Diabetes and Depression Care: 
A Randomized Controlled Pilot Trial

Heather F. de Vries McClintock, PhD, MSc; Kathleen B. Boyle, BS; 
Kathryn Rooney, BS; Hillary R. Bogner, MD, MSCE

Objective: We examined the comparative effectiveness of an integrated intervention for Type 2 diabetes mellitus (T2DM) and depression by employing patient prioritized planning (PPP) to incorporate patients’ financial, social, and emotional needs versus an integrated intervention alone. Methods: A randomized controlled pilot trial randomly assigned 78 patients prescribed pharmacotherapy for T2DM in primary care to an integrated intervention for T2DM and depression employing PPP to incorporate patients’ financial, social, and emotional needs (enhanced intervention) versus an integrated intervention alone (basic intervention). Hemoglobin A1C (HbA1C) assays measured glycemic control and the Center for Epidemiologic Studies Depression Scale (CES-D) assessed depression. Results: Patients in the enhanced intervention had a significantly greater mean change in HbA1C from baseline in comparison with the basic intervention at 12 weeks (enhanced intervention -0.63 vs basic intervention 0.15; p = .027). Patients in the enhanced intervention also had a significantly greater mean change in CES-D from baseline in comparison with patients in the basic intervention group at 12 weeks (enhanced intervention -3.75 vs basic intervention 0.93; p = .041). Conclusions: Our pilot trial results indicate that an integrated care intervention employing PPP to incorporate financial, social and emotional needs for primary care patients with T2DM and depression may be effective.

Key words: primary healthcare; type 2 diabetes; medication adherence; glycemic control; patient financial, social, and emotional needs


Over the next 25 years the number of persons with diabetes will double.1, 2 Risk of depression is increased by a factor of 2 in patients with diabetes and depression is a risk factor for diabetes.3-6 Depression is not only common in patients with diabetes but also contributes to poor adherence to medication and dietary regimens, poor glycemic control, reduced quality of life, and increased health expenditures.7, 8 Depression has been linked to prognostic variables in diabetes such as micro- and macro-vascular complications.9, 10 Integrated care for depression and diabetes has been shown to help improve clinical outcomes and reduce costs.11 Whereas integrated treatments are effective, their success is hindered when patients have multiple competing demands. Patients frequently have priorities that extend beyond biomedical care which, if not addressed, impede clinical prognosis. Attention to individual priorities is critical to improve treatment adherence as well as subsequent clinical and cost-effectiveness outcomes.12

The importance of social determinants as gradients of health has been well established.13, 14 The contributions of clinical factors and behavioral choices to the prevention and management of diabetes do not adequately explain poor clinical outcomes in diabetes.15 As early as 1943 Abraham Maslow noted that a person is only motivated to focus on higher levels of need after basic physiological and safety needs are met.16 Subsequent theorists have updated Maslow’s theory to incorporate the acceptance of change and the importance of re-prioritizing needs with lifetime learning.17 Consistent with self-determination theory, assessing patients’ priorities can motivate patients to participate in self-care.18 Evidence suggest that patients’
perspectives related to their needs are important to consider because they can affect their overall engagement in healthcare.\textsuperscript{12} Just as a strong patient-therapist alliance is associated with better outcomes in specialty mental healthcare improved patient centeredness is expected to lead to improved self-care, treatment adherence and glycemic control by motivating patients to take better care of themselves.\textsuperscript{19,20}

Basic needs may be financial, social, and emotional in nature, and are important for understanding the causes, management, and treatment of diabetes. Financial needs refer to the attainment of basic goods necessary to maintain health and manage illness such as medications, housing, and transportation. Cross-sectional and longitudinal studies report an association between unmet material needs and high diabetes prevalence, poor control, and increased mortality.\textsuperscript{21} Social support is commonly defined as a perception that one is accepted, cared for, and provided with assistance from certain individuals or a specific group or the realization of actual support received from another. A review of the literature concluded that increased social support is associated with improved diabetes self-management, medication adherence, and adoption of nutritional and active lifestyles.\textsuperscript{22} Emotional needs include self-efficacy, motivation, and empowerment which have been linked with improved self-management behaviors.\textsuperscript{23} Depression has been shown to impede diabetes management.\textsuperscript{7,8} Given the importance of these needs, increasing pressure is pushing the arenas of research, practice, and policymaking to incorporate these broader determinants of health, through the development and implementation of interventions that adequately meet patients' needs.\textsuperscript{24,25}

The Chronic Care Model (CCM) encourages a holistic approach in promoting the use of community resources to meet patients' needs. However, community linkages remain the least developed component in the CCM perhaps because they have been under-resourced.\textsuperscript{26,27} The CCM does not discuss the importance of collecting, assessing, and incorporating information on financial, social, and emotional factors that contribute to chronic conditions. The new paradigm presented through the CCM constitutes a valuable and important framework that may enable the assessment and potential incorporation of broader social determinants of health and patient prioritization. Further work is needed to evaluate the feasibility and efficacy of application of models involving financial, social, and emotional needs in the context of the CCM.\textsuperscript{28,29}

Interventions focused specifically on improving outcomes among persons with diabetes have sought to extend beyond the traditional biomedical model and incorporate social support\textsuperscript{30,31} or material needs.\textsuperscript{32} Interventions have focused on the examination of a single need (eg, housing,\textsuperscript{31} insurance coverage,\textsuperscript{32,33} peer/family individual and/or group social support\textsuperscript{33,38}), recruited primarily from community-based settings,\textsuperscript{31,36,37} insurance rosters,\textsuperscript{32,33} or specialty settings\textsuperscript{34} or have examined outcomes such as the medication possession ratio.\textsuperscript{32,33} Reviews of randomized trials on depression treatment in diabetes found no known studies have incorporated the financial, social, and emotional needs of patients.\textsuperscript{39,40} Whereas interventions focusing solely on conventional biomedical needs may improve short-term outcomes, the long-term goals should be centered on sustainably mitigating clinical outcomes and long-term effects of diabetes for the patient.\textsuperscript{41} A broader framework incorporating a social lens, allows for sustainably addressing the underlying contextual needs of patients that supports long-term improvements in health and well-being. Our study is the first study to use patient prioritized planning to incorporate social, financial, and emotional needs in Type 2 diabetes mellitus (T2DM) and depression care with a focus on medication adherence and glycemic control in primary care settings. An adherence-based approach was employed because although efficacious pharmacotherapy for chronic conditions exists, poor adherence remains a significant impediment to improving care, particularly among patients with co-morbid diabetes and depression.\textsuperscript{42}

The purpose of this study was to carry out a randomized controlled pilot trial to test the effectiveness of an integrated intervention for T2DM and depression incorporating patients’ financial, social, and emotional needs using patient prioritized planning (enhanced intervention) versus an integrated intervention alone (basic intervention). Our intervention builds upon prior work with a problem-solving based intervention.\textsuperscript{43} It was hypothesized patients who were randomized to receive the enhanced intervention compared with the basic intervention would demonstrate the following outcomes after a 12-week period: (1) lower glycated hemoglobin; (2) fewer depressive symptoms; and (3) a greater proportion of patients who had 80% or greater adherence to an oral hypoglycemic or antihyperglycemic agent.

**METHODS**

**Recruitment Procedures**

From September 2013 to February 2015, patients with a diagnosis of T2DM and a current prescription for an oral hypoglycemic or antihyperglycemic agent within the past year were identified through electronic medical records. Patients with an upcoming appointment from 3 primary care practices in Philadelphia, Pennsylvania were approached for further screening. The inclusion criteria were: (1) aged 30 and older; (2) a diagnosis of T2DM; and (3) a current prescription for an oral hypoglycemic or antihyperglycemic agent. The age cut-off was selected because of its significance for the detection, screening, and intervention for diabetic patients. Research suggests that screening for type 2 diabetes may be cost effective after age 30 setting the stage for intervention deployment.\textsuperscript{44}
Studies have excluded more participants than they have included limiting their application to real world settings. In this study we sought to include patients with a range of depressive symptoms to reflect the concept of the relapsing, remitting nature of depression in primary care. Exclusion criteria were: (1) inability to give informed consent; (2) significant cognitive impairment at baseline (Mini-Mental State Examination (MMSE) <21); (3) residence in a care facility that provides medications on schedule; and (4) unwillingness or inability to use the Medication Event Monitoring System (MEMS). MEMS that are placed pill bottles provide electronic monitoring data allowing identification of the precise date and time of container opening.

**Study Design**

The first phase of this study involved a 2-week run-in allowing for the collection of pre-intervention medication adherence data for all patients. No intervention was performed during this phase. During this phase, data also were collected for demographics, glycemic control, and depressive symptoms. After completion of the initial 2-week run-in phase, patients entered phase 2 of the study in which they were randomized to the basic or enhanced intervention. To enable collaboration with the study team, physicians were told which patients were enrolled in the basic or enhanced intervention.

**Basic and Enhanced Interventions**

The basic intervention involved the interventionist collaborating with physicians to provide education, guideline-based treatment recommendations, and to monitor adherence and clinical indicators. Key components of the basic intervention were: (1) an individualized program to improve adherence to oral hypoglycemic agents or antihyperglycemic agents; and (2) integration of depression treatment with T2DM management. Our conceptual framework is based on self-determination theory and is the most practical in its approach and provides a framework that allows for flexible, tailored interventions. Employing a 4-step problem solving process, the interventionist worked with patients individually to address factors influencing adherence in our conceptual model (Figure 1). The first step consisted of identifying and defining the problem resulting in poor adherence. This step concluded when a patient understood why it was essential to take their medications and identified circumstances under which they missed medication doses. In the second step patients identified barriers and brainstormed to develop solutions to overcome these barriers. Thirdly, patients selected a solution and strategized about implementation. Lastly, the patient worked to create an action plan for carrying it out. The fourth step consisted of examining whether the action was employed and the desired effect accomplished.

**Figure 1**

**Conceptual Framework**
The enhanced intervention involved all components of the basic intervention plus patient prioritized planning (PPP). PPP recognizes patients’ social and cultural context by addressing health-related priorities identified by the patient. The goal was to identify priorities that were likely to influence adherence to treatment. Biomedical needs as well as financial, social, and emotional needs patients with T2DM and depressive symptoms wished to discuss in the context of their health were assessed. Patients completed a card sort using Websort software that asked them to look at a list of options for discussion (e.g., trouble getting transportation, not enough money to cover expenses, problems with my relationships with family and others, I need a new place to live). Patients then picked an option by “clicking” on it and “dragging” the option to a box labeled with a level of importance. After completing the card sort, the interventionist engaged in the 4-step problem solving process described above. Interventionists had information about available local resources.

Participants received information about local resources for which they indicated that they wanted help. Resources included information about emergency shelter services, the Department of Public Welfare (Welfare and Medical Assistance), disability services, Medicare and Medicaid, social security income, suicide and crisis intervention line, mental health mobile emergency response center, crisis response centers, domestic abuse assistance, child protective services, Philadelphia Corporation for Aging, First Call for Help (United Way of Southeastern Pennsylvania), Early Intervention ChildLink and Connect Helpline, YMCA social groups, Philadelphia Diabetic Divas (Divabetic) social club, shelter services, residence halls, community behavioral health, CareerLink, unemployment assistance, veterans services, city healthcare centers, soup kitchens and shelters, and community legal resources. Our goal was to create a personalized management plan that empowered patients to prioritize their own needs as a first step towards more active participation in care. After the patient and interventionist completed their discussion around goal setting, the interventionist asked permission to discuss patient’s priorities with the clinical team.

Both the basic and enhanced interventions in-
Measurement Strategy
The Mini-Mental State Examination (MMSE) screened potential study patients for significant cognitive impairment at baseline, as assessed by a total score on the Mini-Mental State Examination (MMSE) <21. Patients presenting with more severe cognitive impairment (MMSE <20) commonly suffer from an underlying dementia and were excluded from our study.47,48 The MMSE is a standardized mental status examination widely employed for research and clinical purposes.49 A comprehensive review concluded that reliability and construct validity of the MMSE were satisfactory.50 Patients were queried about whether they resided in a care facility that provided medications

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Basic (N = 41)</th>
<th>Enhanced Intervention (N = 37)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aged greater than or equal to 65, N (%)</td>
<td>15 (36.6%)</td>
<td>19 (51.4%)</td>
<td>.25</td>
</tr>
<tr>
<td>African-American, N (%)</td>
<td>26 (63.4%)</td>
<td>25 (67.6%)</td>
<td></td>
</tr>
<tr>
<td>White, N (%)</td>
<td>11 (26.8%)</td>
<td>8 (21.6%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic, N (%)</td>
<td>3 (7.3%)</td>
<td>1 (2.7%)</td>
<td>.62</td>
</tr>
<tr>
<td>Asian, N (%)</td>
<td>0 (0.0%)</td>
<td>1 (2.7%)</td>
<td></td>
</tr>
<tr>
<td>Other, N (%)</td>
<td>1 (2.4%)</td>
<td>2 (5.4%)</td>
<td></td>
</tr>
<tr>
<td>Sex, female N (%)</td>
<td>30 (73.2%)</td>
<td>29 (78.4%)</td>
<td>.61</td>
</tr>
<tr>
<td>Less than HS education, N (%)</td>
<td>6 (14.6%)</td>
<td>2 (5.4%)</td>
<td>.27</td>
</tr>
<tr>
<td><strong>Type 2 diabetes mellitus</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of diabetes, Mean (SD)</td>
<td>15.9 (11.1)</td>
<td>15.2 (9.2)</td>
<td>.78</td>
</tr>
<tr>
<td>HbA1C, Mean (SD)</td>
<td>7.6 (2.0)</td>
<td>7.5 (2.0)</td>
<td>.78</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CES-D, Mean (SD)</td>
<td>15.2 (11.3)</td>
<td>13.6 (9.9)</td>
<td>.52</td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of medications, Mean (SD)</td>
<td>9.2 (4.3)</td>
<td>9.8 (4.0)</td>
<td>.54</td>
</tr>
<tr>
<td>&gt; 80% adherent to oral hypoglycemic or antihyperglycemic agent, N (%)</td>
<td>19 (52.8%)</td>
<td>20 (55.6%)</td>
<td>.99</td>
</tr>
<tr>
<td><strong>Functional status (SF-36)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical function score, Mean (SD)</td>
<td>58.1 (30.5)</td>
<td>57.0 (31.9)</td>
<td>.87</td>
</tr>
<tr>
<td>Social function score, Mean (SD)</td>
<td>72.3 (34.9)</td>
<td>68.8 (36.4)</td>
<td>.66</td>
</tr>
<tr>
<td>Role physical score, Mean (SD)</td>
<td>54.9 (40.0)</td>
<td>57.4 (44.0)</td>
<td>.79</td>
</tr>
<tr>
<td>Role emotional score, Mean (SD)</td>
<td>78.9 (34.9)</td>
<td>71.2 (41.7)</td>
<td>.38</td>
</tr>
<tr>
<td>Bodily pain score, Mean (SD)</td>
<td>37.6 (28.7)</td>
<td>46.5 (30.1)</td>
<td>.18</td>
</tr>
<tr>
<td><strong>Cognitive status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMSE, Mean (SD)</td>
<td>27.3 (2.9)</td>
<td>27.1 (3.0)</td>
<td>.67</td>
</tr>
</tbody>
</table>

Note. Abbreviations: HS, high school; SD, standard deviation; Hb, hemoglobin; CES-D Center for Epidemiologic Studies Depression Scale; SF-36, Medical Outcomes Study Short Form; MMSE, Mini-Mental State Examination.

a - N = 72 due to missing values.

volved 3 30-minute, in-person sessions (baseline, 6 weeks and 12 weeks) and 2 15-minute telephone-monitoring contacts over 12 weeks of follow-up. Three research coordinators (one Master’s level and 2 bachelor’s level) were trained as interventionists and administered all intervention activities. Prior to trial initiation, the interventionists received training on pharmacotherapy for depression and T2DM management during weekly clinical sessions with the principal investigator.
on schedule and whether they were unwilling or unable to use MEMS. In-person assessments were conducted at baseline, 6, and 12 weeks for persons in both the basic and enhanced intervention. Research assistants were blinded to a patient’s randomization assignment. Standard questions assessed baseline sociodemographic characteristics. Functioning was important to assess because it may make traveling to physician appointments and pharmacies difficult.\textsuperscript{51} Small print on packaging or hard-to-open packaging can make adherence more difficult. The Medical Outcomes Study Short Form (SF-36) assessed functional status.\textsuperscript{52} The SF-36 has been employed in studies of outcomes of patient care and appears to be reliable and valid even in frail elders.\textsuperscript{52-57}

During the 2-week run-in phase, and at 6 and 12 weeks, adherence to oral hypoglycemic agents or antihyperglycemic agents was measured using electronic monitoring data obtained from MEMS Caps. Adherence rates were defined as the percent of prescribed doses taken. It was calculated as the number of doses taken divided by the number of doses prescribed over the observation period times 100%. Because the proportion of pills taken was highly skewed and failed normality assumptions, adherence was dichotomized at a threshold of 80%. A threshold of 80% has been used to assess adherence to medication regimens in prior work.\textsuperscript{58}

In accordance with American Diabetes Association Guidelines, blood glycemic control was assessed at baseline and 12 weeks by trained research coordinators.\textsuperscript{59} The in2it A1C Analyzer was used to obtain Hemoglobin A1C (HbA1C) assays. Point-of-care testing with this device has acceptable precision and agreement in comparison relative to laboratory services.\textsuperscript{60} The Center for Epidemiologic Studies Depression Scale (CES-D) measured depressive symptoms at baseline, 6, and 12 weeks. This tool contains 20 items and has been utilized in diverse samples. It is a self-report instrument with demonstrated reliability and validity in the general population and primary care settings.\textsuperscript{61,62}

**Analytic Strategy**

The analysis was conducted in 4 phases. In the first phase, the t-test and Fisher’s exact test (for continuous or categorical variables respectively) were utilized to compare baseline characteristics in the basic and enhanced intervention. For the second phase, Fisher’s exact test examined whether there were significant differences in the percentage of patients who were adherent (80% or greater adherence rate) at baseline, 6 weeks, and 12 weeks. In the third phase, patient characteristics of those who participated and who refused were also compared using t-tests and Fisher’s exact tests. Lastly, t-tests were used to compare outcomes for our analysis. Outcomes were HbA1C and depressive symptoms assessed as continuous variables in separate models. As randomized, analysis was conducted at the patient level. To account for extra correlation within individual repeated measures linear models in which mean response (mean HbA1C and depressive symptoms) depends on the covariates of interest (treatment assignment and time since randomization) and an unstructured variance-covariance matrix was utilized. The time-by-treatment interaction was the parameter of interest that represents the relative difference in change over time among the patients assigned to the enhanced intervention group compared to the basic intervention group. The expected value of the outcome in each treatment group at 12 weeks was compared to the value at baseline, the time of randomization. The differences of these treatment specific contrasts were the desired effect. Based on our analysis in phase one, there were no significant differences in baseline covariates; therefore, we did not adjust for any covariates in the analysis. Analyses were conducted using SAS version 9.2.

**RESULTS**

Figure 2 depicts the flow of patients through the trial. Of 285 patients identified by electronic medical records, 109 were eligible and were approached and 80 were enrolled (73.4% participation rate). Consent was followed by a 2-week run-in phase in which adherence to medications was assessed during which one patient was lost to follow-up and one patient withdrew from participation. In all, 78 patients were randomized to the basic or enhanced intervention after the 2-week run-in period. One patient in the basic and one patient in the enhanced intervention was lost to follow-up but the remaining 76 patients completed the final study visit.

**Sample Characteristics**

Baseline characteristics of the 78 patients randomized to the basic or enhanced interventions are provided in Table 1. Characteristics of patients in the basic and enhanced interventions did not differ significantly including adherence rates at baseline measured during the 2-week run-in period (Table 1). Patients who participated and patients who refused were similar in age, sex, and ethnicity.

**Adherence Outcomes**

Figure 3 depicts proportions with 80% or greater adherence to an oral hypoglycemic or antihyperglycemic agent over time according to treatment assignment. At 12 weeks, a significant improvement in adherence to oral hypoglycemic agents or antihyperglycemic agents (p = .014) was seen in the enhanced intervention in comparison with the basic intervention.

**Clinical Outcomes**

Table 2 shows the clinical outcomes at 12 weeks. Patients in the enhanced intervention had a significantly improved HbA1C mean change from baseline in comparison with patients in the basic in-
The primary goal of this study was to pilot-test the comparative effectiveness of an integrated intervention for T2DM and depression that employed patient prioritized planning (PPP) to incorporate patients’ financial, social, and emotional needs (enhanced intervention). Our principal finding was that primary care patients randomized to the enhanced intervention in comparison with patients randomized to the basic intervention showed higher rates of adherence to oral hypoglycemic or antihyperglycemic agents as well as greater glucose control and fewer depressive symptoms at the final study visit. Our results support the effectiveness of an intervention integrating care depression and T2DM that employed PPP to incorporate financial, social, and emotional needs for primary care patients.

Our findings deserve attention because previous intervention trials integrating care for T2DM and depression in primary care have not incorporated PPP to address patients’ financial, social, and emotional needs. Our results can have a significant impact on public health because a primary care-based intervention that is simple, brief, and scalable was conducted. The proposed intervention has the potential to enhance the implementation, sustainability, and effectiveness of integrated care especially for vulnerable populations. A broader framework incorporating a social lens may provide a sustainable approach supporting long-term improvements in health and well-being.

Our findings reinforce the importance of evaluating and incorporating financial, social, and emotional needs and align with prior work highlighting the importance of patient preferences and social
determinants of health among persons with diabetes. In contrast to prior work, our study integrated management of both diabetes and depression and used PPP to incorporate patients’ financial, social, and emotional needs. Our findings are consistent with interventions targeting other medical conditions (e.g., HIV/AIDS and cancer) that have sought to address several unmet financial, social, and emotional needs and have shown promising results. In diabetes, interventions have focused on improving peer/family, individual, and/or group social support through a myriad of approaches such as consultations, peer support, internet-based exchanges, education programs, or support groups. In other work, material needs have been targeted through interventions involving vouchers, food prescriptions, food boxes, housing vouchers, expanding coverage, or conditional cash transfers. In our work we sought to incorporate financial, social, and emotional needs through PPP.

PPP has improved engagement in healthcare and overall health function. A patient-centered approach takes into account patients’ perspectives on their illness (e.g., depressive symptoms are attributed to social stressors), and enables more effective communication and goal setting. Drawing on self-determination theory, PPP emphasizes the need to modify the patient-provider interactions in a manner that supports the needs of the patient. By virtue of their exposure to PPP, patients may experience increased autonomy and competence. Attention to individual priorities for care has shown a favorable impact on patient engagement, treatment adherence, and subsequent clinical indicators. PPP may constitute a feasible and effective strategy for identifying priorities and empowering patients to meet their needs.

The limitations of our study require discussion.

First, patients received care at 3 primary care sites that might not be representative of every primary care practice. However, these practices were probably similar to other practices in terms of key characteristics. Second, all methods for assessing adherence have limitations. We chose to use MEMS caps as our primary measure of adherence because MEMS caps have a low failure rate and may be more sensitive than other adherence measures. Any effect of MEMS caps on medication adherence would be experienced equally in both groups. Third, the clinical relevance of the 80% threshold has not been tested for many medications. Lastly, psychological variables, such as depression, cannot be observed directly and the measures employed may not reflect the construct being measured.

Despite these limitations, these findings help inform the development and modification of existing programs and initiatives. The Chronic Care Model, which is widely employed in primary care settings, encourages a holistic approach to care management. The expansion of this approach to recognize, understand, and potentially address financial, social, and emotional needs may be a promising area of inquiry. Currently under this model, when staff members refer a patient to community resources, they do so without understanding the implication of that need (as seen by the patient) or how important that need is relative to the patient’s other priorities. By default, options for treatment and management are framed in a biomedical context, without explicitly empowering patients to express their health-related priorities. Our work suggests that a lack of “framing the problem” within a larger social context is a major impediment to patient engagement in care. The legitimization of patients as decision makers along with an understanding the

---

### Table 2
Clinical Outcomes of Glycemic Control and Depression Symptoms in Basic and in the Enhanced Intervention at 12 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted Estimate</th>
<th>Estimated between-Group Difference (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic (N = 40)</td>
<td>Enhanced Intervention (N = 36)</td>
<td></td>
</tr>
<tr>
<td>Type 2 diabetes mellitus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1C, Mean change from baseline (SD)</td>
<td>0.15 (0.22)</td>
<td>-0.63 (0.27)</td>
<td>0.78 (0.09 to 1.47)</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CES-D, Mean change from baseline (SD)</td>
<td>0.93 (1.65)</td>
<td>-3.75 (1.51)</td>
<td>4.68 (0.20 to 9.16)</td>
</tr>
</tbody>
</table>

Note.
Abbreviations: Hb, hemoglobin; SD, standard deviation; CES-D, Center for Epidemiologic Studies Depression Scale; and Estimates, 95% confidence intervals and p-values from the statistical models.

- Mean group difference (95% CI) from a repeated measures linear regression model.
implications of a need (as seen by the patient) or how important a need is relative to the patient's other priorities bodes well for increased involvement of patients in care.76

Prior studies for patients with Type 2 DM often have had no influence on clinical outcomes and these interventions have had questionable scalability and sustainability.77 High recruitment, low attrition rates, and the statistically significant improvement in adherence, blood glucose control, and depressive symptoms is a sign that this intervention, tailored towards patient prioritized unmet financial, social, and emotional needs is both feasible and effective for implementation in the real world. In entering the era of the primary care medical home and accountable care organizations, primary care will become the venue for addressing all of the patients’ perceived needs related to their health. This study sought to improve linkages between medical, social and community services including links to senior centers, advocacy organizations, mental health services, legal services, employment services and financial counseling. Further investigations could examine the mechanisms by which this intervention was successful such as through access to services or changes in depressive status.

Future examinations could explore the effectiveness of the intervention through training ancillary health personnel, such as licensed practical nurses (LPNs), who already work in primary care practices to carry out the intervention. Problem-solving approaches, such as the approach employed in our study, have been delivered by a wide range of trained interventionists, from graduate students and social workers to nurses, residents, and physicians, demonstrating that the skills can be taught to healthcare workers of differing backgrounds and expertise.78-81 Community nurses in Great Britain with comparable training to LPNs in the United States have been trained to carry out PST successfully.82,83 Thus, problem solving has been a strategy that can be disseminated and can be carried out by community nurses, a key attribute of any program undergoing evaluation.

An integrated approach to T2DM and depression care in which PPP identified and incorporated financial, social, and emotional needs as part of primary care treatment discussions and decisions was successful in improving adherence and glycemic control. This intervention was brief, did not require a high level of expertise, and was adaptable to community-based primary care settings with patients from vulnerable populations including older adults, persons in inner city areas, and minorities.84,85 Findings should propel the creation and dissemination of frameworks that incorporate financial, social, and emotional needs into care for T2DM and depression care.

Human Subjects Statement

We obtained informed consent from all participants before their participation in the study. The University of Pennsylvania Institutional Review Board approved the protocol and procedures for this study.

Conflict of Interest Statement

All authors of this article declare they have no conflicts of interest.

References

Diabetes and Depression Care: A Randomized Controlled Pilot Trial


57. Stadnyk K, Calder J, Rockwood K. Testing the measurement properties of the Short Form-36 Health Survey in a frail elderly population. J Clin Epidemiol. 1998;51:827-