

# Primary care

## Re-engineering systems for the treatment of depression in primary care: cluster randomised controlled trial

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### Abstract

**Objective** To test the effectiveness of an evidence based model for management of depression in primary care with support from quality improvement resources.

**Design** Cluster randomised controlled trial.

**Setting** Five healthcare organisations in the United States and 60 affiliated practices.

**Patients** 405 patients, aged  $\geq 18$  years, starting or changing treatment for depression.

**Intervention** Care provided by clinicians, with staff providing telephone support under supervision from a psychiatrist.

**Main outcome measures** Severity of depression at three and six months (Hopkins symptom checklist-20): response to treatment ( $\geq 50\%$  decrease in scores) and remission (score of  $< 0.5$ ).

**Results** At six months, 60% (106 of 177) of patients in intervention practices had responded to treatment compared with 47% (68 of 146) of patients in usual care practices ( $P = 0.02$ ). At six months, 37% of intervention patients showed remission compared with 27% for usual care patients ( $P = 0.014$ ). 90% of intervention patients rated their depression care as good or excellent at six months compared with 75% of usual care patients ( $P = 0.0003$ ).

**Conclusion** Resources such as quality improvement programmes can be used effectively in primary care to implement evidence based management of depression and improve outcomes for patients with depression.

### Introduction

Depression is frequently treated in primary care,<sup>1</sup> yet there are barriers to its effective management.<sup>2-3</sup> Recent randomised controlled trials in primary care showed benefits for patients with depression from increased telephone support, better cooperation between primary care and mental health professionals, and more systematic follow up.<sup>4-6</sup> Some of these changes are costly, however, and their implementation has required intensive support from research teams. Changes have also proved difficult to sustain outside externally funded research.<sup>7</sup>

To disseminate these models widely, strategies are needed to support their implementation and maintenance in community settings. To be practical, these strategies should be based on available resources. Our project, the re-engineering systems for primary care treatment of depression, relied on established quality improvement programmes. In the United States these programmes are typically part of the infrastructure of large medical groups. Their charge includes the collection of data on

performance quality, the provision of these data to clinicians and administrators, and assistance for clinicians and practices to meet targets through educational support, additional resources, and changes in practice organisation. Similar resources could be developed through national health programmes and professional organisations.<sup>8-9</sup>

We developed and tested a model of evidence based management of depression that could be widely disseminated. We hypothesised that implementation would improve targeted processes for management of depression and improve outcomes at six months.

### Methods

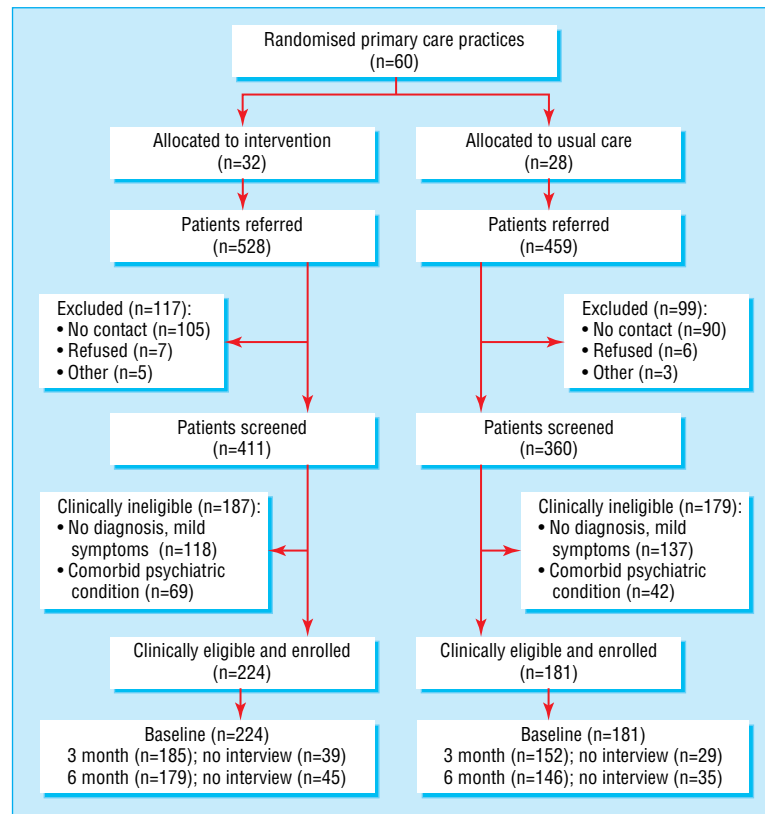
We recruited five healthcare organisations (three medical groups and two health plans) across the United States. To be eligible, each needed to be affiliated with at least 10 primary care practices, have an established quality improvement programme, and be willing to sustain and disseminate our model if it added value at reasonable cost. Methods are described in detail elsewhere.<sup>10</sup>

Leaders of the five organisations invited the affiliated practices to participate. Sixty practices were identified. An evaluation centre randomised these practices after stratification by healthcare organisation. The practices were paired on the basis of clinicians' specialty (internal medicine or family practice), number of clinicians, onsite mental health care (yes or no), and distance from the organisation's central office. Within pairs, practices were randomly assigned to intervention or usual care by flip of a coin.

### Participant flow and follow up

Between February 2002 and February 2003 the clinicians identified patients aged 18 years or older who were starting or changing treatment for depression. Participants had to have a telephone, speak English, and meet the criteria of the *Diagnostic and Statistical Manual of Mental Disorders* fourth edition for major depressive disorder and dysthymia. The evaluation centre determined diagnoses using a structured interview.<sup>11</sup> The severity of depression was assessed with the Hopkins symptom checklist-20, with a score of 0.5 or more required for enrolment.<sup>12</sup>

Patients were excluded if they were unobtainable for an evaluation interview within 14 days of their index primary care visit, were pregnant, or had suicidal thoughts, schizophrenia, bipolar disorder, post-traumatic stress disorder, or a substance misuse disorder. Figure 1 shows the flow of patients through the trial.



Flow of patients through trial

**Intervention**

The intervention concerned a systematic approach to the assessment and management of depression by the clinician, with a centrally based care manager providing telephone support for patients.<sup>15</sup> Most of the care managers had backgrounds in primary care or mental health nursing. The patient health questionnaire-9 was used to aid in diagnosis, to monitor treatment response, and to guide changes in treatment.<sup>11 14 15</sup>

Patients received a follow up telephone call from the care manager one week after their initial visit. Thereafter they were telephoned monthly and as needed until remission. The care managers assisted patients in overcoming barriers to adherence to the protocol. They supported self management practices such as exercise or engaging in social activities. At the monthly calls the questionnaire was re-administered. The clinician was provided with the reports, including the score from the questionnaire.

Psychiatrists employed by the organisations supervised the care managers through weekly telephone contact. During these contacts, the care managers presented new patients and follow up contacts. Based on the participants’ responses to the questionnaire, the psychiatrist could suggest changes either through the care manager or by direct contact with the clinician. Clinicians were also able to contact the psychiatrists for informal telephone advice.

Depending on experience, the care managers received training for 4-8 hours. The psychiatrists received one hour’s training. Intervention clinicians took part in a one to two hour educational programme that addressed the diagnosis of depression, assessment of suicidal thoughts, response to management on the basis of responses to the questionnaire, and modification of management to achieve remission. Staff in the intervention practices received a 45 minute course on the intervention, and

both they and the clinicians were instructed on procedures for enrolling patients.

Clinicians in the practices allocated to usual care took part in a 45-60 minute programme on diagnosis of depression and assessment of suicidal thoughts. Both they and their staff were instructed on procedures for enrolling patients.

With financial support from our project, the five organisations developed the autonomy to implement the model and to maintain it through follow up with the practices. The organisations identified care managers and psychiatrists, who were trained by employees of the organisations. These employees gradually assumed responsibility for training.

**Blinding and data collection**

The evaluation centre assessed the clinical course of the patients through interviews by telephone at baseline and at three and six months. Interviewers were blind to study group assignment, followed computer aided scripts, and had no knowledge of the purpose of the study or of the intervention. The Hopkins symptom check list-20 was used to assess the severity of depression. The interviewers also asked about current drugs, recent care, and satisfaction with care. Interviews lasted about 30 minutes.

**Statistical analysis**

We use means (standard deviations) for continuous variables and percentages for categorical variables. Our primary outcomes included depressive symptoms (scores on the Hopkins symptom check list-20), response to treatment (50% or more reduction in depression score from baseline), and remission (<0.5 depression score). The process of treatment was analysed for the number of patient visits to primary care for depression, the number of follow up telephone contacts, continued use of antidepressants, and use of psychological counselling during the past three months.

**Table 1** Characteristics of practices randomised to manage patients with depression using evidence based model or usual care. Values are numbers (percentages) unless stated otherwise

Characteristic	Intervention practices (n=32)	Usual care practices (n=28)
Mean (SD) No of clinicians	3.8 (3.4)	3.7 (2.7)
Mean (SD) No of km from organisation central office	33.5 (31.7)	33.9 (29.1)
On-site mental health care	7 (22)	8 (29)
Specialty:		
Family practice	21 (66)	19 (68)
Internal medicine	11 (34)	9 (32)
Location:		
Suburban or rural	26 (81)	23 (82)
Urban	7 (22)	5 (18)
Ownership:		
Healthcare organisation	17 (53)	20 (71)
Affiliated to, but not owned by, organisation	15 (47)	8 (29)

We used linear mixed effects regression models, including both fixed and random effects, to analyse the effect of the intervention on continuous outcomes. We analysed the effect of the intervention on binary outcomes with generalised linear mixed effect models with a logit link. The random effects portion of these models provides the structure needed to account for clustering or potential lack of independence that may exist between observations for the same practice.<sup>16</sup> We fitted the mixed effects using SAS Proc mixed and Proc nlmixed. Both programs use all data to yield unbiased estimates of variables for mixed effect models when outcomes are missing at random.<sup>17</sup>

We fit a random intercept model that included the fixed effects of depression severity at baseline, intervention, and time. We also fit models of a two way interaction (intervention by time) for both the continuous and binary outcomes. Further, we tested a three way interaction among intervention, time, and baseline depression scores by testing intervention by time interaction effect within each stratum defined by baseline scores of more than two.

Our sample size calculation is based on a baseline depression score of 1.5, a two tailed *t* test, and a between group clinically meaningful difference of 0.15 (SD 0.50) in depression scores at follow up. Adjusting for potential design effects, we determined that we needed to recruit 60 practices (30 in each group).<sup>18</sup> We analysed our data on an intention to treat basis. Using methodology to adjust for patient clustering within practice and a range of practice intraclass correlation coefficients based on prior results, we found that for a  $\beta$  of 0.2, an  $\alpha$  of 0.05, and allowing for 15% dropouts, we required 400 patients.<sup>19, 20</sup>

## Results

The characteristics of the practices and patients were well balanced (tables 1 and 2). The mean depression score on the Hopkins symptom checklist-20 for the total sample was 2.01, which is consistent with moderate to severe symptoms. According to the mental disorders patient health questionnaire,<sup>21</sup> 47% of usual care patients and 51% of intervention patients ( $P=0.42$ ) had generalised anxiety, panic disorder, or both.

Table 3 describes the process of care. Compared with the usual care clinicians the intervention clinicians more often asked patients about suicidal thoughts, offered educational materials, and assisted in setting self management goals. Intervention patients also received more follow up contact by visits or

**Table 2** Baseline characteristics of patients being managed for depression with evidence based model or usual care. Values are numbers (percentages) unless stated otherwise

Characteristic	Intervention group (n=224)	Usual care group (n=181)
Women	83.5	76.2
Mean (SD) age (years)	41.8 (14.1)	42.2 (15.3)
Mean (SD) education	13.3 (2.4)	13.2 (2.2)
Ethnic minority	36 (16)	32 (18)
Married	127 (57)	97 (54)
Lives with others	193 (86)	162 (90)
Income above poverty level	172 (77)	41 (23)
Paid employment	135 (60)	114 (63)
Mean (SD) severity of depression*	2.03 (0.65)	1.98 (0.65)
Major depression	176 (79)	142 (79)
Major depression and dysthymia	44 (20)	34 (19)
Dysthymia	4 (2)	5 (3)
Generalised anxiety disorder	93 (42)	72 (40)
Panic disorder	51 (23)	32 (18)

\*20 items (Hopkins symptom checklist-20) from Hopkins symptom checklist-90.

telephone and were significantly more likely at both three and six months to report receiving good or excellent care. We found no differences between the groups for frequency with which clinicians presented patients with treatment options or elicited their preferences. The patterns of management (drugs alone, counselling alone, or both) did not differ significantly. No adverse events were reported.

**Table 3** Process of care for patients being managed for depression with evidence based model or usual care. Values are percentages (numbers/total numbers)

Variable	Intervention group	Usual care group	P value
Actions at index visit:			
Asked about suicidal thoughts	88 (190/217)	69 (120/174)	<.0001
Presented treatment options	69 (153/223)	68 (121/179)	0.83
Asked about treatment preference	55 (120/220)	54 (94/175)	0.87
Offered educational materials	71 (156/221)	40 (70/176)	<.0001
Assisted in setting self management goals	31 (68/220)	19 (34/179)	0.007
Taking antidepressants:			
Baseline	92 (204/223)	88 (159/181)	0.23
3 months	88 (161/183)	85 (128/150)	0.48
6 months	79 (140/177)	81 (116/144)	0.74
Receiving counselling (past three months):			
Baseline	16 (35/223)	15 (26/179)	0.75
0-3 months	26 (47/182)	23 (34/149)	0.53
4-6 months	26 (46/177)	24 (35/146)	0.68
≥1 follow up visits for depression:			
0-3 months	85 (156/183)	71 (107/150)	0.002
4-6 months	65 (114/175)	51 (74/145)	0.01
≥1 follow up telephone calls for depression:			
0-3 months	64 (116/181)	8 (12/148)	<0.0001
4-6 months	59 (104/177)	3 (5/146)	<0.0001
Patient rating of care as good to excellent:			
3 months	91 (163/179)	81 (119/147)	0.008
6 months	90 (160/177)	75 (110/146)	0.0003

Denominators vary owing to missing data.

**Table 4** Clinical outcomes for patients being managed for depression with evidence based model or usual care. Values are percentages (number of patients/total number) unless stated otherwise

Outcomes	Intervention patients	Usual care patients	Between group difference or odds ratio (95% CI)*	P value
Mean (SD) severity of depression†:				
Baseline	2.04 (0.66)	1.98 (0.65)	0.15 (-0.03 to 0.33)	0.105
3 months	1.16 (0.80)	1.29 (0.76)	-0.16 (-0.32 to -0.002)	0.048
6 months	0.97 (0.80)	1.09 (0.74)	-0.20 (-0.39 to -0.014)	0.036
Response‡:				
3 months	53.0 (97/183)	34.2 (52/152)	2.2 (1.4 to 3.4)	0.001
6 months	59.9 (106/177)	46.6 (68/146)	1.7 (1.1 to 2.7)	0.021
Remission§:				
3 months	26.2 (48/183)	16.5 (25/152)	2.1 (1.2 to 3.7)	0.018
6 months	37.3 (66/177)	26.7 (39/146)	1.9 (1.2 to 3.3)	0.014

\*Adjusted for variability in practices. All patients have at least 0.5 score on Hopkins symptom checklist-20 at baseline.

†Scores on Hopkins symptom checklist-20.

‡At least 50% decrease in depression score from baseline.

§Score of <0.5 on Hopkins symptom checklist-20.

Table 4 presents depression scores, response, and remission based on intention to treat. Intervention patients had better outcomes on all measures at both follow up intervals. Although mean depression scores declined among patients in both groups, the decline was significantly greater in intervention patients: the intervention effect size on the Hopkins symptom checklist-20 was 0.23 at three months and 0.29 at six months.

Log books completed by the care managers indicated that a mean of 20 minutes was expended for each telephone call, including record keeping. The psychiatrists had infrequent contact with the clinicians (< 5% of patients). The clinicians reported negligible time demands from the model aside from administrative duties such as obtaining consent.

Now that our trial is complete, the leaders of the organisations have sustained the model and disseminated it further with local resources. As of March 31, 2004 an additional 139 practices have been supported to implement the model.

## Discussion

Enhanced management of depression can improve outcomes for patients when implemented through quality improvement resources increasingly available to community practices. Depressed patients in our intervention practices reported significantly milder symptoms of depression and had higher response and remission rates at follow up than patients in the usual care practices. The effect sizes are comparable to those of other trials on depression in primary care.<sup>22</sup>

We identified elements that possibly influence clinical outcomes. The intervention patients had more telephone contacts and more visits. Intervention patients reported that the clinicians were more likely to assess suicide risk, offer educational materials, and assist with self management goals. Counselling and adherence to antidepressants were similar between the groups, suggesting that specific but modest support for patients result in better outcomes for depression and higher patient ratings for quality of care.

Although clinical outcomes were enhanced, these effects were modest. At least four features of our study may help to explain this. Firstly, rather than identifying potentially ambivalent patients through screening, all patients were identified during routine care by the clinicians, had accepted the diagnosis of depression, and had agreed to be managed with drugs or by counselling. Secondly, the usual care clinicians performed well on process and outcome measures compared with those in other trials,<sup>22-23</sup> creating a high standard of comparison. Thirdly, there

was potential for attenuation of the intervention tasks compared with their direct implementation by researchers using a strict protocol.<sup>24</sup> Finally, our intervention was modest compared with other recent large trials. Unlike our trial, IMPACT (improving mood-promoting access to collaborative treatment), PIC (partners in care), and PROSPECT (prevention of suicide in primary care elderly: collaborative trial) offered increased access to mental health services at no or reduced cost.<sup>20-23-25</sup>

Given these design features and dependence of the intervention on training manuals and existing quality improvement resources rather than research protocols and transient resources, the superior outcomes compared with usual care are noteworthy. We acknowledge that remission rates at six months indicate that most patients had at least partial symptoms. These patients continued to receive support and may have improved further, as found in longer term studies.<sup>20-23-26</sup> Evaluation interviews in our study were completed by six months after patient enrolment in keeping with the commitment to provide the model to usual care practices in that time.

We suggest that by recruiting 60 practices in diverse locations, our trial extends the generalisability of earlier findings on efficacy of telephone support and primary care specialty cooperation beyond special settings. Many of these earlier studies took place in health maintenance organisations, academic sites, or veterans administration practices.<sup>27-31</sup> Our trial adds to this knowledge by showing that modest resources delivered through established programmes can approach outcomes achieved by more research intense, resource rich interventions. These findings take on added importance in light of the negative result from the Hampshire depression project in which the intervention was based on clinician education but did not include telephone support or psychiatry for patients.<sup>32</sup> In addition, some US government bodies have called for more intensive monitoring of patients prescribed antidepressants.<sup>33</sup> Our model provides this, including assessment of suicidal thoughts.

The generalisability of our findings to primary care are constrained because the practices had access to established quality improvement programmes and care management staff, resources which are becoming more widely, but not yet universally, available. Attention to quality improvement is growing.<sup>8-9-34</sup> Primary care trusts in the United Kingdom may be able to assume this function, and in some countries professional societies and regional health authorities could play a part.

Our study shows the feasibility of doing rigorous research in community practice settings relying on established resources to

## What is already known on this topic

Trials have shown improved outcomes for depression in primary care patients using models for the management of chronic illness

These models involve more systematic follow up and monitoring, patient telephone support, and cooperation between primary care and psychiatry

Implementation of these models has usually depended on research teams and has not been sustainable when research support ends

## What this study adds

Evidence based models of depression management can be implemented in primary care with support from existing quality improvement resources

These models can improve outcomes for depression

deliver the intervention rather than on transient research teams. Using this approach would enable future research in primary care to explore sustainability and dissemination of interventions. In addition, materials created to support these interventions could be more readily modified for application outside the research setting.

Our model for depression produced significantly better outcomes and more favourable patient responses on quality of care than usual care. The model requires only modest changes from practices and creates a framework to study long term sustainability and dissemination of evidence based care.

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Contributors: AJD, TEO, JWWJr, HCS, KR, PAN, MG, and KK initiated and designed the study. AJD, TEO, JWWJr, HCS, MLB, PWL, PJR, and JLL acquired, analysed, and interpreted the data. AJD, TEO, HCS, MLB, and JLL drafted the paper. AJD, TEO, JWWJr, HCS, MLB, PWL, PJR, SB, MH, KR, PAN, MG, and KK revised the paper. AJD, TEO and JWWJr obtained funding. PWL and PJR provided administrative support. SB acquired an interpreted the data and carried out fieldwork. JLL, MH, and KR provided statistical expertise. MH analysed and interpreted the data. AD is guarantor for the paper.

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