

The Effectiveness of Depression Care Management on Diabetes-Related Outcomes in Older Patients

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Background: Depression frequently occurs in combination with diabetes mellitus, adversely affecting the course of illness.

Objective: To determine whether enhancing care for depression improves affective and diabetic outcomes in older adults with diabetes and depression.

Design: Preplanned subgroup analysis of the Improving Mood—Promoting Access to Collaborative Treatment (IMPACT) randomized, controlled trial.

Setting: 18 primary care clinics from 8 health care organizations in 5 states.

Patients: 1801 patients 60 years of age or older with depression; 417 had coexisting diabetes mellitus.

Intervention: A care manager offered education, problem-solving treatment, or support for antidepressant management by the patient's primary care physician; diabetes care was not specifically enhanced.

Measurements: Assessments at baseline and at 3, 6, and 12 months for depression, functional impairment, and diabetes self-care behaviors. Hemoglobin A_{1c} levels were obtained for 293 patients at baseline and at 6 and 12 months.

Results: At 12 months, diabetic patients who were assigned to

intervention had less severe depression (range, 0 to 4 on a checklist of 20 depression items; between-group difference, -0.43 [95% CI, -0.57 to -0.29]; $P < 0.001$) and greater improvement in overall functioning (range, 0 [none] to 10 [unable to perform activities]; between-group difference, -0.89 [CI, -1.46 to -0.32]) than did participants who received usual care. In the intervention group, weekly exercise days increased (between-group difference, 0.50 day [CI, 0.12 to 0.89 day]; $P = 0.001$); other self-care behaviors were not affected. At baseline, mean (\pm SD) hemoglobin A_{1c} levels were $7.28\% \pm 1.43\%$; follow-up values were unaffected by the intervention ($P > 0.2$).

Limitations: Because patients had good glycemic control at baseline, power to detect small but clinically important improvements in glycemic control was limited.

Conclusions: Collaborative care improves affective and functional status in older patients with depression and diabetes; however, among patients with good glycemic control, such care minimally affects diabetes-specific outcomes.

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See editorial comment on pp 1054-1056.

Major depression and dysthymic disorder affect 5% to 10% of older adults seen in primary care settings (1–3). Late-life depression is often chronic or recurrent (4–6) and is associated with substantial suffering, functional impairment, and diminished health-related quality of life (7). Diabetes mellitus affects 7.8% of all adults and almost 1 in 5 of those age 60 years and older (8). Individuals with diabetes mellitus have a 2-fold higher rate of major depression than those without diabetes (9, 10).

Depression adversely affects the course of coexisting medical illness, contributing to increased symptom burden, functional impairment, and mortality (11, 12). For patients with diabetes mellitus, depression is associated with decreased glycemic control and increased number of micro- and macrovascular complications (13, 14). The mechanism of effect is not understood but may be related to depression-induced abnormalities in neuroendocrine and neurotransmitter function or decreased self-care behaviors (15–20). Integrating evidence-based depression

care for persons with diabetes may improve both depression and diabetes outcomes. Three small randomized, controlled trials have studied the effect of treatment for depression on affective and glycemic outcomes in patients with depression and diabetes mellitus (21–23). These studies have consistently shown improvements in affective outcomes, but effects on glycemic control have been mixed.

Primary care physicians are well positioned to provide integrated care for depression and diabetes mellitus but face many barriers. Controlled trials report that treatment for depression is efficacious in approximately 70% of persons who complete treatment compared with 30% of those who receive placebo (24). However, these results are difficult to replicate in routine primary care practice. Barriers to high-quality care include suboptimal recognition; inconsistent treatment with lack of close follow-up and monitoring; and organizational barriers, such as brief visits, poor integration with specialty mental health care, competing clinical priorities, and lack of decision support systems

Context

Many patients have both diabetes and depression. Some hypothesize that treating depression might improve diabetes outcomes.

Contribution

In this randomized trial, 12 months of depression care management for depressed patients with diabetes improved depression-related outcomes and increased the frequency of exercise. However, care management did not affect diet, diabetes medication adherence, glucose testing, or glycemic control.

Cautions

The study sample had reasonably good diabetes control at baseline. Whether patients with poorly controlled diabetes would benefit from depression care is not known.

—The Editors

(25–27). Simple interventions, such as depression screening and physician education, have little impact on these barriers and patient outcomes (28–30).

Treatment models that use a depression specialist working collaboratively with primary care physicians have shown clinically important improvement in patient outcomes (31–37). We recently reported robust effects of such a model for older adults with major depression or dysthymia (37). In this preplanned analysis, we evaluate the effects on affective and diabetes-specific outcomes. If effective care for depression also benefits adherence to self-care regimens, functional status, and other medical illness outcomes, it would add powerful quality-of-care and economic incentives for the dissemination and maintenance of these models. In addition, if effective care for depression improves self-care behaviors, it may also positively affect other chronic medical illnesses with important self-care components.

For this prespecified subgroup analysis, we focused on older adults with clinical depression and coexisting diabetes mellitus. We hypothesized that the collaborative care intervention would improve affective symptoms, functional status, self-care behaviors, and glycemic control. In addition, we hypothesized that effects on glycemic control would be greatest for patients with baseline hemoglobin A_{1c} values of 8.0% or greater.

METHODS

The Improving Mood–Promoting Access to Collaborative Treatment (IMPACT) study is a multisite randomized, controlled trial of a collaborative care intervention program for late-life depression in primary care (37, 38). Institutional review boards at participating sites approved study protocols, and all participants gave written informed consent.

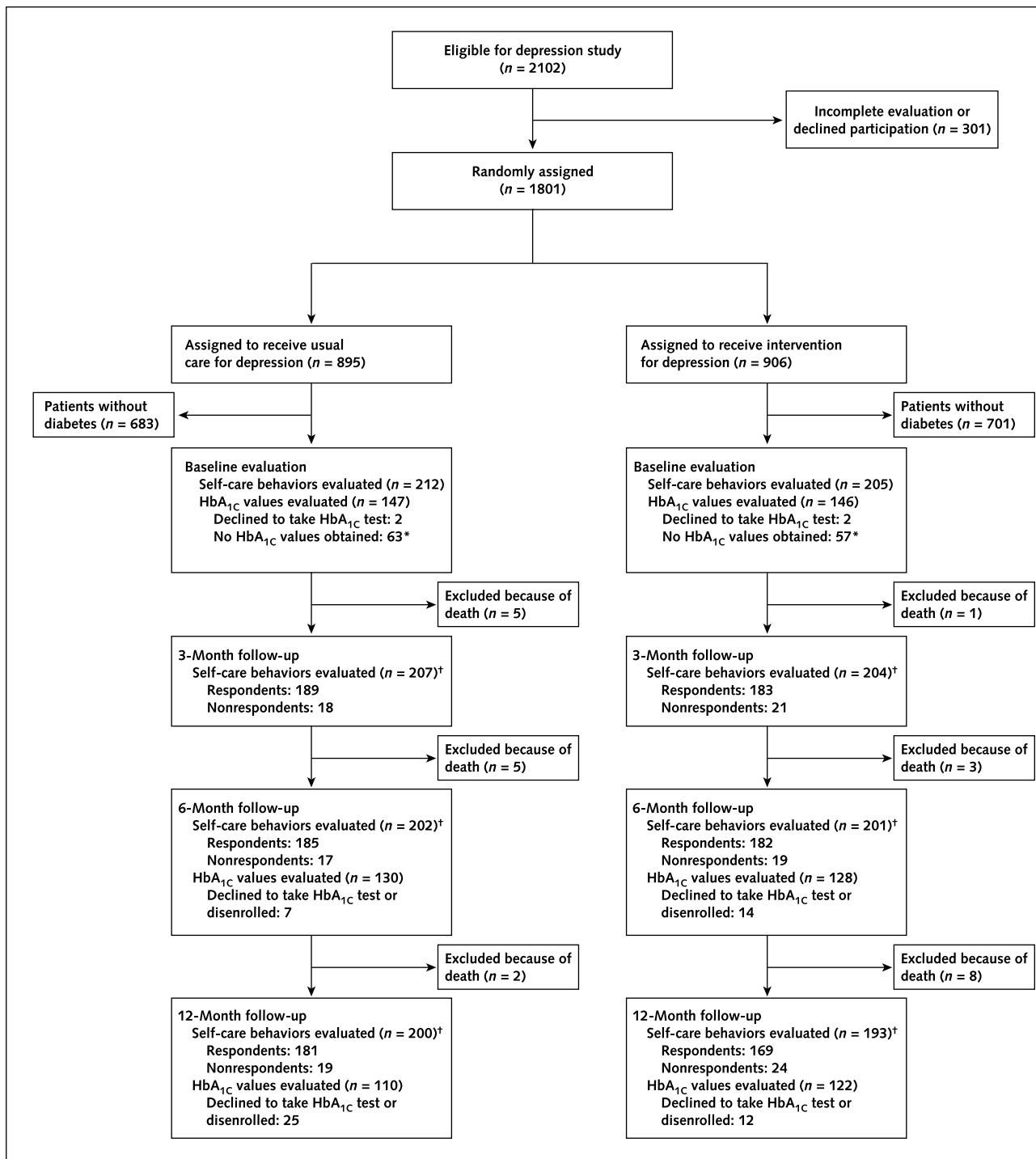
Patients

Seven study sites representing 8 diverse health care organizations with a total of 18 primary care clinics in 5 states participated in the study. From July 1999 to August 2001, depressed older adults were recruited through referrals from primary care practitioners and other clinic staff or through systematic depression screening with a 2-item depression screener adapted from the Primary Care Evaluation of Mental Disorders (39). Of the 2190 patients referred to the study, 308 (14%) declined the initial eligibility screening or additional interviews, 54 (3%) had incomplete initial screenings, and 202 (9%) were ineligible because they were younger than 60 years of age or they did not plan to use the participating clinic over the coming 12 months. Of the 32 908 patients approached for screening, 5246 (16%) declined the initial screening or follow-up interviews. A total of 1791 (5%) of the initial screenings were incomplete and 23 233 (71%) of those screened were not eligible because they did not have one of the core depression symptoms (95%) or because of logistic reasons such as lack of transportation or access to a telephone (5%).

The remaining 1626 (74%) of those referred and 2638 (8%) of those screened completed a computer-assisted structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), to assess whether patients met research diagnostic criteria for major depression or dysthymia (40). Inclusion criteria were age 60 years or older, plans to use one of the participating clinics as the main source of general medical care in the coming year, and a diagnosis of current major depression or dysthymic disorder according to the structured clinical interview for DSM-IV. Otherwise eligible persons were excluded because of a current drinking problem (a score of ≥ 2 on the CAGE questionnaire) (41), a history of bipolar disorder or psychosis (38), ongoing treatment with a psychiatrist, or severe cognitive impairment defined by a score less than 3 on a 6-item cognitive screener (42). We identified 2102 eligible older adults with major depression or dysthymic disorder, of whom 1801 (86%) enrolled in the study. As part of the structured baseline interview, enrolled patients were asked “Has a doctor or another health care worker diagnosed you with or treated you for high blood sugar or diabetes in the past 3 years?” The 417 patients who endorsed this question are the focus of the diabetes-specific analyses.

After the baseline interview, we randomly assigned participants to the IMPACT intervention or usual care. The randomization was stratified by recruitment method (screening or referral) and clinic. Randomization information was contained in a set of numbered, sealed envelopes for each stratum that were used sequentially for newly enrolled patients at each clinic (38). Diagnoses were communicated to enrolled patients and their primary care physicians.

Figure. Flowchart of participants in the trial.



* Because funding for hemoglobin A_{1c} (HbA_{1c}) values was obtained after the trial had begun, some patients were not approached for these values. Neither baseline nor follow-up hemoglobin A_{1c} values were imputed for analysis. † The analysis includes all participants, except those excluded because of death, after multiple imputation of unit-level missing data.

Intervention

Patients in the intervention group received a 20-minute educational videotape and a booklet about late-life depression and were encouraged to have an initial visit

with a depression care manager at the primary care clinic (43, 44). Care managers were nurses or psychologists who were trained for the study as a depression clinical specialist (38, 45). During the initial visit, the depression clinical

specialist conducted a clinical and psychosocial history, reviewed the educational materials, and discussed patient preferences for depression treatment (antidepressant medications or psychotherapy). New patients and patients needing treatment plan adjustments were discussed with a supervising team psychiatrist and a liaison primary care physician during a weekly team meeting. The depression clinical specialist then worked with the patient and his or her regular primary care provider to establish a treatment plan according to an evidence-based treatment algorithm (38). The IMPACT algorithm suggested an initial choice of an antidepressant (usually a selective serotonin reuptake inhibitor) or a course of Problem-Solving Treatment in Primary Care (PST-PC), which consisted of 6 to 8 brief sessions of structured psychotherapy for depression, delivered by the depression clinical specialist in primary care (46–49). For patients who were already receiving antidepressant medications but who were still depressed, the recommendation for partial responders was to increase the dose or augment the antidepressant with a trial of PST-PC; the recommendation for nonresponders was to switch to a different medication or use a trial of PST-PC. Depression clinical specialists also encouraged patients to increase behavioral activation and referred them to additional health or social services, as clinically indicated. The intervention did not specifically address diabetes mellitus or other coexisting medical illnesses.

As care managers, depression clinical specialists attempted to follow patients for up to 12 months; they monitored treatment response with the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (50) and a Web-based clinical information system (51). During the acute treatment phase, in-person or telephone follow-up contacts were suggested at least every other week. Patients who recovered from depression ($\geq 50\%$ reduction in the Patient Health Questionnaire score and < 3 of 9 symptoms of major depression) were engaged in developing a relapse prevention plan and were then followed up with monthly telephone calls by the depression clinical specialist. For patients who did not respond to initial treatment, a “step 2” treatment plan was developed that could include augmentation of an antidepressant, a switch to a different antidepressant, a switch from medications to PST-PC, or a switch from PST-PC to medications. Team psychiatrists were encouraged to see patients who had persistent depression for in-person consultations in the primary care setting. The team again reviewed patients who did not respond after 10 weeks of step 2 treatment, and additional treatments such as new medication changes, psychotherapy, hospitalization, or electroconvulsive therapy were considered.

Data Collection

Trained interviewers who were blinded to treatment assignment performed computer-assisted telephone interviews at 3, 6, and 12 months (38). Response rates were

90% at 3 months, 87% at 6 months, and 87% at 12 months. Response rates were almost identical for the diabetic subgroup (**Figure**). Because funding for collection of hemoglobin A_{1c} values was obtained after patient recruitment had begun, only 297 patients were approached for this measure; 293 (99%) agreed, and follow-up rates were 88% at 6 months and 79% at 12 months.

Baseline interviews assessed sociodemographic characteristics, the severity of depressive symptoms by using 20 depression items from the Symptom Checklist–90 (Symptom Checklist–20) (52), diagnoses of major depression or dysthymia by using the structured clinical interview for DSM-IV (40), and health-related functional status by using mental and physical component scores from a 12-item short form based on the Medical Outcomes Study 36-Item Short-Form Health Survey (53). Respondents rated their overall functional impairment in the previous month (including physical and emotional health) on a scale from 0 (none) to 10 (unable to perform activities) and indicated whether they had received a diagnosis or been treated for any of 10 common chronic medical problems in the previous 3 years. A modified Chronic Disease Score, ranging from 0 to 57, was derived from self-reported medication use to measure overall burden of illness (54, 55). The Cornell Services Index and additional questions about the use of antidepressants, counseling, or psychotherapy assessed the use of health services (56). Diabetes self-care, including the domains of diet, exercise, glucose testing, and diabetes medication, were determined by using the 12-item Summary of Diabetes Self-Care Activities scale, augmented by an item to assess foot care (57). Hemoglobin A_{1c} values were measured at each site by laboratories that used lyophilized calibrators, which were standardized to the method used in the Diabetes Control and Complications Trial (58).

Outcomes Examined

Dependent variables in our analyses included self-reported use of antidepressants or psychotherapy, mean Symptom Checklist–20 depression scores, health-related functional status, diabetes self-care behaviors, and hemoglobin A_{1c} levels. Using a 2-sided α value of 0.05 and a power of 80%, we calculated that a sample size of 246 persons would be sufficient to detect a difference in hemoglobin A_{1c} level of 0.50 percentage point or greater.

Statistical Analysis

We used logistic regression to compare all sociodemographic and clinical characteristics simultaneously between patients in the intervention group and patients in the usual care group (**Table 1**). Mixed-model repeated-measures analyses were used to evaluate the effect of the intervention on diabetes self-management, glycemic control, depression, health-related functional status, and quality of life. Group differences in change from baseline for the 3-, 6-, and 12-month follow-up data were modeled with covariate adjustment for recruitment method (screening or referral).

Table 1. Patient Characteristics*

Characteristic	Overall Sample (n = 1801)	Diabetes Subgroup†	
		Usual Care (n = 212)	Intervention (n = 205)
Female, n (%)	1168 (65)	112 (53)	111 (54)
Mean age, y	71.2 ± 7.5	70.3 ± 7.1	70.1 ± 6.9
Married or living with partner, n (%)	834 (46)	103 (49)	93 (45)
Ethnic group, n (%)			
White	1388 (77)	133 (63)	132 (65)
African American	222 (12)	39 (18)	46 (22)
Hispanic	138 (8)	33 (16)	21 (10)
Other	53 (3)	7 (3)	6 (3)
At least high school graduate, n (%)	1425 ± 79	151 ± 71	146 ± 71
Mean annual income, \$ (in 1000s)	37.2 (61.7)	25.6 (22.5)	24.8 (28.4)
Depression status (SCID diagnosis), n (%)			
Major depression	306 (17)	27 (13)	24 (12)
Dysthymia	542 (30)	61 (28)	59 (29)
Major depression and dysthymia	953 (53)	124 (59)	122 (59)
Mean SCL-20 depression score (range, 0–4) ± SD	1.7 ± 0.6	1.7 ± 0.6	1.7 ± 0.6
Positive result on anxiety screening, n (%)	518 (29)	61 (29)	51 (25)
Positive result on cognitive impairment screening, n (%)	638 (35)	78 (37)	79 (39)
Mean chronic disease score	5.4 ± 3.6	7.3 ± 3.7	6.8 ± 3.5
Mean health-related functional impairment (range, 0–10)	4.6 ± 2.6	5.1 ± 2.4	5.2 ± 2.5
Mean mental component score (range, 0–100)	42.3 ± 7.3	41.3 ± 7.4	42.0 ± 7.5
Mean physical component score (range, 0–100)	40.3 ± 7.4	38.0 ± 6.9	38.8 ± 7.3
Mean duration of diabetes mellitus, y	NA	11.6 ± 10.1	10.5 ± 9.5
Any antidepressant use in previous 3 months, n (%)	769 (43)	96 (45)	91 (45)
Any specialty mental health visits or psychotherapy in previous 3 months, n (%)	151 (8)	11 (5)	15 (7)
Diabetes treatment, n (%)			
Diet only	NA	25 (12)	36 (18)
Oral hypoglycemic agents only	NA	110 (52)	100 (49)
Insulin only	NA	49 (23)	43 (21)
Oral hypoglycemic agents and insulin	NA	28 (13)	26 (13)
Mean hemoglobin A _{1c} level, %‡	NA	7.3 ± 1.5	7.3 ± 1.3

* Values expressed with a plus/minus sign are the mean ± SD. NA = not available; SCID = structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition; SCL-20 = 20 depression items from the Symptom Checklist-90.

† $P > 0.2$ for differences between usual care and intervention patients among the diabetic subgroup considering all baseline characteristics in a logistic regression analysis.

‡ $n = 293$ for hemoglobin A_{1c} results: 147 usual care and 146 intervention.

Participating study organization was entered as a fixed effect in all models. An unstructured within-patients covariance matrix was specified to account for the within-patient correlation over time. For process of care, depressive symptoms, and overall functional status, we used an interaction term to determine whether intervention effects differed for diabetic and nondiabetic persons. In the diabetic subgroup, we tested for an interaction between baseline glycemic control and treatment assignment, hypothesizing that intervention effects would be greater for patients with decreased glycemic control at baseline. In this analysis, we adjusted for baseline depression severity (Symptom Checklist-20) and glycemic control (hemoglobin A_{1c} level $\geq 8.0\%$) (59). For the analysis of diabetes self-care behaviors, we used baseline depression severity (Symptom Checklist-20), diabetes treatment, and duration of diabetes as additional covariates. Group differences in self-reported use of antidepressants or psychotherapy were evaluated by logistic regression.

We used an extended hot-deck multiple imputation technique that modifies the predictive mean matching method to impute item-level missing data (60). The strat-

egy uses the well-established framework of multiple imputation in which the goal is to integrate the contribution of missing values into overall estimates of uncertainty (61). By using hot-deck imputation, imputations were restricted to values that had been observed in other patients. Rates of item-level missing data were less than 2% for all variables discussed in this paper. Rates for unit-level missing data ranged from 9% to 11% across the follow-up assessments. A hot-deck multiple imputation procedure based on a Bayesian bootstrap method, stratifying by propensity scores, was used to impute unit-level missing data (62). SAS PROC MI (SAS Institute, Inc., Cary, North Carolina) was used to generate 5 imputed data sets. The results across 5 imputed data sets were combined by averaging, and standard errors were adjusted to reflect both within-imputation variability and between-imputation variability (61) by using MIANALYZE procedure in Release V8.2 of the SAS System.

Role of the Funding Sources

The Robert Wood Johnson Foundation, John A. Hartford Foundation, California Healthcare Foundation,

and Hogg Foundation funded the study. The sponsors were not involved in the design of the study; the collection, analysis, or interpretation of the data; or the decision to approve the finished manuscript.

RESULTS

The enrolled persons were clinically and sociodemographically diverse (Table 1). Fifty-three percent of participants met diagnostic criteria for major depression and dysthymic disorder, and 29% had positive screening results for panic disorder or post-traumatic stress disorder. The mean (\pm SD) Symptom Checklist–20 depression score was 1.7 ± 0.6 , indicating moderate to severe depression. During the preceding 3 months, 43% of participants had taken an antidepressant, and 8% had seen a mental health professional. More than one third (35%) showed some evidence of cognitive impairment.

Compared with the overall sample, diabetic patients were more likely to be male, to be a member of an ethnic minority, to have major depression and dysthymia, and to have a higher Chronic Disease Score. Diabetic persons were less likely to have completed high school and had lower mean incomes. Patients reported a mean (\pm SD) duration of diabetes mellitus of 11.0 ± 9.8 years and were treated with diet only (15%), oral hypoglycemic medications only (50%), insulin only (22%), or a combination of oral hypoglycemic agents and insulin (13%). Glycemic control was good, as evidenced by a mean (\pm SD) hemoglobin A_{1c} level of $7.28\% \pm 1.37\%$, which corresponds to a mean glucose level of approximately 8.8 mmol/L (159 mg/dL). Sociodemographic and clinical characteristics between the intervention and control groups did not differ significantly.

Intervention Implementation and Process of Care

Most (98%) of the 906 patients in the intervention group completed an initial visit with a depression clinical specialist. These patients worked with a depression clinical specialist for a mean (\pm SD) of 9.15 ± 6.17 in-person visits and a mean (\pm SD) of 6.10 ± 5.13 telephone contacts; 11% were seen for a consultation by a team psychiatrist. Most (80%) had at least one trial of an antidepressant, and about one third (30%) received a course of PST–PC. The mean number (\pm SD) of PST–PC sessions was 6.34 ± 4.26 . Treatment rates were nearly identical for intervention patients in the diabetes subgroup.

In the overall sample at all follow-up visits, patients in the intervention group were significantly more likely to use antidepressants or psychotherapy than were patients in the usual care group (82% vs. 61% at 12 months; $P < 0.001$). Patients in the intervention group reported antidepressant use for a mean (\pm SD) of 6.6 ± 4.9 months of the 12-month study period compared with a mean (\pm SD) of 4.6 ± 5.2 months for patients in the usual care group ($P < 0.001$). At all follow-up assessments, intervention patients were significantly more likely to report a mental health specialty visit or psychotherapy visit during the previous 3 months (43% vs. 16% at 12 months; $P < 0.001$).

The intervention improved the process of care similarly for patients with diabetes mellitus. At all follow-up visits, patients in the intervention group were more likely to use antidepressants or psychotherapy than were patients in the usual care group (76% vs. 51% at 12 months; $P < 0.001$). We used an interaction term to determine whether the intervention varied for diabetic and nondiabetic persons; intervention effects did not differ for antidepressant use ($P > 0.2$ at all follow-up visits), the likelihood of men-

Table 2. Depression and Functional Status Outcomes*

Outcome	Diabetic Persons (n = 417)			Nondiabetic Persons (n = 1384)			Interaction Effect P Value‡
	Unadjusted Estimates, Mean ± SD		Between-Group Difference† (95% CI)	Unadjusted Estimates, Mean ± SD		Between-Group Difference† (95% CI)	
	Usual Care	Intervention		Usual Care	Intervention		
SCL-20 depression score (range, 0–4)							
Baseline	1.72 ± 0.63	1.67 ± 0.62	−0.03 (−0.14 to 0.09)	1.66 ± 0.60	1.69 ± 0.60	0.03 (−0.03 to 0.09)	
3-mo follow-up	1.51 ± 0.66	1.24 ± 0.70	−0.26 (−0.40 to −0.12)	1.44 ± 0.66	1.16 ± 0.66	−0.28 (−0.36 to −0.21)	>0.2
6-mo follow-up	1.28 ± 0.72	0.93 ± 0.67	−0.34 (−0.48 to −0.20)	1.18 ± 0.72	0.93 ± 0.67	−0.25 (−0.34 to −0.16)	>0.2
12-mo follow-up	1.46 ± 0.68	1.00 ± 0.68	−0.43 (−0.57 to −0.29)	1.37 ± 0.67	0.99 ± 0.67	−0.38 (−0.46 to 0.30)	>0.2
Overall functional impairment (range, 0–10)							
Baseline	5.14 ± 2.42	5.20 ± 2.46	0.12 (−0.35 to 0.59)	4.40 ± 2.58	4.52 ± 2.68	0.12 (−0.15 to 0.39)	
3-mo follow-up	4.79 ± 2.47	4.27 ± 2.87	−0.51 (−1.04 to 0.04)	4.41 ± 2.69	3.70 ± 2.68	−0.69 (−0.99 to −0.40)	>0.2
6-mo follow-up	4.63 ± 2.70	4.37 ± 2.67	−0.20 (−0.78 to 0.39)	4.11 ± 2.65	3.74 ± 2.77	−0.35 (−0.67 to −0.03)	>0.2
12-mo follow-up	4.90 ± 2.63	3.91 ± 2.76	−0.89 (−1.46 to −0.32)	4.40 ± 2.75	3.46 ± 2.80	−0.92 (−1.25 to −0.60)	>0.2

* SCL-20 = 20 depression items from the Symptom Checklist-90.

† Mixed-effects linear regression adjusted for recruitment method and study site.

‡ P value for test of interaction between treatment assignment and presence or absence of diabetes mellitus.

Table 3. Effects on Self-Care Behaviors

Self-Care Behavior	Unadjusted Estimates, Mean \pm SD		Adjusted Analysis for Intervention vs. Usual Care*	
	Usual Care	Intervention	Between-Group Difference (95% CI)	P Value
Followed recommended diet (range, 1 = always; 5 = never)				0.05
Baseline	2.63 \pm 1.23	2.93 \pm 1.40	0.26 (–0.05 to 0.57)	0.10
3-mo follow-up	2.64 \pm 1.12	2.58 \pm 1.23	–0.38 (–0.71 to –0.05)	0.02
6-mo follow-up	2.61 \pm 1.14	2.69 \pm 1.26	–0.19 (–0.51 to 0.12)	>0.2
12-mo follow-up	2.54 \pm 1.04	2.57 \pm 1.08	–0.26 (–0.65 to 0.12)	0.18
Took prescribed medication (range, 1 = always; 5 = never)				>0.2
Baseline	1.07 \pm 0.34	1.16 \pm 0.55	0.05 (–0.05 to 0.15)	>0.2
3-mo follow-up	1.16 \pm 0.47	1.13 \pm 0.41	–0.04 (–0.17 to 0.10)	>0.2
6-mo follow-up	1.23 \pm 0.61	1.15 \pm 0.48	–0.11 (–0.28 to 0.06)	0.20
12-mo follow-up	1.19 \pm 0.50	1.16 \pm 0.53	–0.01 (–0.18 to 0.15)	>0.2
Weekly exercise days				0.001
Baseline	1.33 \pm 1.30	1.13 \pm 1.20	–0.12 (–0.41 to 0.16)	>0.2
3-mo follow-up	1.32 \pm 1.23	1.12 \pm 1.05	–0.07 (–0.42 to 0.28)	>0.2
6-mo follow-up	1.19 \pm 1.14	1.23 \pm 1.15	0.08 (–0.27 to 0.43)	>0.2
12-mo follow-up	1.10 \pm 1.09	1.41 \pm 1.23	0.50 (0.12 to 0.89)	0.01
Weekly glucose testing days				0.16
Baseline	4.43 \pm 2.95	3.78 \pm 3.18	–0.54 (–1.17 to 0.09)	0.10
3-mo follow-up	4.74 \pm 2.71	4.35 \pm 2.86	0.26 (–0.31 to 0.82)	>0.2
6-mo follow-up	4.78 \pm 2.78	4.27 \pm 2.81	0.25 (–0.39 to 0.89)	>0.2
12-mo follow-up	4.82 \pm 2.71	4.16 \pm 2.88	–0.21 (–1.08 to 0.66)	>0.2
Weekly foot inspection days				>0.2
Baseline	5.04 \pm 2.73	5.13 \pm 2.70	–0.04 (–0.66 to 0.58)	>0.2
3-mo follow-up	5.15 \pm 2.52	5.59 \pm 2.35	0.50 (–0.20 to 1.21)	0.16
6-mo follow-up	5.33 \pm 2.36	5.53 \pm 2.29	0.14 (–0.51 to 0.80)	>0.2
12-mo follow-up	5.46 \pm 2.26	5.84 \pm 2.12	0.28 (–0.48 to 1.05)	>0.2

* Between-group difference at follow-up is calculated as the change over time in intervention group minus the change over time for the usual care group, adjusted for baseline Symptom Checklist-20 score (20 depression items from the Symptom Checklist-90), diabetes treatment, and hemoglobin A_{1c} level.

tal health specialty visits, or psychotherapy visits ($P > 0.2$ at all follow-up visits).

Affective and Functional Status Outcomes

For patients with and without diabetes mellitus, depression was significantly less severe for those in the intervention group (measured by Symptom Checklist-20 depression scores) at all follow-up points (Table 2). Positive effects on overall health-related functional status appeared later. No interaction occurred between the intervention and diabetes status at any time point, indicating that the intervention produced similar improvements in depressive symptoms and functional status for participants with and without diabetes mellitus. By 12 months, patients with diabetes in the intervention group had significantly improved functioning on the mental (between-group difference, 2.44 [CI, 0.79 to 4.09]) and physical (between-group difference, 3.21 [CI, 1.78 to 4.63]) components of the 12-item short form.

Diabetes Self-Care and Hemoglobin A_{1c} Outcomes

We evaluated 5 diabetes self-care behaviors (Table 3): adherence to a recommended diet; taking prescribed medication; and the mean number of exercise, glucose testing, and foot inspection days over the previous week. Patients

in the intervention group showed a significantly greater increase in exercise days at month 12 (mean difference, 0.50 day; $P = 0.01$). At baseline, patients reported almost-perfect adherence to prescribed medication and moderate adherence to the recommended diet, glucose testing (mean days [\pm SD], 4.1 \pm 3.1), and foot inspections (mean days [\pm SD], 5.1 \pm 2.7). Adherence to any of these latter self-care behaviors was not significantly greater in the patients in the intervention group compared with patients in the usual care group. The mean (\pm SD) hemoglobin A_{1c} level decreased from 7.28% \pm 1.43% to 7.11% \pm 1.37% at 12 months. Intervention did not affect glycemic control ($P >$

Table 4. Hemoglobin A_{1c} Values

Variable	Overall Sample	Mean Hemoglobin A _{1c} Values \pm SD, %	
		Usual Care	Intervention
Baseline	7.28 \pm 1.43 (n = 293)	7.30 \pm 1.54 (n = 147)	7.26 \pm 1.32 (n = 146)
6 months	7.07 \pm 1.27 (n = 258)	7.08 \pm 1.32 (n = 130)	7.07 \pm 1.23 (n = 128)
12 months	7.11 \pm 1.37 (n = 232)	7.11 \pm 1.42 (n = 110)	7.11 \pm 1.33 (n = 122)

0.2). We used a treatment by baseline hemoglobin A_{1c} level interaction term to test our hypothesis of greater effects for patients with hemoglobin A_{1c} levels of 8.0% or greater at baseline; interaction had no effect ($P > 0.2$).

DISCUSSION

The IMPACT intervention improved the quality of depression care, as well as affective and functional status outcomes in older adults with major depression or dysthymia and coexisting diabetes mellitus. Positive effects on depressive symptoms appeared early and were similar to those seen for the IMPACT study sample overall. These results are encouraging because some trials have found that chronic medical illness moderates the effectiveness of depression treatments (63). The intervention also improved overall, mental, and physical functioning, but these effects were more modest and appeared later. Other studies report gains in functional status that lag behind improvement in affective status (64), which suggests that high-quality depression care needs to be sustained beyond acute-phase treatment to realize these benefits. Because benefits for symptoms and functional status increased over time, long-term follow-up should be a priority for future studies.

A major goal of clinicians caring for older adults is to maximize functioning; thus, gains in overall and physical function were a welcome intervention effect. These data suggest that enhancing the quality of depression care for older adults with multiple chronic illnesses may limit functional decline. The increase in exercise days among patients in the intervention group may be one mechanism that explains this finding.

Three short-duration efficacy trials have evaluated the effects of depression treatment in patients with coexisting depression and diabetes. All showed positive effects on depression symptoms, but results of diabetes outcomes varied. In a study of 51 patients with major depression and poorly controlled type 2 diabetes (mean glycosylated hemoglobin level $> 10\%$), cognitive behavioral therapy plus diabetes education improved glycosylated hemoglobin levels by more than 1% compared with education alone; however, glucose monitoring was adversely affected (21). A trial of nortriptyline for 28 patients with major depression and diabetes showed no effect on glycemic control or glucose monitoring, but path analysis showed a negative effect of nortriptyline on glucose control and power to detect clinically significant differences was limited (22). The third study evaluated fluoxetine in 60 patients with type 1 or type 2 diabetes and major depression (23). Improvement in glycosylated hemoglobin levels was not statistically significant; self-care behaviors were not measured. These efficacy trials suggest that depression treatments, with the possible exception of tricyclic antidepressants, may improve glycemic control in patients with poorly controlled diabetes. Effects on self-care behaviors have not been adequately evaluated.

In our study, intervention effects on diabetes-specific outcomes were limited. Of 5 self-care behaviors, only exercise days increased significantly; glycemic control was unaffected. It is possible that high-quality depression care does not benefit glycemic control, but we believe that this conclusion would be premature. Our patients were significantly older, were less likely to be receiving hypoglycemic medications, and had much better mean hemoglobin A_{1c} levels at baseline than did patients in other studies that showed benefits on glycemic control. Second, our measure of self-care behavior showed ceiling effects for medication adherence. A revised measure has been developed with improved psychometric properties (65). Third, our intervention did not include any diabetes-specific interventions, such as diabetes education, that in combination with depression treatment were associated with the largest effect seen in earlier studies. Achieving clinically important effects in patients with good baseline glucose control would probably require an integrated biopsychosocial intervention that addresses both depression and diabetes self-care.

Our study has many strengths, including participation by 8 diverse health care organizations nationally. These organizations represent a wide variety of practices and patients. Although this sample of depressed older adults with diabetes is a subgroup of the original sample, the IMPACT study was originally designed to examine effects of an improved depression program on outcomes of comorbid medical illnesses. The comparison groups were balanced at baseline with respect to demographic and clinical characteristics. Follow-up rates were high, and the analyses used intention-to-treat methods. Our study also has several limitations. Although medication use and hemoglobin A_{1c} values supported the diagnosis, diabetes mellitus was based on self-report alone. We carefully evaluated all depression-specific interventions but did not assess changes in treatment for diabetes. Although unlikely, it is possible that ongoing treatment for diabetes differed for the intervention and usual care groups. Finally, our study design may have biased our comparisons in favor of the usual care group. Because of ethical concerns, referring providers were notified if a patient meeting study criterion was assigned to usual care, possibly resulting in additional depression treatment that would not have occurred in true usual care. Because providers treated patients in both the intervention and usual care groups from 1999 to 2002, a “spillover” effect may have occurred as a result of primary care providers applying improved skills learned from exposure to the intervention to the treatment of their usual care patients.

In summary, the IMPACT model, a collaborative, stepped-care management intervention, improves depression and functional status in older adults with coexisting depression and diabetes but has limited benefit for diabetes outcomes. Future studies should evaluate integrated care for depression and diabetes, a model that is conceptually appealing to clinicians and patients.

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APPENDIX: STUDY PARTICIPATING SITES AND THE IMPACT INVESTIGATORS

The study participating sites are Duke University, Durham, NC; The South Texas Veterans Health Care System, San Antonio, TX; The Central Texas Veterans Health Care System, Austin, TX; The San Antonio Preventive and Diagnostic Medicine Clinic, San Antonio, TX; Indiana University School of Medicine, Indianapolis, IN; Health and Hospital Corporation of Marion County, Indianapolis, IN; Group Health Cooperative of Puget Sound in cooperation with the University of Washington, Seattle, WA; Kaiser Permanente of Northern California, Oakland and Hayward, CA; Kaiser Permanente of Southern California, San Diego, CA; and Desert Medical Group, Palm Springs, CA.

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