

Can Depression Treatment in Primary Care Reduce Disability?

A Stepped Care Approach

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Objective: To assess effects of stepped collaborative care depression intervention on disability.

Design: Randomized controlled trial.

Setting: Four primary care clinics of a large health maintenance organization.

Patients: Two hundred twenty-eight patients with either 4 or more persistent major depressive symptoms or a score of 1.5 or greater on the Hopkins Symptom Checklist. Depression items were randomized to stepped care intervention or usual care 6 to 8 weeks after initiating antidepressant medication.

Intervention: Augmented treatment of persistently depressed patients by an on-site psychiatrist collaborating with primary care physicians. Treatment included patient education, adjustment of pharmacotherapy, and proactive monitoring of outcomes.

Main Outcome Measures: Baseline, 1-, 3-, and 6-month assessments of the Sheehan Disability Scale and the social function and role limitation subscales of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).

Results: Patients who received the depression intervention experienced less interference in their family, work, and social activities than patients receiving usual primary care (Sheehan Disability Scale, $z=2.23$; $P=.025$). Patients receiving intervention also reported a trend toward more improvement in SF-36–defined social functioning than patients receiving usual care ($z=1.63$, $P=.10$), but there was no significant difference in role performance ($z=0.07$, $P=.94$).

Conclusions: Significant disability accompanied depression in this persistently depressed group. The stepped care intervention resulted in small to moderate functional improvements for these primary care patients.

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DISABILITY associated with common physical illness is often readily apparent, while functional limitations accompanying major depression are often overlooked. Epidemiologic research conducted in different settings consistently describes the link between depression and functional disability.^{1,2} Moreover, the functional status of persons with depression is often more compromised than that of patients with chronic physical conditions.³ This disability accounts for lost productivity and impaired quality of life.^{4,5} During the last decade, clinical trials conducted in a variety of primary care settings have consistently shown that patients participating in enhanced depression treat-

ment programs experienced better depression outcomes than those who received routine primary care.⁶⁻¹⁰ Many of these studies also reported that patients receiving intervention had less disability than patients receiving usual care.^{7-9,11}

These randomized trials used a variety of indicators to measure disability, including physical function, role function, days with activity limitations, and employment. The World Health Organization International Classification of Impairments, Disabilities and Handicaps defined disability as a health-related restriction or lack of ability to perform an activity, within a range considered normal.¹² Much of the current research on the impact of depression treatment on patient function uses the Medical Outcomes Study 36-Item Short-Form

PARTICIPANTS AND METHODS

SETTING

Group Health Cooperative of Puget Sound (GHC) is a prepaid health plan serving approximately 450 000 members in Washington State. Four large primary care clinics, with a population of approximately 88 000 enrollees and 73 full- or part-time board-certified family physicians participated in this study. Members of the GHC are similar to the area population in age, sex, and ethnicity but include fewer persons with high annual household incomes.

SAMPLE SELECTION

A population-based screening strategy was developed to select patients at increased risk for persistent depression. Use of the GHC automated diagnostic, pharmacy, and visit databases allowed us to identify patients who received a diagnosis of depression or anxiety and a new prescription of antidepressant medication from the primary care population mentioned. Potentially eligible patients between the ages of 18 and 80 years who had a new episode of depression (ie, no antidepressant prescription in the previous 120 days) and who gave informed consent were contacted by telephone 6 to 8 weeks (mean time, 48.7 days) after initiating pharmacotherapy. The Human Subjects Review Committees of GHC and the University of Washington, Seattle, approved the study procedures and intervention.

We conducted a 2-stage interview using the Structured Clinical Interview¹⁹ for the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*,²⁰ followed by a second interview using depression items in the Hopkins Symptom Checklist (SCL-20).²¹ Subjects were included if, after 6 to 8 weeks of antidepressant treatment, they reported 4 or more DSM-IV major depressive symptoms and a score greater than 1.0 on the SCL-20, or if they reported fewer than 4 DSM-IV major depressive symptoms but a score 1.5 or greater on the SCL-20. Exclusion criteria were (1) a score of 2 or greater on the CAGE (Have you ever felt the need to cut down on your drinking? Have you ever felt annoyed by criticism of your drinking? Have you ever felt guilty about your drinking? Have you ever taken

a drink [eye opener] first thing in the morning?) alcohol use questionnaire,²² (2) pregnancy or current nursing, (3) plans to disenroll from the GHC insurance plan in the next 12 months, (4) care by a psychiatrist, (5) limited command of English, and (6) recent use of lithium or antipsychotic medication.

RANDOMIZATION

After complete description of the study to the subjects and obtaining written informed consent, participants were stratified into a severe depression group (SCL score, >2.0) or a moderate depression severity group (SCL score, 1.0-2.0). Within each stratum, subjects were randomized in blocks of 8 to receive the collaborative model of care provided by both a psychiatrist (W.K., G.S., J.U., and E.W.) and their primary care physician or to usual care with their primary care physicians. Usual care could include any services normally available to GHC members, including antidepressant pharmacotherapy or referrals to GHC's specialty mental health services.

STEPPED COLLABORATIVE CARE INTERVENTION

Since a significant proportion of patients with depression receiving routine primary care services experience favorable outcomes,²³ a stepped care strategy was adopted to focus on patients who remain persistently depressed for 6 to 8 weeks after starting pharmacotherapy. This intervention consisted of educating and activating patients with depression, bolstering the functions of primary care physicians, and providing on-site psychiatric consultations. Primary care and psychiatric collaborative treatment focused on the patient, provider, and organization of service delivery. The collaborative intervention included a book and a videotape for patient education developed by the study team.²⁴ Treatment for these persistently depressed patients was bolstered to improve care of patients with treatment resistance, adverse effects with medication, and psychosocial stresses. As an example, the psychiatric consultant would help the primary care physician alter antidepressant medication or change the dose. For patients with severe psychosocial stresses, the psychiatrist might

Continued on next page

Health Survey (SF-36)¹³ and its abbreviated versions to assess disability. The SF-36 assesses general health status, health perceptions, as well as measures of limitations on activity or role performance.

An important distinction exists between the subjective report of symptoms, such as feeling downhearted, and indicators of disability, such as how well one functions socially and at work. Subscales of the SF-36, such as mental health, vitality, and general health perception, assess a patient's subjective sense of well-being

and depression rather than disability.^{14,15} In contrast, ratings of role performance, work productivity, and employment status assess daily functioning directly.

Using the World Health Organization's definition of disability¹² to examine the effects of recent depression trials on function, we found that most depression interventions did not improve physical function (ie, activities of daily living and self-care).^{8-10,15-17} Not surprisingly, the mental health factor, which contains several symptom and mood subscales, improved in most of these studies.

recommend additional psychotherapy, such as marital counseling, and facilitate referral to the GHC Behavioral Health Unit. The intervention also provided proactive monitoring of depression outcomes and antidepressant medication refills by the psychiatrist and primary care physician at a frequency consistent with the Agency for Health Care Policy and Research guidelines.²⁵ Visits with the psychiatrists occurred throughout the initial 3 months after randomization (mainly acute phase treatment). Thereafter, primary care physicians and their teams were reminded to contact a patient if his or her pharmacy refill data revealed premature discontinuation of antidepressant medication. A more detailed description of the intervention and methods has been reported.¹⁸

STUDY MEASURES

Depression outcomes and disability were assessed at 1, 3, and 6 months after a baseline interview by a telephone survey team that was blind to the patient's randomization status. A Structured Clinical Interview for *DSM-IV* diagnoses^{19,20} measured current depressive symptoms and prior history of major depression, while a 20-item depression scale modified from the SCL-20 helped assessed depression severity.²¹ At the baseline interview, 7 items from the NEO (neuroticism-extroversion-openness) inventory (a 5-point Likert scale) measuring personality were also included.²⁶

Disability was measured by the Sheehan Disability Scale (SDS).²⁷ This scale has been widely used in trials of panic disorder, had been previously adapted to depression trials, and has shown sensitivity to change over time in medical patients.²⁸ The SDS contained 3 questions, which assessed interference in 3 domains—work and school, family life and home responsibilities, and social life. Scores were reported as an average on a 10-point Likert Scale (10 indicating inability to carry out any activity). Mean (SD) scores for primary care population norms for the work, social, and family subscales are 2.01 (2.49), 2.02 (2.70), and 2.08 (2.68), respectively.²⁹

To select additional disability measures contained in the SF-36 for use in this study, we used the World Health Organization definition of disability as a health-related restriction or lack of ability to perform an activity.¹⁵ Two subscales, social function and role performance as limited by

emotional problems (role-emotional), were administered. We chose not to use 4 subscales—vitality, mental health, bodily pain, and general health perception—because they measure health perception and symptoms, not disability. Measures of physical disability—function and role-physical—were also not examined because most prior depression intervention trials showed little effect in the physical domain (ie, activities of daily living and self-care).

The Chronic Disease Score,³⁰ a standardized measure of chronic medical illness based on medication use, identified the severity of medical comorbidity. In prior research, the Chronic Disease Score has been able to predict subsequent hospitalization and mortality and is less influenced by psychological distress than self-rated health status measures.

STATISTICAL ANALYSES

Random regression models (RRM)³¹ tested whether the stepped collaborative care intervention reduced disability over time. The 3 dependent variables evaluated were Global SDS score and 2 SF-36 disability subscales (social function and role-emotional). The RRM procedure permits the inclusion of patients with missing data and allows for individual varying slopes and intercepts over time. This approach allowed us to use the data from all patients in an intent-to-treat analysis. The RRM yields 3 maximum likelihood estimates for the effects of time, treatment group, and the time \times treatment group interaction. We employed a model with uncorrelated errors. Age, sex, NEO score, and chronic disease score were used as fixed covariates for each analysis. A significant time \times treatment group interaction is interpreted as the treatment groups having different patterns of change in disability over time. A significant time effect is interpreted as the 2 groups having different courses of change in disability over the 4 assessments (baseline, 1, 3, and 6 months). A significant treatment effect would mean that collapsed over time, the intervention and control groups differed in disability. Significant interaction terms, or main effects, were further investigated using planned univariate analyses of covariance (ANCOVAs) at each assessment to determine at which point in time the groups differed while controlling for sex, age, chronic disease score, and personality.

Enhancement in social role function and employment, resulting from these depression management programs has been observed in many (but not all) of the studies.^{8-11,16,17} The magnitude of enhanced role functioning resulting from depression interventions has been variable.

A structured depression treatment with pharmacotherapy or interpersonal psychotherapy resulted in better social functioning and reduced emotional limitations in role performance.¹¹ A multisite investigation by Katzelnick et al¹⁸ of people with depression who were fre-

quent users of health services demonstrated that a depression management program resulted in better social functioning. Most recently, Wells et al¹⁹ demonstrated increased retention of employment among a large depressed population who received depression management enhanced by a nurse in primary care. Yet, other randomized trials that also enhanced depression outcomes of primary care patients did not find statistically significant improvement in disability measures.^{10,16,17} However, these studies with no demonstrable intervention ef-

fect had control groups that were receiving “usual care” treatment for depressive illness rather than untreated controls.

The purpose of this study is to test whether augmenting depression management with a stepped collaborative care program would improve disability outcomes of patients who remain persistently symptomatic after initial pharmacotherapy in primary care. Just as importantly, we wanted to better comprehend the magnitude of intervention effect on functional status. In a randomized trial using this stepped care approach, we recently reported results showing improved depression outcomes, adherence, and patient satisfaction among patients receiving intervention compared with patients receiving routine care.¹⁸ This article reports specific disability outcomes of patients receiving intervention and patients receiving usual care at 1, 3, and 6 months.

RESULTS

This sample was drawn from an initial invitation letter mailed to 2699 eligible patients who had a diagnosis of depression and started receiving antidepressant medicine in any of 4 GHC primary care clinics. Of these patients, 2051 (76.1%) completed the telephone screening interview that resulted in 272 patients (13.3%) who had 4 or more DSM-IV symptoms and were eligible for the persistent depression study. One hundred fifty-nine subjects (58.5%) completed the baseline interview and were randomized. Additionally, 694 patients (33.9%) had 3 or fewer DSM-IV symptoms but had a history of major depression or dysthymia and were eligible for the relapse prevention study. Among these, 69 (9.9%) became eligible for the persistence study (SCL score, >1.5) and were randomized. Thus, a total of 228 patients were randomized to the persistence study following screening and baseline interviews. Subjects who agreed to the screening interview or the baseline interview did not differ from those who refused on the basis of age or sex. A more detailed description of our sample is described in a previous publication.¹⁸

Among the 228 patients randomized, 209 (91.7%) completed the 1-month follow-up, 193 (84.6%) completed the 3-month follow-up, and 192 (84.2%) completed the 6-month follow-up. Eighty-seven (76.3%) of the intervention patients vs 80 (70.2%) of the patients receiving usual care completed all 3 follow-ups. There were no significant differences on any of the demographic or clinical variables (**Table 1**) between the 61 patients who missed completing at least 1 follow-up and the 167 patients who completed all 3 follow-up interviews.

PATIENT CHARACTERISTICS

The only significant difference at baseline between the intervention group and the control group was the higher

Table 1. Demographic and Clinical Characteristics of Depressed Sample*

Characteristics	Intervention (n = 114)	Control (n = 114)
Demographic		
Mean ± SD age	47.2 ± 14.0	46.7 ± 13.4
Women, %†	67.5	81.6
≥1 Year of college, %	77.2	78.1
Employed, %	72.6	64.9
White, %	79.8	80.7
Clinical		
Mean ± SD chronic disease score	1191.3 ± 978.5	1368.3 ± 1292.9
Mean ± SD NEO neuroticism inventory	22.7 ± 5.5	23.0 ± 5.5
Mean ± SD SCL-diagnosed depression	1.9 ± 0.5	1.9 ± 0.5
With recurrent depression, %	76.3	83.3
With dysthymia, %	50.0	59.8
With panic disorder, %	8.8	10.5

*Recurrent depression indicates 3 or more episodes of depression. NEO indicates neuroticism-extroversion-openness; SCL, the Hopkins Symptom Checklist.

†For percentage of women, $P \leq .02$.

percentage of women in the control arm of the study ($\chi^2 = 5.20$, $P = .02$). The high rates of recurrent major depression (76%-83%) and dysthymia (50%-60%) that were reported in this primary care population are noteworthy and can be explained by study selection criteria of persistent depressive symptoms after initial antidepressant treatment.

BASELINE FUNCTIONAL CHARACTERISTICS

Persistently depressed patients commonly reported significant interference in social, work, and family activities (SDS). They also experienced significant disability in social function and role performance (**Table 2**). There were no differences between the intervention and usual care groups in functional measures at baseline.

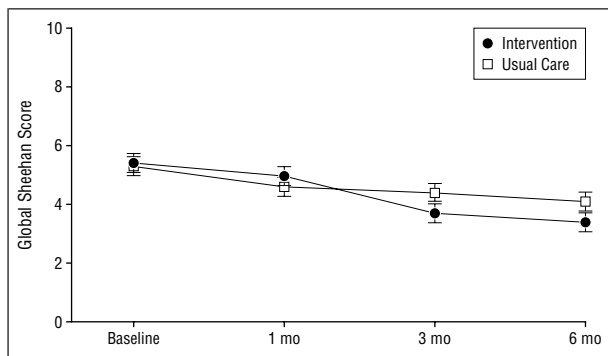
SHEEHAN DISABILITY SCALE

During the 6-month period, both groups reported decreasing interference associated with depression. The **Figure** shows that in the first 6 months following randomization, patients receiving intervention reported significantly less interference with activities than patients receiving usual care on the Global SDS ($z = 2.23$ and $P = .025$ for the time × treatment group interaction). Table 2 presents the adjusted means and 95% confidence intervals for the groups during the assessment periods. Analyses of covariance at each time point showed the intervention group reporting less interference at 3 months ($F_{1,185} = 3.74$, $P = .05$) and a trend toward significance at

Table 2. Adjusted Means of Disability Over Time for the Intervention and Control Groups*

	Baseline Mean (95% CI)	1 mo Mean (95% CI)	3 mo Mean (95% CI)	6 mo Mean (95% CI)	Normative Reference (SD) Values
Sheehan Disability Scale					
Intervention	5.4 (5.0-5.8)	5.0 (4.2-5.8)	3.7 (3.2-4.2)	3.4 (2.9-3.9)] 2.04 (2.62)
Control	5.3 (4.9-5.7)	4.6 (3.8-5.4)	4.4 (3.9-4.9)	4.1 (3.6-4.6)	
SF-36 social functioning					
Intervention	49.4 (44.6-54.2)	61.4 (55.7-67.1)	69.8 (64.5-75.1)	71.3 (66.0-76.6)] 83.28 (22.69)
Control	52.2 (47.5-56.9)	58.2 (52.5-63.9)	64.5 (59.2-69.8)	68.3 (63.0-73.6)	
SF-36 Role limitation due to emotional problems					
Intervention	26.4 (21.1-31.7)	43.0 (35.9-50.1)	50.8 (43.0-58.6)	55.1 (47.1-63.1)] 81.28 (33.04)
Control	24.3 (19.0-29.6)	31.9 (24.8-39.0)	44.3 (36.5-52.1)	52.4 (44.4-60.4)	

*Means are adjusted for age, sex, NEO (neuroticism-extroversion-openness), and chronic disease scores. SF-36 indicates Medical Outcomes Study 36-Item Short-Form Health Survey.



Global Sheehan Disability Scale scores (intervention vs usual care).

6 months ($F_{1,185} = 2.73$, $P = .10$). Each of the 3 SDS subscales, work, family, and social activities, showed similar patterns of significant improvement in the intervention group compared with the usual care group ($z = 2.23$, $P = .025$).

SOCIAL FUNCTION AND ROLE LIMITATION DUE TO EMOTIONAL PROBLEMS

During the course of the study, both the intervention and usual care groups improved similarly in social function and role limitation (Table 2). The social function subscale of SF-36 showed a trend toward greater improvement among the intervention group compared with the control group ($z = 1.63$ and $P = .10$ for the time \times treatment group interaction). The subscale of role limitation due to emotional problems showed no significant difference between intervention and control groups ($z = 0.07$ and $P = .94$ for time \times treatment group interaction).

COMMENT

Primary care patients with persistent depression at 6 to 8 weeks after initiating antidepressant pharmacotherapy experienced significant disability. They reported limitations in the major domains of daily life: work,

family, and social activities. Their social functioning was poor, and their role performance was substantially curtailed by emotional problems. In an earlier report, patients who received this stepped collaborative care intervention experienced significantly better depression outcomes than their counterparts receiving usual care. Our research found that the stepped care depression treatment resulted in small to modest reductions of disability among these persistently symptomatic patients. Compared with the usual care group, patients in the intervention group reported that depression interfered less with their work, family, and social activities 3 months after receiving the enhanced depression treatment. Social functioning as measured by the SF-36 revealed a similar trend toward more improvement over time in the intervention group compared with the usual care group. However, the SF-36 role performance as influenced by emotional problems was not different over time for the 2 treatment groups.

This study has a number of limitations. First, the population studied consisted of patients with depression who are persistently symptomatic at 6 to 8 weeks after starting pharmacotherapy and who had accepted randomization to receive an augmented depression intervention. The high rates of dysthymia and prior recurrent major depression describe a more severe and chronically depressed population than most primary care patients. The augmented depression intervention was targeted for this population with less favorable outcomes. Our findings may not generalize to the large proportion of patients with depression whose symptoms have resolved substantially during the first 6 to 8 weeks of treatment.²³ Second, our sample would not be representative of patients whose depression was not recognized by their primary care physician or who declined antidepressant medication. Third, our sample size may have been insufficient for detecting a significant intervention effect in the SF-36 subscales given that the control group was also being treated, albeit not as effectively. Sturm et al³²

have recently shown that much larger sample sizes (1392 for social functioning and 1784 for role-emotional) would be needed to show a 30% difference in effect size between intervention and control groups. Lastly, patients from the 4 large clinics of this prepaid health maintenance organization may differ from other primary care populations in ethnicity, socioeconomic status, and insurance coverage.

To minimize the likelihood that our measures of disability would be proxy measures of depressive symptoms, we avoided using SF-36 subscales such as vitality, the mental health subscale, and self-rated health status. The vitality and mental health subscale questions overlap with symptom criteria for major depression. We therefore used the WHO definition¹⁵ of disability and chose measures of disability from SF-36¹² such as social function and role performance.

The magnitude of the reduction in disability during the 6-month period as measured by the SDS was modest. The intervention group reported 15% less interference with daily activities than the control group at 3 months and 14% less at 6 months. The trend improvement in social function as reported by intervention group subjects was 17% more than control group subjects at 3 months and 13% more at 6 months. Although these differences achieved statistical or trend significance, it is unclear if the benefits of this depression intervention would translate into clear clinical differences in functioning.

However, these modest intervention effects on functional improvements are encouraging when we consider how this study differs from other depression and disability trials in recruitment of controls, patient characteristics, intensity of intervention, and selection of disability measures. Control groups in previous studies have ranged from untreated subjects to patients already receiving antidepressant treatment. Many randomized trials with robust functional effects^{8,9,11} identified their sample by screening primary care populations for major depression. These control groups were predominantly untreated. In contrast, depression trials, with less apparent effects on function,^{16,17} compared patients receiving intervention with controls receiving usual care who were also recognized as having depression and who similarly were administered antidepressant medication by their primary care physician. Automated pharmacy refill data revealed that a large proportion of those in the usual care group (43.8%) in this study received adequate levels of pharmacotherapy, compared with 68.8% in the intervention group.¹⁸ Thus, if the intervention group were compared with an untreated control group, one would expect greater intervention effects on disability.

Primary care patients in this sample were selected for a stepped collaborative care intervention because they had moderate or severe depressive symptoms after 8 weeks of antidepressant treatment. Their depression history com-

monly followed a recurrent or chronic course. Walker et al³³ reported that the two thirds of patients with less severe depression in this sample were more likely to show an intervention effect than patients with more severe depression. Comparing the intensity of depression interventions, this intervention is moderate in intensity relative to studies such as that of Schulberg et al,⁷ which are more intensive, while studies such as that of Simon et al¹⁰ are less intensive. Based on cost-effectiveness analyses of this randomized trial, Simon and colleagues then reported an interesting relationship between the intensity and cost of an intervention and the resulting decrease in depression.³⁴ This direct relationship seems to apply to functional improvements as well since randomized trials with robust functional effects^{8,9,11} also resulted from more intensive and costly interventions, while trials with less intensive and less costly interventions resulted in less robust functional improvements. It is possible that we could achieve a more robust functional improvement with a more intensive intervention. An equally plausible explanation is that potential for functional improvement from a depression intervention is limited for the more severely depressed population.

Through a better understanding of the factors influencing the magnitude of intervention effects, we can design strategies to maximize the benefits of depression treatment on patient functioning. Increasing the intensity of treatment for the more severely depressed and disabled patients could improve their outcomes. In addition to focusing solely on depression, designing individualized interventions specifically aimed at enhancing function might substantially enhance the daily lives of primary care patients.

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