A randomised controlled trial to test the feasibility of a collaborative care model for the management of depression in older people

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ABSTRACT

Background
Depression is the most common mental health disorder in people aged over 65 years. Late-life depression is associated with chronic illness and disability.

Aim
To investigate the feasibility of a collaborative care model for depression in older people in a primary care setting.

Design of study
Randomised controlled trial with 16-weeks follow up.

Setting
A primary care trust in Manchester.

Method
Participants were 105 people aged 60 years or older who scored 5 or more on the Geriatric Depression Scale; 53 were randomly allocated to an intervention group and 52 to a usual care group. The intervention group received care managed by a community psychiatric nurse who delivered an intervention comprising a facilitated self-help programme with close liaison with primary care professionals and old-age psychiatry according to a defined protocol. The usual care group received usual GP care. A nested qualitative study explored the views of the health professionals and patients regarding the acceptability and effectiveness of the intervention.

Results
The main outcome measure was recovery from depression. Patients in the intervention group were less likely to suffer from major depressive disorder at follow up compared with usual care (0.32, 95% confidence = interval = 0.11 to 0.93, $P = 0.036$). The qualitative component of the study demonstrated the acceptability of the intervention to patients.

Conclusion
A model of collaborative care for older people with depression, used in a primary care setting with a facilitated self-help intervention is more effective than usual GP care. This study demonstrates that the implementation of a collaborative care model is feasible in UK primary care and that the intervention is effective and acceptable to patients.

Keywords
depression; elderly; older people; primary care; randomised controlled trial.

INTRODUCTION

Depression is predicted to be the leading illness associated with negative impact and disease burden by 2020.[1] Depressive disorder affects about one in 10 people aged over 65 years,[2] making it the most common mental health disorder of later life. Depression is associated with physical limitation, greater functional impairment, increased use of healthcare provision, and raised mortality.[3,4] Low levels of detection and treatment of late-life depression[5] have been highlighted in primary care, where evidence suggests a relapsing or chronic course.[6,7] However, once it is detected, depression in older people is treatable.[8]

Given the association of late-life depression with chronic illness and disability, interest has grown in adopting a chronic disease management model for depression, analogous to models for diabetes and asthma.[9] The 'collaborative care model' derives from

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successful research conducted on working-aged adults.[10] The main components of the model include the deployment of a care manager and timely access to the expertise of specialist mental health professionals[9] with the use of multi-modal management approaches known to have some efficacy in older people (for example, problem-solving, cognitive behavioural therapy, and interpersonal therapy).[5] Two studies from the US have shown the effectiveness of such an intervention,[11,12] but these approaches have yet to be translated into UK clinical practice, despite calls for implementation of new models of care for older people with depression.[13,14]

This paper reports a feasibility study of the implementation of the collaborative care model in one primary care trust (PCT). The study is known as the PRIDE trial (Primary care Intervention for Depression in the Elderly).

METHOD

The study was carried out in a PCT with a population of 120 000 in North West England between February 2004 and June 2005. The study was approved by the local research ethical committee and complied with local research governance requirements.

GPs and practice nurses in all 43 practices, and district and community nurses in the PCT were invited to refer patients to the trial who were over the age of 60 years and who they had clinically identified as depressed. For inclusion into the trial patients were required to score 5 or more on the Geriatric Depression Scale (GDS)[15] and 24 or more on the Mini-Mental State Exam (MMSE).[16] Those who did not score ≥5 on the GDS were referred back to their GP with a letter detailing their score and a note inviting them to refer the patient again should their mood worsen. Those who scored ≤23 the MMSE were referred back to their GP with a letter recommending a referral to an old-age psychiatrist. Those who met the inclusion criteria were accepted into the trial and participated in a structured baseline interview consisting of the Structured Clinical Interview for DSM-IV (*Diagnostic Statistical Manual for Mental Disorders*) axis 1 disorders (SCID), which is a diagnostic tool to identify major depressive disorder. The HSCL-20 (Hopkins Symptom Checklist) was used to measure the severity of depression symptoms, the short Health Assessment Questionnaire (HAQ) to measure disability, and the Burville physical illness scale. All assessments were carried out in patients' homes. Patients were then randomised to the intervention or usual care groups.

Intervention

A collaborative care approach was used. The intervention was delivered by a community psychiatric nurse (CPN) based in primary care who liaised closely

How this fits in

Two studies from the US have shown the effectiveness of a collaborative care model for the management of depression in older people, but there has been no study of this in the UK. The current feasibility study conducted in one PCT has demonstrated that a collaborative care model for depression in older people is effective and is acceptable to patients.

with primary care professionals and acted as a care coordinator for depression management with regular access to advice from an old-age psychiatrist according to a defined protocol. The CPN reviewed patients' progress with the old-age psychiatrist every 4 weeks; if the CPN had concerns about a patient, their discussions were more frequent. The protocol did not define how often the CPN liaised with the GP (by post, e-mail, telephone, or face to face) regarding a trial patient, but the CPN did send a written report to the GP after each patient's initial assessment and after assessments at 4 weeks, 8 weeks, and at the end of the intervention at 12 weeks. In between, the CPN liaised with the GP in person if changes in medication were required or if there were concerns about concordance or risk. The algorithm of care is available from the authors.

The complex intervention included education about depression, advice about antidepressant medication, a manualised facilitated self-help intervention (SHADE),[17] and sign-posting to other services, particularly voluntary agencies. The intervention lasted for 12 weeks and consisted of six face-to-face sessions in each patient's home and five sessions delivered via the telephone. Fidelity of the intervention was ensured by regular supervision of the CPN with the author of the manualised facilitated self-help package (SHADE).

Usual care

All practices in the PCT were supplied with hand-delivered guidelines which outlined diagnostic criteria, suggestions of appropriate investigations, and the primary care management of depression in older people. Usual care for older patients with depression is likely to vary between practices, and the behaviour of practice nurses and district nurses will vary with older patients who are depressed.[18] Thus it is difficult to specify what 'usual care' is.

Randomisation

Patients were allocated to intervention or usual care groups using a computer programme for stochastic minimisation controlling for the factors age (≥80), sex, and SCID depression score (≥5) by the trial secretary. The research associate was blind to the randomisation as it was carried out by the research secretary. Information about allocation was kept between the
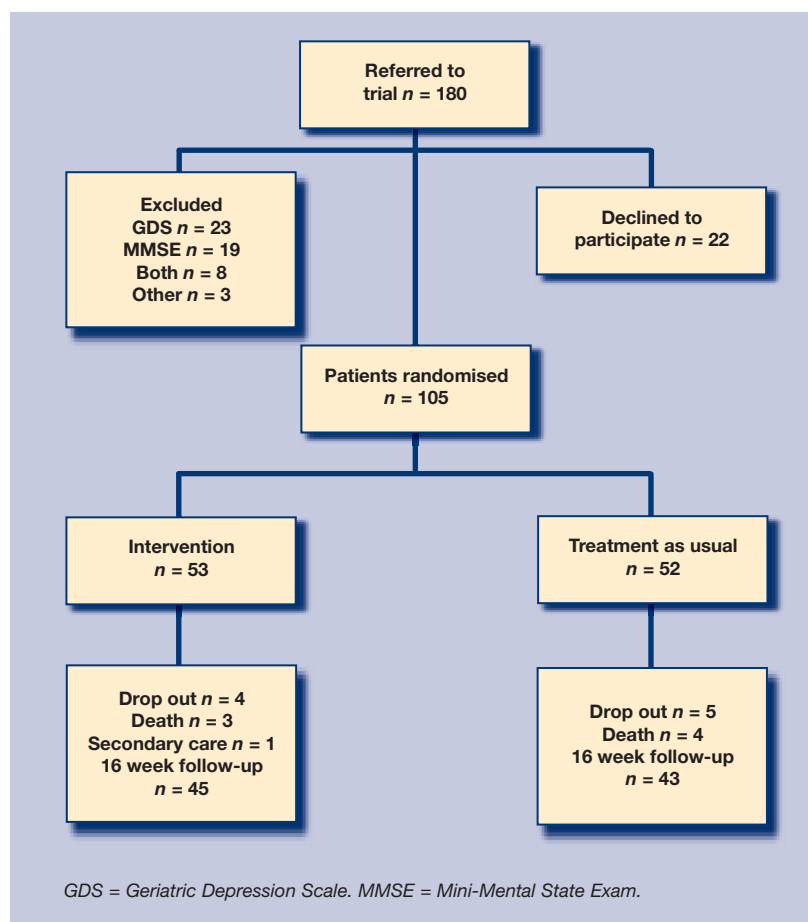
Referred to trial *n* = 180

Excluded
GDS *n* = 23
MMSE *n* = 19
Both *n* = 8
Other *n* = 3

Declined to participate *n* = 22

Patients randomised *n* = 105

Intervention *n* = 53

Treatment as usual *n* = 52

Drop out *n* = 4
Death *n* = 3
Secondary care *n* = 1
16 week follow-up *n* = 45

Drop out *n* = 5
Death *n* = 4
16 week follow-up *n* = 43

GDS = Geriatric Depression Scale. MMSE = Mini-Mental State Exam.

Figure 1. Referral and randomisation of participants.

research nurse and the research secretary.

Data collection and outcome measures
Patients were assessed at baseline (before randomisation) and following either the intervention or usual care (4 weeks after the end of treatment or 16 weeks after randomisation).

The main outcome measure was the proportion of patients with five or more symptoms on the SCID[19] depression scale. Secondary outcomes measures were the HSCL-20,[20] which consists of questions about depression symptoms and severity; the short HAQ,[21] which assesses patient reported pain and disability; and the Burville[22] physical illness scale, which is a structured physical health measure for acute and chronic ill health.

In accordance with the Medical Research Council complex interventions framework,[23] qualitative methods were used in addition to the trial to examine potential causal mechanisms and explore the acceptability of the intervention.[24] Interviews were conducted with 20 patients who had received the intervention, and 20 primary care practitioners. The interview for practitioners consisted of open-ended questions exploring practitioners' views on the aetiology and diagnosis of depression in later life, and

the management approaches they used. The trial CPN was interviewed by an independent researcher to explore his views on the model of care and specific aspects of the intervention.

Interviews were taped with consent and transcribed verbatim. Patient and practitioner interviews were analysed thematically by constant comparison.[25] Interview schedules were modified in response to emerging data. Analysis was completed independently by two researchers and themes were agreed through discussion. The single interview with the CPN was used, with case-notes and supervision notes, to attempt to define the active parts of the intervention. Only data from interviews with patients and the trial CPN are presented in this paper.

Sample size and statistical analysis
In a trial comparing 33 patients receiving an intervention delivered by a psychogeriatric team with 36 patients receiving usual care, Banerjee *et al*[8] found that 56% of the intervention patients improved compared with 25% of controls. Based on this it was estimated that a total of approximately 100 patients would be needed to detect a similar effect with 80% power and two-sided 5% significance, assuming 0% non-response/loss to follow up. A logistic regression model was used to analyse the main outcome (SCID ≥5) adjusting for age, sex, and baseline severity (baseline SCID ≥5). Statistical analysis of quantitative outcomes was based on an analysis of covariance adjusting for age, sex, and baseline value of the particular outcome measure. Data were analysed using SPSS statistical software (version 13.0). Statistical analysis was conducted according to the intention-to-treat principle subject to the availability of data. For the primary outcome (SCID ≥5), an intention-to-treat analysis was also carried out by assuming that all missing data (due to referral to secondary care, declined follow up, or loss to follow up) represent adverse outcomes.

RESULTS
Baseline
One hundred and eighty patients were referred to the trial from 62 primary care health professionals: 52 GPs (based at 26 different practices), four district nurses, four practice nurses, one case manager, and one specialist heart failure nurse. Of the 180 patients referred, 105 were subsequently randomised (Figure 1). Table 1 summarises the characteristics of patients at baseline. Mean age of all patients was 75.5 years (range = 60–92 years); 72% (76/105) were female; 41% (43/105) were widowed; and 53% (56/105) were living independently in their own homes. Very few patients were in residential care (2/105). Mean number of symptoms at baseline using the SCID depression scale

checklist was 5.8 (range = 2–9). On the SCID, five or more symptoms indicates an episode of major depression disorder.

HAQ disability is scored from 0 (not disabled) to 3 (disabled in every category). HAQ pain is scored from 0 (in no pain) to 3 (in the most pain). On the HAQ the mean disability score was 0.82 (range = 0–2.5). The mean pain score was 0.86 (range = 0–2.8).

Follow up

At 16-weeks' follow up three patients in the intervention group and four receiving usual care died (none from suicide or for reasons attributable to depression or treatment). Three of the intervention group declined follow up, one was lost to follow up (having moved house), and one was referred to secondary care old-age psychiatry. Four of the usual care group declined follow up and one was lost to follow up. Table 2 presents outcomes at 16 weeks. Significant beneficial effects of randomisation to the intervention group were apparent using the SCID depression scale. In the intervention group 20% (9/45) had 5 or more symptoms compared with 40% (17/43) in the group receiving usual care. The adjusted odds ratio of being 'depressed' in the intervention group compared with treatment as usual was 0.32 (95% confidence interval [CI] = 0.11 to 0.93, P = 0.036). When referral to secondary care, declined follow up, and loss-to-follow up were included as adverse outcomes, the adjusted odds ratio was 0.38 (95% CI = 0.15 to 0.97, P = 0.042).

Table 2 summarises the analysis of quantitative outcomes scales. Because the measures were non-normal and showed evidence of skewness for quantitative outcomes, the robustness of the parametric analysis presented was checked using a non-parametric bootstrap.[26] For all outcomes these bootstrap CIs were very similar but slightly narrower. On the SCID intervention patients had a better outcome than treatment as usual patients (P = 0.036). The HSCL-20 was not significant (P = 0.062). There was no evidence of benefit for the intervention group on the HAQ pain and disability measures.

Defining the intervention

Qualitative interviews were semi-structured and formed the basis of a dialogue between interviewer and responder (patients and practitioners). Patients were asked their views about the causes of depression, their help-seeking behaviour, relationship with primary care professionals, and how they felt about treatment options offered to them. In later interviews patients were asked about their experiences of the intervention. Analysis of early interviews with patients revealed that they had limited expectations of treatment (reported previously[18]):

Table 1. Patient characteristics at baseline.

	Intervention group (n = 53)	Usual care group (n = 52)
Age, mean (range)	75 (60–92)	76 (60–92)
Female, n (%)	39 (73)	37 (71)
Marital status, n (%)		
Married	8 (15)	15 (29)
Single	4 (8)	4 (8)
Widowed	22 (42)	21 (40)
Divorced	8 (15)	2 (4)
Not known	11 (20)	10 (19)
Living situation, n (%)		
In own home	36 (68)	39 (75)
Sheltered accommodation	9 (17)	7 (13)
Residential home	1 (2)	0 (0)
Hostel	1 (2)	1 (2)
In relative's home	2 (4)	0 (0)
Not known	4 (7)	5 (10)
Number of systems affected by physical illness (Burville)		
Mean (range)	1.69 (0–4)	1.96 (0–4)

Interviewer: *'Going back to depression, do you know much about it?'*

Responder: *'No, not a lot.'*

I: *'Do you know what sort of treatments might be available?'*

R: *'No.'*

I: *'Had you ever heard of it before you got depressed?'*

R: *'My doctor knew, he knows me inside out. He knew immediately. He's a lovely doctor.'* (ID 48)

Interviews conducted at the end of the intervention explored with patients their recall of communication with the trial nurse and their views about and attitudes towards these contacts. The intervention was acceptable to most patients. Face-to-face contact was preferred to telephone consultations, unlike studies from the US:[11]

I: *'When he rang you up, did you find that useful?'*

R: *'Well he just said how are you going … just a quick telephone call, nothing very important really.'* (ID 42)

The personal qualities of the trial nurse in making patients feel listened to and supported were detailed by patients:

Table 2. Baseline and 16 weeks for quantitative outcome measure.

	Intervention			Usual care			Treatment		
	Mean	SD	*n*	Mean	SD	*n*	Effect[a]	95% CI[a]	*P*
SCID									
Baseline			53			52	0.38	(0.15 to 0.97)	0.042
16 weeks			45			43			
HSCL-20[b]									
Baseline	28.0	13.7	51	23.8	14.6	50			
16 weeks	10.3	13.0	44	14.5	14.5	42	−5.12	(−10.5 to 0.27)	0.062
HAQ disability[b]									
Baseline	0.71	0.72	50	0.93	0.77	52			
16 weeks	0.78	0.74	44	1.05	0.75	43	0.01	(−0.10 to 0.11)	0.91
HAQ pain[b]									
Baseline	0.65	0.92	50	1.07	1.05	52			
16 weeks	0.64	0.88	44	1.11	1.06	43	0.04	(−0.12 to 0.21)	0.63

[a]*Intervention: usual care adjusted for age, sex, and baseline value of outcome.* [b]*Higher scores indicates more depression, disability, or pain. SCID = Structured Clinical Interview for DSM-IV (Diagnostic Statistical Manual for Mental Disorders) axis 1 disorders. HSCL = Hopkins Symptom Checklist. HAQ = Health Assessment Questionnaire.*

'I couldn't fault him in any way. He was brilliant with me. If he goes elsewhere and they say different, then it's something where they are not actually connecting with him. They're not reaching out to him. As I say, I could talk to me daughters but with [the CPN] *I could talk about anything, anything that was worrying me and the way I felt. I found that connection; so whatever I said I was getting a comeback and good advice and helpfulness. I'll tell you what, I'd have him back here next week because he is brilliant.'* (ID 42)

'I found him very, very ... I found him a very nice chap. He was somebody that you could have a conversation with which is, I mean today I can go in places, pubs, and everywhere like that, you can't get a conversation.' (ID 55)

In contrast was the poorer recall of the specific components of SHADE, although some components, such as keeping a diary and setting goals, relaxation, and behavioural activation were described by some patients. However, descriptions of the use of the SHADE manual were limited:

'Well [the CPN] *left me this great* [large] *book thing. I didn't feel like doing anything about that. I couldn't get into it at all. I couldn't concentrate on it. So I left it. I thought he'd be annoyed … but he wasn't.'* (ID 41)

The trial nurse described the theoretical basis and process of his work, and the use of the self-help intervention in detail. He disclosed that what he perceived was most valuable to patients was personal contact with someone who was empathic and showed interest in the patient as an individual:

'Depression isn't loneliness. I mean I'm very clear that it's not the same thing. But, one of the themes that comes through people I see, it's a very high percentage of the people when I start looking through the records, the word loneliness comes up or at least isolation … What I tend to do, I try and focus in on things that I can get them to talk about, because I genuinely believe that everyone has a story to tell and that's the first bit of engagement. You know there's no matter how depressed people are, it's trying to re-humanise [them] *… It's trying to find what maybe we've got in common. How I can gauge someone, how I can get them on board … So the more I can know about them, not necessarily about their illness, about them as a person.'*

The nurse described using components of SHADE flexibly and agreed which components would be used through negotiation with individual patients:

'It is very very flexible … if someone asked me what I was really doing I'd say I use a very eclectic common sense non-rocket-science approach, that's very, very individual to whatever the patient's needs are.'

DISCUSSION

Summary of main findings

This paper reports a feasibility study, using the collaborative care model, which has been shown to be effective with late-life depression in the US.[11] The collaborative care model in the US involves an active case manager (for example, CPN, active case

manager) working between primary care physicians and secondary care psychiatrists according to a defined protocol.

This study shows that the model can also be developed in UK primary care, across one PCT, and that effective depression management can be achieved for older people in the primary care setting.

Patients in the intervention group had significantly fewer symptoms at follow up than those receiving usual GP care alone, suggesting that the model of care was effective with an effect size similar to other studies of older people in the US[11] and adults of working age in the UK.[27]

Strengths and limitations of the study

This trial, funded as a feasibility study, is limited by its size (across one PCT) and only one CPN was used. Thus, whether the model is generalisable is unknown until a definitive randomised controlled trial is carried out. Further research is needed to define the therapist's required level of skill, and to determine whether such an intervention can be delivered by a less well-trained, experienced (and therefore less expensive) therapist.

The nested qualitative data were important in defining the active components of the intervention from patients' perspectives. As with other studies,[28] patients seemed to find it difficult to engage with, and expressed ambivalent feelings towards, the self-help material. They experienced a sense of dissonance between prior expectations of treatment and their experience of the self-help aspects of the intervention. What was valued by patients was contact with someone whom they perceived as empathic, caring, and interested in them as a person. It is unclear how much of the response was due to the assisted self-help intervention or to the trial nurse's considerable professional and interpersonal qualities in forming a therapeutic relationship with older people. Future research that includes other measures, such as audio-taping patient–therapist interactions to define more specifically the active components of the intervention and therapeutic alliance, are needed for a larger trial of this model of care.

It is uncertain whether the collaborative care model, with the trial nurse acting as case manager liaising between GP and old-age psychiatry, or the intervention at patient level is effective in improving outcomes. No information on prescribing of, or concordance with, antidepressant medication was collected, yet it could be the medication management component of the intervention (with improved concordance) that is the effective ingredient. Patients' attitudes to medication in intervention and usual care groups were ambivalent, which require further investigation.

Comparison with existing literature

The effect size is similar to other studies in primary care involving older[8] and working-age populations.[27] There are significant public health implications considering the large numbers of over 60 year olds with depression, especially as depression has an adverse effect on physical comorbidities.[3,4]

Implications for clinical practice and future research

The study results provide sufficient support for the funding of further research in the form of a larger randomised controlled trial, with full economic costings. Other studies using therapists with different skill levels are needed to define the level of skill required to deliver the intervention of this collaborative care model.

This randomised controlled trial was funded to evaluate the feasibility of establishing a collaborative care model in one PCT to manage patients with late-life depression. The trial demonstrated a positive outcome and acceptability, but further research is needed before services are widely commissioned based on such a model of care.

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