Effects of Enhanced Depression Treatment on Diabetes Self-Care

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ABSTRACT

PURPOSE Among patients with diabetes, major depression is associated with more diabetic complications, lower medication adherence, and poorer self-care of diabetes. We reported earlier that enhanced depression care reduces depression symptoms but not hemoglobin A1c level. This study examined effects of depression interventions on self-management among depressed diabetic patients.

METHODS A total of 329 patients in 9 primary care clinics were randomized to an evidence-based collaborative depression treatment (pharmacotherapy, problem-solving treatment, or both in combination) or usual primary care (routine medical services). Outcome measures included the Summary of Diabetes Self-Care Activities (SDSCA), reported at baseline and 3, 6, and 12 months, and medication non-adherence as assessed by automated pharmacy refill data of oral hypoglycemic agents, lipid-lowering agents, and angiotensin-converting enzyme inhibitors. We used mixed regression models adjusted for baseline differences to compare the intervention with usual care groups at follow-up assessments.

RESULTS During the 12-month intervention period, enhanced depression care and outcomes were not associated with improved diabetes self-care behaviors (healthy nutrition, physical activity, or smoking cessation). Relative to the usual care group, the intervention group reported a small decrease in body mass index (mean difference = 0.70 kg/m², 95% CI, 0.17 to 1.24 kg/m²) and a higher rate of nonadherence to oral hypoglycemic agents (mean difference = –6.3%, 95% CI, –11.91% to –0.71%). Adherence to lipid-lowering agents and to antihypertensive medicines was similar for the 2 groups.

CONCLUSIONS In general, diabetes self-management did not improve among the enhanced depression treatment group during a 12-month period, except for small between-group differences of limited clinical importance. Research needs to assess whether self-care interventions tailored for specific conditions, in addition to enhanced depression care, can achieve better diabetes and depression outcomes.

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INTRODUCTION

Self-care is a cornerstone of diabetes management. Daily practice of healthy nutrition and physical activity can slow disease progression.1-3 Adherence to medical regimens for diabetes can lessen the disease burden and reduce the morbidity and mortality associated with diabetic complications.4 Poor self-management of diabetes is, however, the norm and intensifies the burden of this epidemic condition.5-7

The prevalence of depression is roughly twice as high among diabetic patients as among the general population.8 Depressed patients with diabetes have poorer glycemic control, more severe diabetes symptoms and disability, added complications, and higher health care use relative to patients with diabetes but no depression.5,8-14 Self-management is even less adequate among diabetic patients with depression than among those without it. Nonadherence to diabetes medications, physical inactivity, poor nutrition, and smoking are highly correlated with depression, while self-monitoring
of blood glucose is similar in depressed and nondepressed diabetic patients. Poor medication adherence is related not only to worse clinical outcomes, but also to subsequent hospitalizations and increased health care costs. This relationship of depression and poor self-management is consistent across different socioeconomic and cultural groups.

The clear association between depression, inadequate self-management, and adverse outcomes has led many to advocate for better identification and treatment of depression among diabetic patients. Thus far, cross-sectional studies have provided most of the evidence regarding the association of depression with poor diabetes self-management and adverse outcomes. Recently, McKellar and colleagues used structural equation modeling to test the relationship between depressive symptoms, poorer self-care, and subsequent glucose dysregulation. These studies found that depression increased symptoms of glucose dysregulation through lower adherence to self-care; however, depression did not significantly influence subsequent diabetes-related symptoms above and beyond their impact on patients’ self-care behaviors.

Randomized controlled trials to improve depression among diabetic patients have had mixed effects on diabetes outcomes. Among patients with poorly controlled diabetes receiving specialty care, an earlier study of cognitive behavioral therapy and diabetes education showed a clinically significant reduction in hemoglobin A1c (HbA1c) level at the 6-month follow-up when compared with a control group receiving diabetes education only. An unexpected finding was that intervention patients receiving cognitive behavioral therapy and diabetes education showed less self-monitoring of glucose levels relative to the education group during the intervention period. Trials comparing antidepressant pharmacotherapy with placebo found that nor triptiline therapy did not change the glycemic index among patients with diabetes and depression, while fluoxetine therapy was associated with a trend toward a lower HbA1c level.

Two recent randomized trials of systematic depression management in primary care both found a significant improvement in depression among patients with diabetes and depression, but no significant effect on glycemic control. In a study of older adults with depression and diabetes, Williams and colleagues reported that the intervention patients increased their physical activity relative to usual care patients. There was, however, no intervention effect on other self-management activities, and diabetic medication adherence was not assessed. In a randomized trial of a mixed-age primary care population with diabetes, Katon and colleagues found that a systematic depression care program significantly increased quality of depression care and reduced depressive symptoms but did not have a significant impact on glycemic control. We used data from this same trial to examine the impact of improved depression treatment on self-care behaviors, including adherence to diabetes medications.

**METHODS**

**Study Setting**

From March 2001 to May 2002, 9 primary care clinics of Group Health Cooperative (GHC), a prepaid health plan enrolling about 500,000 Washington State residents, participated in this study. Demographic characteristics of GHC enrollees are representative of the Seattle-area population. Board-certified family medicine physicians and internists provide the majority of medical services for GHC enrollees. The Human Subjects Review Committees of Group Health Cooperative and the University of Washington approved the study procedures.

**Sample Recruitment and Randomization**

Enrollees aged 18 years or older were recruited from the GHC diabetes registry that included individuals with any of the following: (1) at least 2 fasting plasma glucose levels of greater than 126 mg/dL or a random plasma glucose level of greater than 200 mg/dL, (2) current use of any diabetic medication, and (3) an inpatient or outpatient diagnosis of diabetes. Exclusion criteria included the following: not having diabetes, having gestational diabetes, cognitive impairment, terminal illness, disenrollment or planned disenrollment from the health plan, language or hearing barrier, psychotic disorder, bipolar disorder, use of mood-stabilizing or antipsychotic medication, and current care by a psychiatrist.

A questionnaire was sent to 7,841 eligible individuals with diabetes. In all, 62% responded, and 4,839 were enrolled in the cohort epidemiologic study. To be eligible for the randomized trial, participants were required to have a score of 10 or higher on the Patient Health Questionnaire-9 (PHQ-9) at the initial screening and evidence of persistent depression as measured by a mean item score of 1.1 or higher on the Hopkins Symptom Checklist-20 (SCL-20) 2 weeks later. Patients were not excluded if they had taken antidepressants in the previous 3 months as long as they had persistent depressive symptoms. Among the 375 patients eligible for the depression and diabetes clinical trial, 46 declined randomization. A computer algorithm randomly assigned 164 patients to the intervention group and 165 patients to the usual care group. A detailed description of sample recruitment is described in our earlier publication.
Main Outcome Measures

Self-Care for Diabetes
We used a recently revised version of the Summary of Diabetes Self-Care Activities (SDSCA)27 to assess diabetes self-management behaviors for diet, exercise, blood glucose testing, foot checks, and smoking. The SDSCA is a brief, reliable, valid, and multidimensional measure of diabetes self-care behaviors based on self-report. Patients reported how many days in the previous week they engaged in a certain activity.

Medication Adherence
The GHC automated pharmacy database has recorded all prescriptions filled by enrollees since 1976. We used computerized records of pharmacy refills to derive measures of adherence to oral hypoglycemic agents, antihypertensive agents, and lipid-lowering medications for the year before each patient’s interview date. For each prescription, the days of medication supply were added to the date that the prescription was filled. This second date was considered the expected refill date. If the next refill was obtained after the expected refill date, then the number of days between the expected refill date and the next refill date (days during which a patient lacked oral hypoglycemic, lipid-lowering, or antihypertensive medicines) were labeled as nonadherent days. The percentage of days a patient was nonadherent was then estimated by dividing the total number of nonadherent days in the previous year (numerator) by the total number of days the patient was prescribed oral hypoglycemic agents, including the nonadherent days (denominator). The percentage of days nonadherent allowed us to combine information across patients with varying lengths of follow-up.

The observation window, that is, the number of days a patient was prescribed oral hypoglycemic agents in the year, was estimated to be either 365 for patients already using these medications at the beginning of the year or the number of days between the first prescription and the interview date for patients started on these medications during the year. Patients whose first oral hypoglycemic agent prescription had not been exhausted by the interview date were excluded. A similar measure, using automated pharmacy data, was used in an earlier study to evaluate nonadherence with antihypertensive medications.28

Study Groups
Intervention: Collaborative Depression Care Management
Our year-long intervention focused on enhancing depression treatment, not on diabetes management. Nurses received training on depression diagnosis and pharmacotherapy, behavioral activation, and problem-solving treatment for primary care, similar to the intervention developed for the IMPACT study.29 Nurses collaborated with behavioral health consultants and primary care physicians to provide individualized management of depression care according to patient preference and treatment response. Patients were offered an initial choice of 2 evidence-based treatments: antidepressant medication or problem-solving treatment. The goal of depressive symptom remission was achieved through a stepped care approach that augmented pharmacotherapy, problem-solving treatment, or both with psychiatric consultations and group and community services. Nurse care managers supported depression self-management through behavioral activation, such as exercise, goal setting, and problem solving. Neither diabetes education nor diabetes clinical management was a component of this depression intervention; however, patients could choose physical activity or healthy nutrition for behavioral activation, or could identify another diabetes self-care activity as a problem to tackle in a problem-solving treatment session.

Treatment included an initial hour-long visit followed by twice-monthly, half-hour appointments (telephone and in-person) in the acute phase of treatment (0-12 weeks). Once patients experienced a substantial (at least 50%) reduction in clinical symptoms, the nurse began continuation phase treatment, which consisted of monthly scheduled telephone contacts. For patients who had persistent symptoms or who were socially isolated, nurses offered monthly continuation groups instead of monthly telephone calls. Each nurse was supervised twice per month by a team of a psychiatrist (WK, GES, or EW), psychologist (EJL), and family physician (EHBL) in the review of new cases and patient progress. Nurses interacted regularly (via written notes and verbally) with the primary care physician treating the patient. Our earlier publication details the intervention design and procedures.24

Usual Care
Usual care patients were advised to consult their primary care physician regarding depression treatment. Primary care physicians at GHC frequently prescribe antidepressant medication and can refer patients to the GHC Mental Health Services. Both intervention and usual care patients could also self-refer to a GHC mental health clinician. Primary care physicians provide most of the diabetes care in GHC with occasional support from diabetes consultants for complex patients.

Statistical Analyses
We used t tests to compare characteristics of intervention and usual care groups at baseline. We used regression analysis to model outcomes as a function of intervention status while adjusting for potential con-
founders (age, sex, race, education, comorbid disease severity, diabetic complications, and insulin use) and the corresponding baseline measure. For example, models describing physical activity at follow-up adjusted for physical activity at baseline in addition to potential confounders. We estimated regression models using generalized estimating equations (GEE) with robust covariance estimation to adjust variance estimates for the clustering of patients within primary care physician and of physicians within clinics. Models for outcomes measured at 3, 6, and 12 months used all available data and adjusted for repeated measures within patients over time. We used logistic regression for dichotomous outcomes and linear regression for ordinal outcomes and continuous outcomes (ie, adherence measures).

RESULTS
Sample
Among the 329 randomized patients—164 in the intervention group and 165 in the usual care group—respective rates of completion of assessments were 91% and 93.3% at 3 months, 87.8% and 90.9% at 6 months, and 88.5% and 86.1% at 12 months. In all, 80.5% of intervention patients and 79.4% of usual care patients completed all assessments during 1 year of follow-up.

Baseline Characteristics
The intervention and usual care groups were demographically similar and clinically balanced at baseline with respect to diabetes and depression measures (Table 1). This primary care population with diabetes and coexisting depression had a mean age of 58.5 years; two thirds were women, and one fifth were racial or ethnic minorities. Patients predominantly had type 2 diabetes, with a mean HbA1c value of 8.0%, and 1.5 diabetic complications. About 40% required insulin treatment. A majority of the sample had chronic or recurrent depression (dysthymia or 3 or more previous episodes of depression). Approximately two thirds met criteria for major depression and had moderate depression severity as measured by SCL-20.26 One half of patients had been treated with an antidepressant medication in the preceding 3 months.

Intervention Participation and Depression Outcomes
Almost all of the intervention patients (97.6%) completed the initial visit; among the intervention group, only 14 patients (8.5%) received neither antidepressant nor problem-solving treatment. As reported previously, relative to usual care patients, intervention patients had more adequate antidepressant pharmacotherapy over a 1-year period and less severe depression over time.24

Diabetes Self-Care
There were gaps in quality of self-care activities at baseline for both treatment groups (Table 2). Practicing healthy nutrition or following a recommended diet was reported for about one half the number of days in the preceding week. This largely sedentary and overweight population reported that they engaged in at least 30 minutes of continuous activity for only 2 to 3 days in the previous week. Specific exercise sessions were carried out on fewer than 2 days in the previous week. The proportion of cigarette smokers was lower (but not significantly so) in the intervention group (18%, SD = 11.1%) than in the usual care group (28%, SD = 17.3%). The only significant baseline differences in diabetes self-care found between usual care and intervention groups were a slightly higher number of days with exercise sessions ($P < .005$) and a slightly lower body mass index (BMI) ($P < .03$) among intervention patients relative to usual care patients.

Overall, there was no difference between intervention and usual care in diabetes self-management during the 12-month period (Table 2). When controlling for baseline differences, the intervention group maintained a lower BMI at the 1-year follow-up ($P < .01$). No difference was observed between the 2 groups in healthy

| Table 1. Demographic and Baseline Clinical Characteristics |
|-----------------------------------------------------------|
| Characteristic                                             | Usual Care (n = 165) | Intervention (n = 164) |
|-----------------------------------------------------------|
| Dichotomous characteristics                               | % (No.)              | % (No.)                |
| Female                                                    | 64.8 (107)           | 65.2 (107)             |
| Married                                                   | 54.9 (90)            | 54.8 (94)              |
| Employed (full- or part-time)                            | 45.2 (71)            | 54.2 (84)              |
| White                                                     | 81.1 (133)           | 75.2 (115)             |
| Type 2 diabetes                                           | 95.8 (158)           | 96.3 (157)             |
| Taking insulin                                            | 43.0 (71)            | 38.4 (63)              |
| Major depression                                          | 69.1 (114)           | 62.6 (102)             |
| Lifetime dysthymia                                        | 70.3 (116)           | 67.5 (110)             |
| ≥3 previous episodes of depression                        | 60.5 (92)            | 68.6 (107)             |
| Antidepressant use in previous 3 months                   | 54.0 (101)           | 46.0 (86)              |
| Mean (SD)                                                 |                      |                       |

| Continuous characteristics                                |                      |                       |
|-----------------------------------------------------------|----------------------|
| Age, y                                                     | 58.1 (12.0)          | 58.6 (11.8)           |
| HbA1C, %                                                  | 8.0 (1.5)            | 8.0 (1.6)             |
| Number of diabetic complications                          | 1.5 (1.4)            | 1.5 (1.3)             |
| Baseline SCL-20 score                                     | 1.6 (0.5)            | 1.7 (0.5)             |

HbA1C = hemoglobin A1C; SCL-20 = Hopkins Symptom Checklist-20.
nutrition, following a recommended diet, days with 30 or more minutes of continuous physical activity, days with specific exercise sessions, or smoking status (18%, SD = 12.3% for the intervention group vs 24%, SD = 16.9% for the usual care group; 95% confidence interval for the odds ratio = 0.4-4.9).

**Medication Adherence**

The rate of nonadherence to oral hypoglycemic and lipid-lowering agents and angiotensin-converting enzyme (ACE) inhibitors was quite high among both intervention and usual care patients, ranging from roughly 20% to 30% (Table 3). During the 12-month intervention (postrandomization) period, diabetic patients with depression did not have medication to control diabetes or to prevent complications for about 2-1/2 to 3-1/2 months. At baseline, there were no significant differences in adherence between intervention and usual care groups. After controlling for baseline status, the depression care intervention group had a slightly higher rate of nonadherence to oral hypoglycemic agents compared with the usual care group during the 12-month period ($P < .03$). We did not find significant differences in adherence to ACE inhibitors or lipid-lowering medication in intervention group patients relative to their usual care counterparts.

**DISCUSSION**

In an earlier study, we found that enhancing depression care among patients with diabetes and depression increased adherence to antidepressant pharmacotherapy and problem-solving treatment, and reduced depressive symptoms,$^{24}$ but glycemic control in the intervention and usual care groups was similar. Examining the effects of the intervention on diabetes self-care behaviors showed that improved quality of depression care and depression outcomes were not associated with increases in healthy nutrition, physical activity, or smoking cessation, or increased adherence to ACE inhibitors or lipid-lowering agents. Small but statistically significant between-group differences were seen in adherence to oral hypoglycemic agents and in BMI during the 12-month period. Compared with patients receiving usual care, intervention patients reported lower BMI but poorer adherence to oral hypoglycemic agents; however, these findings were small and of uncertain clinical importance.

Limitations of our study include unknown generalizability of a sample consenting to a randomized controlled trial to other patients with diabetes and depression. Pharmacy refill records were used to measure adherence; these data indicate only prescriptions that were filled, not medications actually taken.$^{30}$ Our measure may even underestimate actual patient adherence. Nonadherence rates of 20% or higher, as reported in this

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**Table 2. Self-Care Activities of Patients With Diabetes and Depression in the Past 7 Days at Baseline and at Various Follow-up Times**

| Activity                          | Usual Care (n = 165) | Intervention (n = 164) | Adjusted Mean Difference (95% CI)† |
|----------------------------------|----------------------|------------------------|-----------------------------------|
| Generally healthy diet, number of days |                       |                        |                                   |
| Baseline                         | 3.7 (2.1)            | 3.7 (2.1)              | —                                 |
| 3 mo                             | 4.3 (2.0)            | 4.1 (1.9)              | 0.15 (–0.15 to 0.45)              |
| 6 mo                             | 4.4 (1.9)            | 4.2 (2.0)              | 0.07 (–0.21 to 0.35)              |
| 12 mo                            | 4.5 (2.1)            | 4.5 (1.9)              | –0.01 (–0.56 to 0.54)             |
| Recommended diet, number of days |                       |                        |                                   |
| Baseline                         | 3.2 (1.6)            | 3.5 (1.7)              | —                                 |
| 3 mo                             | 3.6 (1.7)            | 3.8 (1.8)              | –0.07 (–0.34 to 0.20)             |
| 6 mo                             | 3.8 (1.7)            | 3.9 (1.8)              | –0.01 (–0.22 to 0.20)             |
| 12 mo                            | 3.8 (1.8)            | 4.1 (1.9)              | –0.05 (–0.42 to 0.32)             |
| Physical activity (≥30 min), number of days |               |                        |                                   |
| Baseline                         | 2.3 (2.2)            | 2.6 (2.4)              | —                                 |
| 3 mo                             | 2.7 (2.4)            | 2.7 (2.5)              | 0.08 (–0.43 to 0.59)              |
| 6 mo                             | 2.4 (2.3)            | 2.3 (2.3)              | 0.19 (–0.21 to 0.60)              |
| 12 mo                            | 2.6 (2.5)            | 2.7 (2.4)              | –0.12 (–0.50 to 0.26)             |
| Exercise session, number of days |                       |                        |                                   |
| Baseline†                        | 1.2 (1.8)            | 1.9 (2.2)              | —                                 |
| 3 mo                             | 1.7 (2.4)            | 1.9 (2.3)              | –0.12 (–0.84 to 0.59)             |
| 6 mo                             | 1.7 (2.2)            | 1.6 (2.2)              | 0.19 (–0.37 to 0.76)              |
| 12 mo                            | 1.6 (2.1)            | 1.9 (2.3)              | –0.19 (–0.57 to 0.19)             |
| BMI, kg/m²                       |                       |                        |                                   |
| Baseline§                        | 36.3 (11.1)          | 33.9 (8.6)             | —                                 |
| 12 mo¶                          | 36.1 (10.0)          | 33.0 (7.9)             | 0.70 (0.17 to 1.24)               |

CI = confidence interval; BMI = body mass index.

* Means and SDs are unadjusted.
† Adjusted mean differences and 95% CIs are based on regression models that adjusted for the baseline value, age, sex, race, education, comorbid conditions other than diabetes and depression, complications, and use of insulin, with variance estimates that accounted for clustering of measurements within patients, patients within physicians, and physicians within clinics.
‡ Intervention and usual care groups differ significantly, with adjustment, $P \geq .005$.
§ Intervention and usual care groups differ significantly, without adjustment, $P \geq .05$.
¶ Intervention and usual care groups differ significantly, with adjustment, $P \geq .01$. 

CI = confidence interval; BMI = body mass index.

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study, are clinically important and found to predict subsequent hospitalization rate.\textsuperscript{15} Diabetes-specific self-care behaviors, such as foot checks and self-monitoring of blood glucose, were not examined in this study because those activities levels were similar for depressed and nondepressed patients in our earlier survey.

Contrary to the clinical hypothesis that improving depression treatment and outcomes would enhance diabetes self-care activities and medication adherence, these results show no increase in healthy nutrition or physical activity and lower adherence to oral antidiabetic medications among intervention participants. Our hypothesis was based on cross-sectional findings showing the association of depression with lower adherence to diabetes self-care and medication regimens. Perhaps this seemingly logical assumption reflects too simplistic an understanding of the relation between depression and behavior changes, such as improving levels of healthy nutrition, physical activity, and medication adherence. Increasing these behaviors is achievable but often requires fairly intensive interventions specific to each behavior.\textsuperscript{31-36} A second possibility is that the modest effects of the intervention on depression outcomes may not have been powerful enough to increase optimism and motivation, prerequisites for good self-care.

From a patient's perspective, diabetes self-management is no small task. It has been estimated that about

| Table 3. Nonadherence to Prescribed Medications (Percentage of Days Nonadherent During the 12-Month Prerandomization and Postrandomization Periods) |
|---------------------------------|------------------|------------------|------------------|
| **Medication**                  | **Usual Care**   | **Intervention** | **Adjusted Mean Difference** |
|                                 | % of Days Mean (SD) | No. of Patients | % of Days Mean (SD) | No. of Patients | (95% CI)† |
| Oral hypoglycemic agent         |                   |                 |                   |                 |          |
| Prerandomization                | 22.9 (24.0)       | 103             | 19.8 (21.3)       | 103             | –6.3     |
| Postrandomization\textsuperscript{‡} | 24.0 (24.7)       | 103             | 28.2 (28.9)       | 103             | –11.91 to –0.71 |
| ACE inhibitor                   |                   |                 |                   |                 |          |
| Prerandomization                | 29.7 (29.3)       | 65              | 27.4 (27.1)       | 54              | –2.5     |
| Postrandomization               | 18.9 (17.4)       | 52              | 24.2 (22.7)       | 59              | –8.69 to 3.70 |
| Lipid-lowering agent            |                   |                 |                   |                 |          |
| Prerandomization                | 24.5 (23.0)       | 52              | 29.3 (26.7)       | 50              | –0.2     |
| Postrandomization               | 27.7 (24.0)       | 63              | 28.8 (27.1)       | 54              | –7.23 to 6.76 |

CI = confidence interval; ACE = angiotensin-converting enzyme.

* Means and SDs are unadjusted.

† Estimated differences and 95% CIs are based on regression models that adjusted for the baseline value, age, sex, race, education, comorbid conditions other than diabetes and depression, complications, and use of insulin, with variance estimates that account for clustering of measurements within patients, patients within physicians, and physicians within clinics.

‡ Intervention and usual care groups differ significantly, \( P < .03 \).
adverse outcomes are linked in a bidirectional and reciprocal manner, thus resulting in adverse outcomes. Just as effective diabetes management may be compromised by depression and associated characteristics, such as pessimism and fatigue, effective depression management may also be undermined by symptoms of poor diabetes control, such as neuropathic pain and functional disability. Maximal benefit of treating depression for improving broader outcomes is likely to require direct targeting of specific behaviors most relevant to the patient’s role in managing their coexisting chronic illness.

Because the population is aging, most patients seeking care from primary care physicians will have more than 1 chronic illness. A coordinated therapeutic approach that considers coexisting chronic diseases will be essential. Patients with depression and co-occurring medical illnesses require interventions that advance beyond single-disease case management, such as nurse case managers trained to manage care for related chronic conditions (eg, diabetes and heart disease) and coexisting depression in general medical settings.20 Focusing patients on disease management of 1 chronic illness can have unintended adverse effects on management of other important disorders. Further research is needed to determine whether integrated diabetes and depression care management, including specific support for diabetes medication adherence and self-care activities, as well as systematic depression care, can help patients achieve better psychological and diabetes outcomes.

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