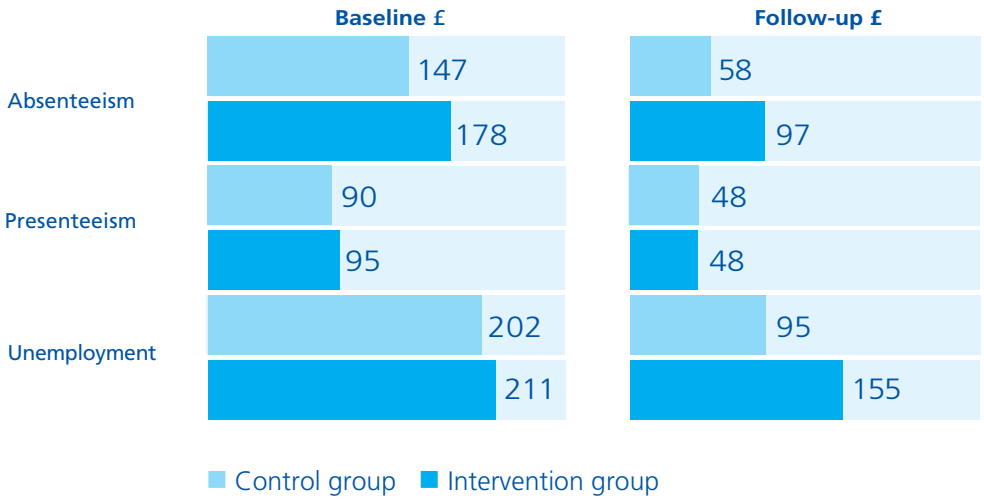
The impact of depression on the ability to work can be severe. In England, the average annual cost of lost employment due to depression in 2007 has been estimated at £9,311 per person.[38] Productivity losses have been estimated using three categories.

— Absenteeism: Absence from paid employment or volunteering (based on median earnings from the Annual Survey of Hours and Earnings).

— Presenteeism: Reduced productivity while at work (estimated at about 15 per cent per day).[39]

— Unemployment: values as wages forgone based on the minimum wage for England.

Figure 3: Amount of lost productivity at baseline and follow-up



As Figure 3 shows, productivity losses in all three categories were very similar for both groups at baseline. After adjusting for baseline, the reduction over time in losses from presenteeism and unemployment was significant at the 90 per cent level for both groups. However, the value of lost productivity from unemployment remained higher for the intervention group.

Although overall productivity loss fell, the intervention group did not fare better in this regard than the control group.

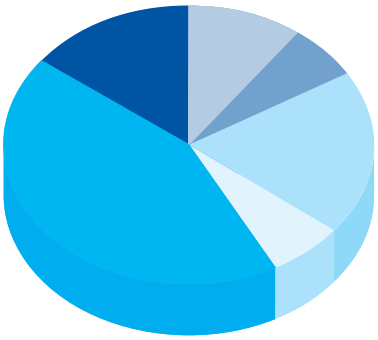
Costs to the public sector and to society

What were costs associated with service use, informal care and productivity losses and did ProCEED have an impact?

When looking at the baseline public sector costs there were significant differences between the groups in the costs for complementary therapies (for example hydrotherapy pools, spiritual healers) and social care, but the amounts were small. Figures 4 and 5 show the fall in the value of lost productivity. The category 'All mental health' includes inpatient stays, outpatient contacts and primary care contacts due to depression as well as depression medication and specialist mental health services.

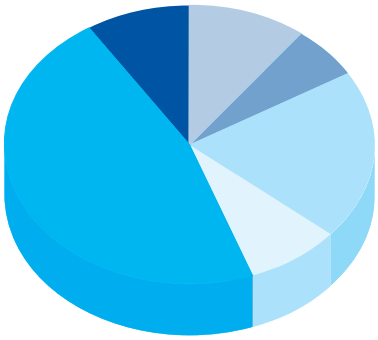
Figure 4: Baseline costs by category

Control group



	£
Hospital	105
Primary care and medication	63
All mental health	198
Other services	68
Productivity loss	440
Informal care	150

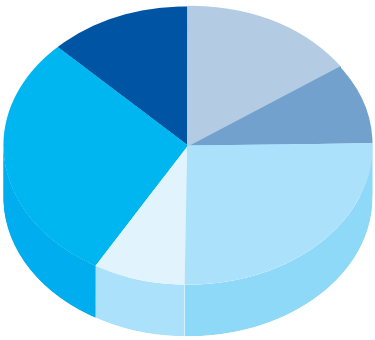
Intervention group



	£
Hospital	108
Primary care and medication	63
All mental health	206
Other services	87
Productivity loss	484
Informal care	93

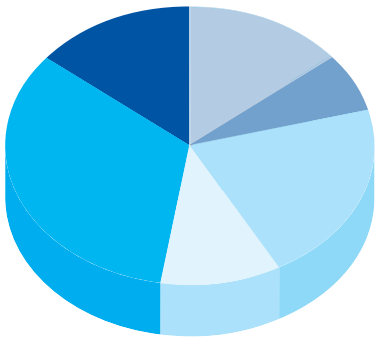
Figure 5: Follow-up costs by category

Control group



	£
Hospital	107
Primary care and medication	65
All mental health	176
Other services	56
Productivity loss	201
Informal care	86

Intervention group



	£
Hospital	127
Primary care and medication	64
All mental health	191
Other services	96
Productivity loss	301
Informal care	128

— The value of lost productivity accounted for more than 40 per cent of total societal costs at baseline but reduced to about a third at follow-up.

— At follow-up – taking into account baseline costs – the intervention group had significantly higher costs for community health services, medications, loss from unemployment and contacts with practice nurses for depression.

— In the control group, the costs of GP and practice nurse visits for depression and for depression medication decreased significantly over time.

— In the intervention group, the costs of GP visits for depression decreased significantly, while the costs of practice nurse visits for depression and depression medication increased significantly over time.

Figures 4 and 5 show the extent to which different agencies fund the support packages. At baseline, total 'societal' costs (public sector, plus productivity losses plus informal care) were similar for the intervention and control groups at £1,041 and £1,024 respectively and there is little difference between the groups in the way costs are dispersed between the sectors. Total societal costs for the control group decreased significantly from baseline to follow-up. At follow-up, not only has the way costs are borne by each sector changed, but total societal costs for the intervention group were significantly higher than for the control group; £906 compared to £690. In part, this was due to higher levels of continuing formal and informal support for the intervention group and in part related to levels of unemployment.

Total societal costs for the intervention group were significantly higher than for the control group following the intervention.

Cost effectiveness

Was ProCEED cost effective in the longer term from a public sector and societal perspective?

The probability – the chance – that ProCEED was more cost effective than treatment as usual was identified by combining information on the costs data shown above, the positive outcomes generated by the intervention, and a range of monetary values that a care provider might be willing to pay (WTP) for a one point improvement in outcome. The lowest WTP value was £0, and the highest or maximum value was £3,000 per point of improvement in depression (using the BDI-II scores) or social functioning (WSAS) and £30,000 per quality adjusted life year, or QALY, gained (estimated form the EQ-5D).

Table 11: Probability that ProCEED is cost effective

	Service costs only		Societal perspective	
	WTP=£0	Maximum WTP	WTP=£0	Maximum WTP
QALY	13%	44%	3%	17%
BDI-II	16%	95%	3%	89%
WSAS	17%	98%	3%	93%

Table 11 summarises the results of the analysis; the higher the percentage figure, the more confidence can be given to the intervention being the more cost effective option. The probability of cost effectiveness for quality-adjusted life years is the lowest. Assuming that the commissioner or provider would pay £30,000 for an additional QALY gained, there is only a 44 per cent chance that this would be more cost effective than treatment as usual. There is, however, much debate about whether the EQ-5D is sensitive enough to assess changes in mental health.[40]

The picture is more encouraging when looking at BDI-II and WSAS. For both measures, Table 11 shows that at £3,000 per point of improvement there is a very high probability that ProCEED is the more cost effective option. In fact, at WTP of £300 for services (£800 societal costs) per point of improvement there is a greater than 50 per cent probability of cost effectiveness.

At relatively low WTP values for the clinical outcomes (BDI-II and WSAS), ProCEED is likely to be more cost effective than treatment as usual.

Qualitative results

Subjects

Participants: 26 study participants were interviewed, 12 male and 14 female; their ages ranged from 33 years to 78 years. There were two Asian males interviewed and the rest were all white British. Eight were employed, one of these was on a part-time basis and one was self-employed. Seven were unemployed, with four on long-term disability benefit. The other 11 were retired. Eight lived alone.

Ten of the participants interviewed had a diagnosis of recurrent depression, nine had been diagnosed with chronic major depression and seven had a diagnosis of chronic dysthymia. Attendance at appointments varied, 10 people had attended all appointments and two missed only one appointment. Nine participants missed two or more sessions and five missed over half the sessions. Two of those interviewed had only attended two nurse appointments each.

Nurses: There were 15 practice nurses involved in the interviews, of these nine were seeing participants regularly in a clinical practice nurse capacity, while the other six worked on research studies involving clinical contact with participants. The level of nursing experience was highly varied, with the nurses reporting having been practice nurses for between eight and 31 years.

A large amount of qualitative data was collected and it is not possible to present it all here, but we will present the data which reflects the objectives of the main trial and the study overall. Additional results will be available in forthcoming journal publications currently being prepared.

In most of the sections that follow we have given both participant and nurse data to show areas of agreement and difference. We have also indicated where some nurses or participants expressed more negative views about delivering or receiving the intervention.

What was the participant and nurse experience of being involved in the intervention sessions?

The importance of being listened to and focusing on particular issues

Many participants reported that the process of talking openly about their depression and being listened to was helpful. They said that talking to someone professional but neutral allowed them access to impartial, constructive feedback and a different perspective on their issues.

"It makes you reassess and look at, and try and look at your life differently and see how you can make, you know, make things better." Participant 6

Several of the participants commented on how they had found the problem solving approach helpful.

"I think it was the fact I was asked what the problems were and I, you know, I was at that moment in time able to say them. And she worked through them very good, very progressively, it was quite, it had order to it. I thought that went very well." Participant 8

This perspective was often mirrored in the practice nurse data. Most felt that the regular reviews allowed them to identify and focus on particular issues with the participants.

"To sort of advise and motivate and just sort of help them see, see the wood for the trees because often they just feel a bit bogged down and they don't know what to do first. And they don't feel they can cope with doing anything." Nurse 10

However some participants had found it hard to make use of the suggestions which were made and felt that despite the nurse intervention they still had great difficulty in getting motivated to do things.

"I do know what sort of things I should be doing to try and help myself, but I didn't always do them because it's easier said than done. So the right things were being said, but nothing maybe to motivate me into trying to do things." Participant 25

Improvement in self-confidence and awareness of triggers for depressive episodes

Both the practice nurse and participant interviews highlighted that one of the main impacts on the participant was an increased self-awareness relating to their depression, the long-term nature of the problem and how they could use this knowledge to identify and tackle future episodes of low mood.

"Provide ongoing support with one person who the patients can confide in. And I think again trying to alert them to triggers so you hope you know that they're not going to have any major relapses." Nurse 11

As a result of this feedback from the nurses several of the participants interviewed reported becoming more insightful and aware of their own feelings and how they were perceived. The participants were also encouraged to seek help for relapses earlier and a few of the participants identified that focusing on their periods of being well helped them to place low mood in context and proportion.

"I've come to grips with it, I've learnt to live with it. I've learned to try to understand myself a bit more in the last two years." Participant 12

What were the characteristics of helpful and unhelpful sessions?

Sessions that went well or were perceived as helpful

The participants provided a lot of data in this section, describing features of the actual sessions which they found useful, for example that the sessions were dedicated to discussing depression and that both the participant and the nurse were aware of this prior to the session. They felt that this made it easier for them to discuss their depression in the clinical setting. Other session characteristics highlighted by the participants as useful were the length of the sessions and the fact that it was based conveniently at the local GP surgery.

"I think I was glad in a way because she was specifically for that whereas other things it's not always specific. And if you go and go to the doctor or anything you talk about umpteen different things but this was specific. I think that was all helpful really." Participant 15

Most people described having someone to talk to who was impartial and removed from their personal situation as useful. Several participants also highlighted the problem solving nature of the sessions and that they found focussing on specific problems and guidance related to these issues beneficial.

"The talking about my depression openly, the problems that I've had, what we can do to solve those problems, any goals that we can do, any tasks that we can do to actually solve those. So I think it's just been a big learning curve for me to pick up tips, as I say to treat something which is going to be a chronic condition and I've just got to learn to manage it the best I can." Participant 17

Several participants commented on the nurse's ability to help them think and talk about areas of difficulty which had previously not been addressed.

"Yes and she was quite direct and she asked a lot of questions and some… Actually it was really interesting because she asked me about some stuff that I've just never discussed with anybody." Participant 3

The nurses found it more difficult to verbalise what it was that made a session go well. When nurses reported a good session it was usually linked to the consultation style. They felt they had developed a good rapport with the participant or that they had begun to open up and were more comfortable, allowing discussion about difficulties or interests and to build on these.

"He just seemed a lot stronger at the end of his sessions, and everything. And you could almost tell physically from the way he walked and the way he talked and sat, that he actually had an awful lot more confidence. It was almost really as though a weight had been lifted off." Nurse 2

Sessions that didn't go well or were perceived as unhelpful

When asking participants what constituted a 'bad' experience of a session or what they found less helpful they did not provide as much detail. For two of the participants the sense that the nurses only seemed interested in getting the research questionnaires completed meant they only attended a couple of sessions.

"It was just answer the questions and we'll see you next time, you know. And that's all I got really. There was no discussion. It was just answer the questions." Participant 16

In contrast the nurses reporting sessions which had not gone so well often related them to the participant characteristics of that session, for example participants who would talk about the same thing at each review, those who were not keen on the suggestions being made, and those with whom they found it difficult to develop a rapport.

"I probably just wonder whether it's really worked, especially with the people who just go round in circles. I just wonder whether it's really benefiting them, or whether it's wasting their time. But then they keep coming, so..." Nurse 3

What impact did the intervention have on participant's mental health and other factors?

Several of the participants interviewed stated that they felt clear progress had been made. They felt they coped better with their problems and had developed strategies to deal with their depression. An increased self-awareness of their depression seemed key, as well as a more positive outlook and an improvement in their confidence and self-esteem which impacted positively on their mental health.

"I'm just more aware of my strengths and my weaknesses. Before I used to dwell more on the weaknesses. Now I think about my strengths. I still sometimes have negative days, but I tend to do things more positively than I used to." Participant 20

This was mirrored by the nurses reporting that factors which linked with improvements in the participants' mental health seemed to be related to improving the participants' confidence and self-esteem, allowing them to feel more in control and better able to cope with the stresses they were under.

"Once she sort of got more of an understanding of how she was looking at herself and it was more a confidence thing, and that people weren't criticising her and judging her all the time, she actually could see a way forward. So each session got better with her." Nurse 14

Impact on lifestyle

Most participants reported an impact on some aspect of their lifestyle, although these impacts were quite varied. Healthy lifestyles were discussed and participants were encouraged regarding diet, increasing exercise and sleep. The nurses also provided more practical support for participants, putting them in touch with carers associations, organising OT assessments and arranging equipment required. They were also encouraged to take up social activities and outside interests such as yoga, piano lessons and other hobbies and encouraged to take time out for themselves.

"Just talking to her give me, you know more of a boost, more of a thing in life, you know, to get on and get out there and do things." Participant 26

The practice nurses also provided health education, encouraging healthy eating and an increase in physical activity and directed participants to services supporting the reduction and abstention from alcohol and smoking. This was a role in which they felt comfortable and confident.

"I mean that's where I'm grounded basically do you know what I mean, doing the healthy lifestyle bit. So yes it was very much part of the interviews which was something they all wanted to discuss anyway because weight and appearance and all the rest of it goes very much with the general self- esteem picture." Nurse 12

Impact on work/finance

Two of the participants interviewed had severe money problems and were referred to debt advice centres. Other participants were signposted to the Citizens Advice Bureau and their local MP and as a result one participant avoided being evicted from his accommodation.

"I've now got a debt relief order in place, because that was a really big worry. And I think that's probably why I couldn't sleep night-times as well." Participant 18

What impact did the nurses feel that being involved in the trial had on their abilities and confidence?

Previous training and experience

When asked about their previous experience of working with participants with depression or mental health problems most nurses reported that they had limited or no experience in the GP practice setting. If they did report contact with depressed participants, it was not care directly related to the participant's mental health problem and they were often seeing the participant about other things. With regards to prior training in mental issues most nurses reported that the only mental health training they had received was during their basic nursing training, and in several cases this appeared to have been quite a negative experience.

"It's not something I have a huge interest in. I've had quite a bad experience in my training with the mental health side of it. I had a few issues. I was put on the psychiatric intensive care, and spent most of the time in the little hub, watching what was going on rather than interacting with people." Nurse 3

Several of the nurses appeared to have had a rather apprehensive or even negative attitude to participants attending with depression, before taking part in the trial. They reported being dismissive and sometimes apprehensive about discussing symptoms of depression with participants. They felt that, although this was a topic that they would be expected to raise in the long-term condition clinics, they were concerned about how the participants would answer and felt unable to tackle the situation themselves, often referring to GP colleagues if low mood was disclosed.

"Sometimes you ask the question and you think, oh please don't have a problem because if you have – you know. Which is awful to say it, but it's a reality sometimes. You're almost relieved that everything is fine. I don't think that's right, but that's how you sometimes feel." Nurse 15

They indicated that their attitudes prior to taking part in the trial were largely linked to their confidence and previous experience of dealing with participants with mental health problems. They were concerned that they would not know what to say to the participants and worried about missing suicidal risks.

"I think I rather avoided mental health to be honest, because as I said I was a bit scared of it." Nurse 13

Impact of being involved in the trial on the nurses' abilities and confidence

The nurses felt that being part of the trial had developed their awareness and understanding of depression. The insights they gained from working with the participants, as well as the structured training provided, was reported as having increased the nurses' knowledge base.

"I'm more confident about talking to people about how they feel and not so worried about, you know, what they're gonna throw at me and say back." Nurse 10

All the nurses reported an increase in confidence in dealing with depressed participants in primary care and most of them described feeling confident in discussing the issues and discussing the difficult questions regarding suicide and self-harm.

"Previously if a patient turned up and they were clearly very depressed and possibly suicidal I'd want to run screaming from the building. But actually no I feel now I can deal with that." Nurse 5

However, some nurses also reported negative feelings engendered. The main emotion evoked was one of frustration and sometimes irritation. This was more likely when nurses felt that their suggestions were being rebuffed, or if participants didn't attend appointments and when they were dismissive of the study. Nurses who had been asked to get involved in the trial by the practice, rather then it being something they were personally interested in doing seemed to be more affected by this, although they may have also had positive interactions with some of the participants they worked with.

"It's very frustrating to see these same people over and over again and they just make your heart sink. Some people are very good at it. Some people really enjoy working with the elderly. Some people really enjoy working in theatre. I can't see mental illness as being my bag, and that's just being honest." Nurse 14

How did this intervention compare with usual care?

Perceived problems with GP care

It was quite striking how many participants felt that their GPs were not interested in talking about depression, which led to them thinking they would be wasting the doctor's time to ask to discuss this. Several participants reported that they would only request a GP appointment when they were feeling very low, or if they wanted a specific item such as a medical certificate or medication. Some participants described their GPs as excellent, but unable to spend the time which would allow a proper discussion of their difficulties.

"With the best will in the world GPs haven't got an enormous amount of time to – I suppose waste is the wrong word – on a question and answer session with a patient over the ins and outs of medication. They make a diagnosis, they make a decision based on what you tell them, and prescribe what they believe to be the right medication." Participant 1

There was a general sense that the nurses would be more likely to be able to offer more time, care and support.

"I have huge faith in my doctor and if I go with a medical problem that's fine but I think depression isn't an acute medical problem. I think it's more something that you need to have time with somebody. And the time to me is more important than the prescription. That time to me [with the nurse] was worth 100 prescriptions." Participant 22

Several participants reported being apprehensive about attending the doctors' surgery, especially for depression. They describe putting on a 'front' for the GP and building themselves up for the appointment.

"I suppose nurses are not quite so scary are they? Not so formal. Yeah, maybe with doctors I feel I have to be a bit more formal, a bit more on best behaviour, whereas with nurses I feel I can relax a bit more." Participant 14

Overall impressions of proactive care

We asked participants to give their overall view of receiving proactive care. Approximately half the participants found the process a positive experience and reported the intervention sessions as being very helpful.

"It has changed my life. It's made a huge difference. I don't feel as though I've been part of a research study. I feel as though I've been cared for as an individual and recognised as having needs in a way that's never happened before." Participant 10

Many of those who reported positive benefits from the approach had been through a traumatic time in their lives during the period of the study and had found the nurse to be very supportive.

"The fact the awful things that did go through with me, the fact that I came through it. And I really believe it was the lifeline of knowing that I'd got these appointments or knowing there was a phone call coming or knowing I could come and see her." Participant 22

However, several of the participants interviewed had a more negative view point, getting little back from the sessions, finding it very time consuming and difficult to fit into life or finding it uncomfortable due to the poor interaction with the practice nurse.

The main advantage that the nurses reported was that they felt that they were able to provide complete care to the participant by signposting them to services and treating them as an individual, talking about and dealing with the wider social, financial and physical problems as guided by the participants' needs.

"I think the proactive care did look more in-depth at those areas and what the patient wanted, rather than just, well let's increase your medication and come back and see me. Sort of really finding out how they were and sort of what they wanted." Nurse 7

The nurses felt that their medical background meant that they were able to introduce health education and tackle physical health issues as well as psychological issues during the sessions.

"A lot of patients said they felt happy that we've got medical backgrounds and understand depression and the antidepressants and whatever. And then we can also bring in health education." Nurse 11

The main disadvantages discussed by the nurses related to the practicalities of providing this form of proactive care in the primary care setting. They were also very aware that whilst they had enjoyed providing this sort of care other nurses might not be so keen.

"I don't think it's something that all nurses could or should be made to do, which is difficult because if you're providing a service you're providing a service. You either are or aren't." Nurse 5

Section 6
Discussion

Discussion

The ProCEED trial examined the impact of a primary care based intervention for a group of patients who have significant ongoing problems with long-term depression, often accompanied by other physical and social difficulties. In the UK they are predominantly supported in primary care settings, but to date there has been no intervention developed which specifically looks to address their needs.

These are people with significant difficulties and often unmet needs, who may end up being marginalised by both society and some health professionals.

It was possible to recruit a large number of participants to the trial over a relatively short time period, suggesting that people with this condition were keen to be involved in assessing this intervention. The qualitative data indicates that many of the participants interviewed found their regular care from the practice lacking and that they often felt that their GPs were operating under very tight time constraints and lacked the time (and sometimes the inclination) to discuss many of their concerns around their depression, tending to just provide medication and sickness certificates. This is a finding that should be of interest to GPs and policy makers.

The main results of this trial indicate that practice nurse-led proactive care was beneficial for some participants, with all measures showing positive trends. However, the outcomes for the intervention group as a whole were borderline significant, suggesting that the intervention was not successful for everyone. There are a number of possible reasons for these findings.

Nurse intervention

The conceptual model for this trial was based on work from the USA involving a managed or proactive care approach which has been tested for a variety of long-term physical conditions as well as for depression. This includes primary care clinicians making the initial diagnosis of the condition, followed by allied health professionals having regular contact with the patients when relevant to monitor symptoms, review treatments and side-effects and give support for self-management activities. This model also involves a specialist supervising the health professional working as a case manager. There is evidence for positive outcomes for practice nurses as case managers for many long-term physical diseases such as asthma and heart disease. The situation with depression is somewhat more complex, including deciding which health professional may be best placed to have the case manager role. Most of the studies involving case managers for longer-term depression have involved mental health professionals in this role.

Relevant mental health training for practice nurses in the UK is severely under-resourced, as demonstrated in participant and nurse observations from the qualitative data, where it was clear that some nurses had found the intervention challenging. This study included a relatively brief training element for the nurses involved but, if the intervention were to be rolled out more widely, additional training and support probably would be required to ensure all nurses had sufficient skills and felt empowered to deliver proactive care for depression. In addition, the study highlighted an urgent need to improve the basic level of training given to all practice nurses in working with people with anxiety and depression, as this appears to currently be very limited and of poor quality.

Severity of symptoms and social functioning

The results of this trial indicate positive results at follow-up across all the outcome measures examined. Assessment using the Beck Depression Inventory (BDI-II) looked at the severity of depressive symptoms experienced at regular time intervals and it appears that the positive impact may be continuing to increase at the point when the trial ended. The measure of social functioning used, the Work and Social Activity Schedule (WSAS) showed a statistically significant difference at 24 months, which is a very important finding given that this is a participant group where social functioning is often very impaired and can be difficult to impact on. Many people in the mental health field consider that assessing how people function in society is more important than measures of symptom severity, which are more likely to fluctuate at different points in time. Two years is a relatively short period of time in the illness trajectory of many of these participants who had very long histories, and it would be interesting to see whether there were any longer-term improvements in these outcomes.

Looking at the graph of the BDI-II results over time, it can be seen that the outcomes in both groups improved over time. This is usual in large randomised trials and is called 'regression to the mean'. What is important, in terms of the results, is whether the participants in the intervention group experience a significant benefit in addition to this. This phenomenon is probably also partly responsible for the overall improvement in both groups as regards the severity of the diagnoses made using the CIDI. Another important consideration is that people in general tend to have better clinical outcomes if they take part in clinical research whether they are in the control or intervention group – this is probably due to both participant and clinician factors.

Session attendance

Given the positive indications from the two year outcomes, the per session analysis is particularly important in the assessment of this intervention. The per session change calculated this way was significantly positive for both the BDI-II and WSAS and indicates that, as well as a significant change in social functioning, someone attending all 10 sessions of the intervention offered might expect an improvement in their BDI-II score in the range of 3.7 units, which can be considered clinically meaningful. It also means that the more sessions someone was able to attend the more likely they were to benefit. The qualitative data suggest that participants and nurses varied in their engagement and motivation, which had an impact on session attendance, and these factors need to be explored further. Decisions about rolling out this form of intervention would need to account for this and to explore alternative solutions for participants and practices with nurses who expressed low levels of engagement and motivation.

The only measure which did not show statistical significance on this analysis was the EQ-VAS, which is a patient self-report scale of their health state. It is however quite a crude measure and tends not to be very sensitive to changes in mental health outcomes – it was included as part of the Euroquol which is the measure conventionally used in cost effectiveness analyses. There is currently a debate about the use of the Euroquol in mental health studies, as many mental health service users do not consider that the questions asked are a good way of accurately assessing the quality of life issues of most concern to them.

Cost effectiveness of intervention

The relevance of the Euroquol may be important to consider when reflecting on the fact that the intervention was not judged as cost effective using the convention of quality adjusted life years (QUALYs) favoured by NICE, which are derived from the Euroquol data. When examining the costs potentially associated with changes in the two most clinically important outcomes of symptom severity and social functioning, data indicate that this could be achieved at a relatively low unit cost. Productivity losses due to factors such as unemployment and time off work fell in both groups, although not more in the intervention than the control group. However, significant productivity changes, such as those gained from getting back to work can take a long time to achieve. People with chronic and recurrent depression often face greater challenges with employment than the general population, and access to employment support is limited. The cost-effectiveness data was obtained from self-report data for two short time periods of three months at baseline and follow-up which could also have affected the productivity loss findings.

The fact that the intervention group reported receiving significantly more support from friends and family at follow-up should be interpreted as a positive finding, given that they would have been encouraged to increase their use of social contacts during their session with the nurse.

Health service data

Two different methods were used to collect health service usage data, which is likely to account for some of the differences in the reported findings. The data reported in the Results section is taken from service usage forms completed by the nurses from the GP records and covering the 24 month period prior to the start of the trial (baseline) and the 24 months of the trial period for the follow-up. As stated, the health economics analysis data was collected via a participant self-complete questionnaire which only covered the three month periods before starting in the trial and prior to the final end-point for each person. This is mainly because self-report data is only thought to be accurate for a relatively short time period as people forget things very quickly, but it means that some findings may differ due to the different time periods examined.

When considering the health service data collected over the two 24 month periods there was no significant difference between the two groups in terms of GP attendances. This is not surprising given that the qualitative data indicates that those participants interviewed did not find seeing their GP about their depression particularly helpful – the number of GP attendances fell slightly in both groups. The number of nurse attendances increased significantly more in the intervention group over the study time-frame, but this is accounted for by the fact that the nurses were providing the intervention. Interestingly, the average number of months on antidepressants fell in both groups. However, the average number of months on antidepressants was significantly higher in the intervention group in the 24 months study period, compared to the control group. This is likely to be associated with the nurses having addressed participants' concerns about their medication and arranging reviews and

changes of formulation when the current treatment was reported to be ineffective. All these factors are likely to have improved concordance. Although we were clear that we were not necessarily advocating the prescription of antidepressants unless they were found to be helpful by the participants, there are studies in the literature linking improvements in peoples' level of depression with improved adherence to appropriate medication.

The only significant change in uptake of psychological therapies was an increase in the number of counsellor visits in the intervention group compared with controls, although this was not statistically significant. We were surprised that there weren't more documented referrals to psychological therapies in the intervention group, as the nurses had been encouraged to actively consider such strategies in their discussions with the participants. Unfortunately, it appeared that psychological therapies such as CBT (cognitive behavioural therapy) were still not readily available to a large number of trial participants despite the IAPT (Improving Access to Psychological Therapies) initiative and, where they were available, referrals were not always clearly documented in the GP electronic systems. In addition, we learnt from feedback at the clinical supervision sessions that quite a few participants were reluctant to try psychological therapies or felt that they had tried this before and it hadn't been particularly helpful – even if this had been counselling previously and the suggestion now was to try CBT.

Qualitative data

The qualitative study provides some very interesting data which helps to understand some of the research findings and bring together future recommendations for both policy and research. These qualitative findings are from a sub-sample of the intervention participants and the practice nurses delivering the intervention, so can only give indications rather than definitive outcomes. The aim was to sample representatively across a range of characteristics which might influence interviewees' views and to include more negative as well as more positive feedback.

As regards the participants interviewed, many viewed the intervention positively and felt that they had benefited. Factors considered important in the sessions included that the nurse had more time available to discuss things, often had an empathic, non-judgemental manner and excellent listening skills – this appeared to have been found lacking in many GP consultations. Continuity and seeing someone familiar was also appreciated by the participants, as was the fact that there was a clear focus on the sessions being to discuss the management of their depression with a problem solving approach. Both participants and nurses described how a range of factors had been addressed in some of the sessions, including physical health, social factors and relationships, lifestyle, financial and work issues. Providing health education and lifestyle advice was a role in which the nurses generally felt comfortable and confident.

Participant factors perceived by the nurses as more often associated with appearing to benefit from the intervention included those who were open to the intervention in the first instance and those who had significant life events immediately before or during the intervention. It may be that some of the participants who found the intervention less helpful also experienced significant life events but they may have found it more difficult to disclose and discuss these. Certainly some of the participants described finding it difficult to open up to the practice nurse or lacking in motivation to follow-up on the suggestions which had been made. In some cases a clear link was made with a perception that the nurse was disinterested and only focusing on completing the nurse questionnaires, while other participants felt that some of the nurses seemed less sure of themselves in this role, which several nurses agreed with.

However, in other cases there are likely to have also been participant factors associated with limited progress being made.

The nurse interviews indicated that their involvement improved their confidence and skills in working with the range of depressed patients they might meet in the surgery, not just those with severe and enduring depression, and several said that they had used these skills with other patients they had seen. This was against a background of having had minimal training in working with people with common mental health problems before taking part in the trial, quite often associated with feeling very unsure about discussing such issues with their patients.

Quite a few of nurses reported enjoying seeing participants with depression for regular reviews, although they all said that they would not want to have whole clinics on this theme and would want to mix seeing people with mental health problems with those with other more physical health problems. However, not all the nurses enjoyed the level of contact and responsibility for people who often had quite severe depression and some felt they would not want to provide such an intervention on a regular basis.

Strengths and limitations of the study

The large number of participants recruited was a clear strength of the trial, as was the variety of participating practices throughout the UK and the involvement of the MRC GPRF (Medical Research Council GP Research Framework) which ensures the active involvement of practice nurses in primary care research, as well as having robust quality control measures in place.

A limitation was the fact that it was only possible to give the participating practice nurses relatively brief training in delivering the intervention and that there was a range of interest amongst them in being involved in such work – however, this would be the same in normal practice. Response rates to the outcome measures were very good at baseline and the two year follow-up assessment but were sub-optimal at below 70 per cent at some of the intervening time-points. This may have had an impact on the BDI-II results, although established imputation techniques were used to deal with missing data.

Section 7
Conclusion and recommendations

Conclusion

Overall, the ProCEED intervention has shown some positive findings and leaves a number of areas open for further investigation. The significant improvement in social functioning is a very important result, and one that is often difficult to achieve for this group. There was a trend towards a reduction in the severity of people's depression that would benefit from further study, and there was a significant positive impact from attending all 10 sessions offered. The economic analysis has shown that the intervention is likely to be cost effective in terms of reducing symptoms and improving function, and there are some interesting findings about the impact on service usage. The qualitative interviews offered some interesting insights into some of the reasons these results have been observed, with levels of motivation and engagement appearing to be crucial. Many respondents felt the practice nurse was a more suitable professional than the GP to deliver ongoing proactive care, and the model of focused appointments with clear but holistic approach appeared effective for many participants and nurses.

Recommendations

Current Primary Care Trusts and future Clinical Commissioning Groups should ensure adequate primary care services are commissioned for anyone with recurrent or chronic depression. The Department of Health should also consider this within the context of the delivery of its cross-Government mental health strategy.

GP practices should offer anyone with recurrent or chronic depression the choice of accessing a system of proactive care. This could and should involve practice nurses, GPs with a specialist interest in mental health and mental health professionals working in a primary care setting.

Research bodies should fund and/or carry out further research into proactive care for people with recurrent or chronic depression in a primary setting. This is in order to better predict who is most likely to benefit from this form of intervention and who is likely to not respond and will need some other form of intervention. One model will not suit all.

Researchers and health professionals should work together to further refine and test interventions for people with recurrent or chronic depression. Examples may include computer based interventions, behavioural activation or motivational interviewing techniques.

The Royal College of Nursing and local NHS Trusts should ensure mental health is prioritised for all practice nurses through structured peer group training and support. This is particularly pertinent as practice nurses are often expected to broach the topic of depression as part of their standard workload.

The Royal College of Nursing and other appropriate bodies should make available appropriate training for practice nurses in order for them to be able to provide long-term, proactive interventions for people with depression.

The Royal College of General Practitioners should improve GP communication skills training, taking into account feedback from participants regarding the difficulties they had in discussing issues apart from medication with their general practitioners.

The Royal College of Nursing and Mind should continue working together on training and support for practice nurses in managing depression, building on the training pack developed from this project.

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