Randomized Trial of a Tailored Cognitive Behavioral Intervention in Type 2 Diabetes With Comorbid Depressive and/or Regimen-Related Distress Symptoms: 12-Month Outcomes From COMRADE

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OBJECTIVE

This study evaluated the effect of cognitive behavioral therapy (CBT) plus lifestyle counseling in primary care on hemoglobin A_{1c} (HbA_{1c}) in rural adult patients with type 2 diabetes (T2D) and comorbid depressive or regimen-related distress (RRD) symptoms.

RESEARCH DESIGN AND METHODS

This study was a randomized controlled trial of a 16-session severity-tailored CBT plus lifestyle counseling intervention compared with usual care. Outcomes included changes in HbA_{1c}, RRD, depressive symptoms, self-care behaviors, and medication adherence across 12 months.

RESULTS

Patients included 139 diverse, rural adults (mean age 52.6 ± 9.5 years; 72% black; BMI 37.0 ± 9.0 kg/m^2) with T2D (mean HbA_{1c} 9.6% [81 mmol/mol] ± 2.0%) and comorbid depressive or distress symptoms. Using intent-to-treat analyses, patients in the intervention experienced marginally significant improvements in HbA_{1c} (−0.92 ± 1.81 vs. −0.31 ± 2.04; P = 0.06) compared with usual care. However, intervention patients experienced significantly greater improvements in RRD (−1.12 ± 1.05 vs. −0.31 ± 1.22; P = 0.001), depressive symptoms (−3.39 ± 5.00 vs. −0.90 ± 6.17; P = 0.01), self-care behaviors (1.10 ± 1.30 vs. 0.58 ± 1.45; P = 0.03), and medication adherence (1.00 ± 2.0 vs. 0.17 ± 1.0; P = 0.02) versus usual care. Improvement in HbA_{1c} correlated with improvement in RRD (r = 0.3; P = 0.0001) and adherence (r = −0.23; P = 0.007).

CONCLUSIONS

Tailored CBT with lifestyle counseling improves behavioral outcomes and may improve HbA_{1c} in rural patients with T2D and comorbid depressive and/or RRD symptoms.

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The daily self-management of type 2 diabetes (T2D) by patients seen in primary care settings is associated with a variety of health outcomes. However, prior literature suggests that comorbid behavioral problems such as depressive or diabetes-related distress symptoms are common and are associated with poor self-care behaviors and worse intermediate and long-term health outcomes. Specifically, patients with T2D are approximately twice as likely to have depressive symptoms, and this relationship may be bidirectional (1). Depressive symptoms have been shown to impact glycemic control and adherence to treatment (2). Recognizing this comorbidity, Katon et al. (3) described a multidisciplinary care approach using a care manager specifically trained in both diseases, with psychiatrist back-up. Although useful in many settings, this approach may not work in communities without psychiatric support or in populations where psychiatric care may be limited by stigma.

Polonsky et al. (4) described the symptoms of diabetes-related distress, which is a separate and distinct entity from depression (5) but may be associated with depressive symptoms. Diabetes-related distress reflects the emotional distress associated with the disease, defined as "patient concerns about disease management, support, emotional burden, and access to care." A subscale of this instrument that specifically measures regimen-related distress (RRD), or the distress associated with the treatment and monitoring regimen, has been shown to be related to treatment outcomes. The authors have shown that high levels of this specific subscale for RRD have been associated with poor medication behaviors, lower self-efficacy, and higher levels of hemoglobin A_{1c} (HbA_{1c}) (6). Moreover, early evidence by Hessler et al. (7) using an electronic intervention model suggests that reductions in RRD are associated with improvements in medication behaviors and glycemic control. However, this trial was conducted mostly in urban areas, and this may not be generalizable to rural areas or populations with less than optimal Internet access.

New care strategies are needed for busy primary care settings where T2D is most commonly managed. In these settings, comorbid behavioral symptoms may go unrecognized, perhaps in part because of unclear strategies for management once the behavioral symptoms are identified. Preliminary data suggest that formal cognitive behavioral therapy (CBT) may be efficacious in patients with diabetes and comorbid depressive symptoms (8). Whereas large diabetes centers may have staff and programs to identify and manage these comorbid behavioral problems, it is presently unclear whether formal CBT can be successfully provided in busy primary care practice settings and whether this approach can result in improvements in both behavioral and clinical outcomes. The current study was specifically designed to evaluate the pragmatic effectiveness of delivering a carefully designed program of severity-tailored CBT and lifestyle counseling on behavioral and glycemic outcomes in patients with T2D and comorbid depressive and/or distress symptoms at screening in a busy rural primary care practice setting.

RESEARCH DESIGN AND METHODS

Design and Setting

The design, rationale, and methods for the study have been previously published (9). In brief, the current study was designed as a 12-month randomized clinical trial with two parallel arms and 1:1 allocation of eligible patients either to a tailored CBT intervention plus lifestyle counseling and standard medical care (10), or to usual care. The study took place in a large academic family medicine practice in the southeastern U.S. that provides primary care to a large rural population. The practice is a training site for residents, medical students, and other learners and delivers care to a diverse population of African American and Caucasian patients. The study was approved by the East Carolina University Institutional Review Board and registered with ClinicalTrials.gov (NCT02863523), and each participating patient signed a statement of informed consent.

Inclusion/Exclusion Criteria and Study Orientation

Screening criteria for potential inclusion included adult patients (18–75 years) with a medical record–established history of T2D with an HbA_{1c} at screening >7.0% (53 mmol/mol) and with a positive screen for symptoms of distress using the Diabetes Distress Scale 2 (DDS-2) item screener (positive = mean score ≥3 on DDS-2) and/or a positive screen for symptoms of depression on the Patient Health Questionnaire 2 (PHQ-2) item screener (positive = total score ≥3 on PHQ-2). These two-item versions of the full instruments have excellent sensitivity (95% and 97%, respectively) and are defined in greater detail below. Exclusion criteria for screening included a medical record–established diagnosis of advanced disease (e.g., end-stage renal disease, advanced heart failure, blindness, or metastatic cancer) or the presence of alcoholism, cognitive impairment, or major psychiatric illness that would preclude active participation. If the patient signed consent and met all the screening criteria described above, including having an HbA_{1c} value that day that was >7.0%, then he/she was scheduled for an enrollment visit. At enrollment, the patient completed the full DDS-17 and PHQ-9 plus additional baseline instruments that are defined below and was randomized to one of two treatment arms. Patients were then scheduled for an initial orientation visit where arm-specific study content and assessments were reviewed (see Fig. 1 for CONSORT diagram of patient flow). Patients were randomized at the beginning of the orientation visit, held 1 week after the screening visit. Randomization used a blocked randomization process, involving a computer-generated allocation sequence with allocation concealment from treating providers, with eligible patients randomized in blocks of four to the intervention or control group. Consenting patients in both study arms were provided with pictorially rich educational materials about T2D (*Living with Diabetes*, American College of Physicians, product 11033420E). Patients in the usual care arm received general information about follow-up study assessments that are detailed below. Those randomized to the intervention arm also received a weight scale and a patient-friendly Tracking for Success Calendar developed for daily monitoring of self-management behaviors, including fasting blood glucose, weight, medication taken, abbreviated food intake, step count, and mood.

Intervention

The intervention was envisioned as an integrated care delivery model in primary

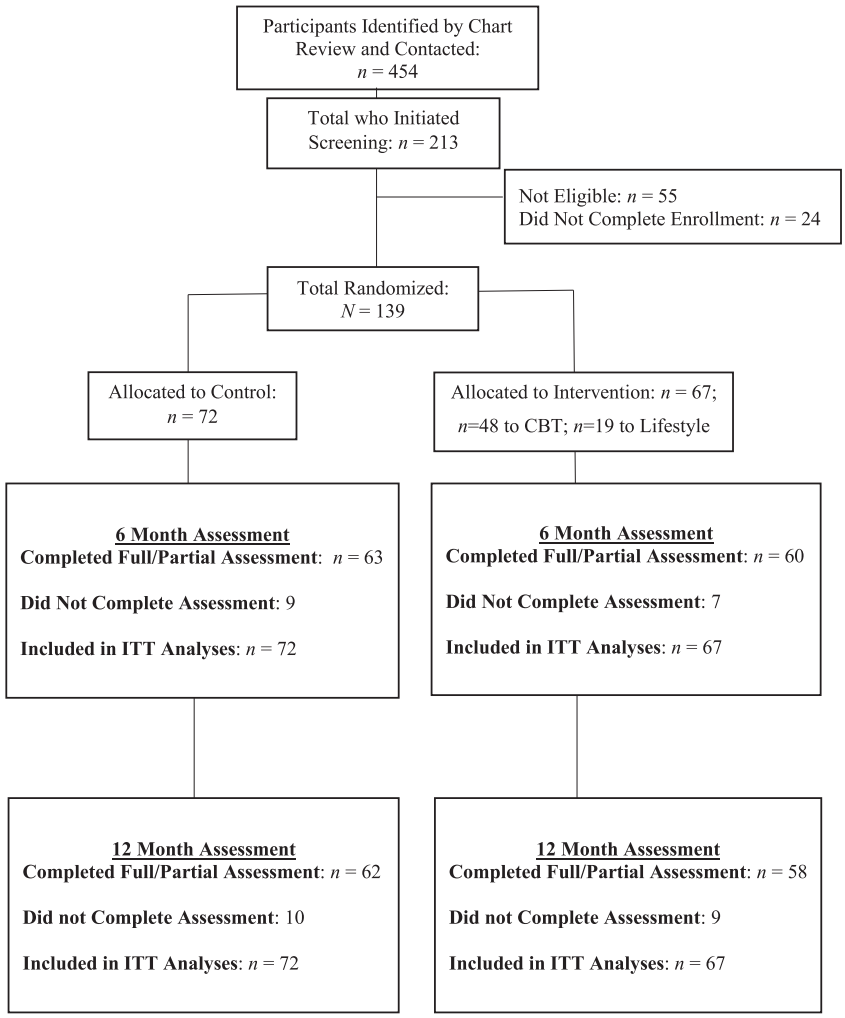

Figure 1—CONSORT diagram of study participants. ITT, intent to treat.

care, bringing together active behavioral intervention with diabetes medical care in the same setting. The intervention was designed to be tailored or severity stratified such that intervention arm patients were assigned to one of two levels of behavioral treatment based on the level of their baseline distress (DDS-17) and depression (PHQ-9) scores, i.e., small-changes lifestyle coaching (if PHQ-9 $<$10 and/or mean DDS-17 $<$2) or CBT (if PHQ $\geq$10 and/or mean DDS-17 $\geq$2). This design was specifically chosen for pragmatic reasons related to *1*) insuring generalizability in primary care where patients with diabetes frequently have either or both of these comorbidities and *2*) exploring whether evidence-based but tailored treatments would relieve varying levels of symptoms of diabetes-related distress and/or depression and facilitate diabetes control when delivered in this integrated care fashion in the context of a busy primary care practice. The proposed stratification design may also have the potential to be more efficient and cost-effective than a standard stepped-care model. This behavioral health intervention had the overarching goal of improving the patient's glycemic control (i.e., HbA_{1c}) as well as improving depressive and/or distress symptoms.

The behavioral intervention was delivered by a team of trained behavioral providers working together, including a nurse care manager who provided small-changes lifestyle coaching (11), a psychologist and clinical health psychology doctoral student who provided CBT sessions including elements of problem-solving therapy (PST) where indicated, and a community health worker (CHW) who provided navigation and social support. In the first 6 months of behavioral treatment, all patients in the intervention arm received one individual orientation session and 12 individually tailored behavioral treatment sessions that included the content described below, delivered by the study staff. Session duration ranged from 30 to 60 min depending on treatment content and individual patient needs; patients were not charged for the behavioral intervention. Sessions could also be provided via the telephone. It should be noted that $<$7% of the intervention arm received one or more phone-based sessions and that these phone-based sessions were provided when barriers prevented patients from attending in-person sessions (e.g., for patients experiencing health or financial difficulties that limited travel).

The small-changes lifestyle treatment subgroup included intervention arm patients with low levels of diabetes-related distress and/or depressive symptoms, and the nurse care manager delivered a twice-monthly telephonic intervention focused on lifestyle modifications to improve diabetes and mood based on the small-changes health behavior change model that we have previously described in detail (11).

The CBT subgroup intervention focused on the reduction of depressive and/or RRD symptoms through modification of negative thoughts and problematic behaviors as well as improvement of diabetes self-management strategies. Sessions were delivered by a clinical health psychologist as well as a doctoral student in clinical health psychology. CBT intervention components were guided by two evidence-based treatment manuals (12,13) for behavioral activation. Session content used cognitive techniques to identify and challenge general and diabetes-specific cognitive distortions that result in maladaptive behavior, in combination with behavioral techniques, including behavioral activation and specific behavior-change strategies related to diabetes and/or mood (self-monitoring, sleep hygiene, eating habits, etc.). These sessions occurred face to face (in the primary care clinic) or via telephonic visits with the health psychologist. Patients who met criteria for the CBT subgroup intervention and yet had more intermediate concerns were provided PST. The PST intervention was based on PST for primary care (14), which is an adapted version of PST specifically for use in primary care clinics. PST, a variant of CBT, focuses on the facilitation of

effective coping and adaptive problem-solving skills and has been shown to be an effective intervention strategy for improvement in diabetes-specific outcomes (15,16).

Standard medical care was continued for both arms. However, primary care providers for patients in the intervention arm were offered consultation with a diabetologist to optimize medical management. Primary care providers were asked to titrate medications to appropriate therapeutic dosages based on finger-stick blood glucose response and subsequent HbA_{1c} values. Patient response, adherence, and potential for side effects were monitored approximately quarterly by the nurse care manager during face-to-face and telephone follow-up, with particular attention to the potential for hypoglycemia associated with insulin and sulfonylurea drugs.

Community-Based Support

All intervention patients had access to a trained CHW who had extensive experience promoting healthy behaviors for chronic disease management in the targeted region. This CHW provided quarterly telephonic peer support and served as a navigator to community resources that helped patients address logistical challenges to implementing healthy behaviors, problem solving, and accessing healthy food/activity in the target community.

Reassessment and Maintenance Treatment

Patients were reevaluated at 6 months using the same validated psychological instruments used to determine initial treatment level (i.e., DDS-17 and PHQ-9), and, at which point, the intervention intensity was adjusted to the severity of patient symptoms. Patients initially receiving small-changes lifestyle intervention were provided a CBT intervention if their depression and/or distress symptoms increased or remained the same. Improved patients who initially began in the small-changes intervention entered a "maintenance phase" consisting of four calls with the nurse care manager to reinforce behavioral changes for the second 6 months. Improved patients who received the CBT intervention during the first 6 months of treatment were provided with the small-changes lifestyle intervention. Patients who did not demonstrate improvement after the CBT intervention were provided with PST, an alternative evidence-based cognitive behavioral treatment for depression. This level of intervention was then maintained from months 6 to 12.

Biological and Psychosocial Measures

Patients in both intervention and usual care groups completed a demographic questionnaire at baseline (age, sex, race [African American, Caucasian, or other], highest education level completed [high school or less, some college, college degree, or any graduate education], marital status [single, married, separated, divorced, or widowed], annual household income [$<$\$40,000/year vs. $\geq$\$40,000/year], duration of diabetes [years; self-reported], and number of doctor visits in the last 12 months). In addition, biological and psychosocial assessments were completed at baseline and at the 12-month follow-up. Weight was obtained using an Eatsmart Precision Plus Bathroom Scale, model ESBS-05. Height was measured using a wall stadiometer. Blood pressure was obtained using an Omron Intellisense Automatic BP Monitor (model BP760; Omron, Inc., Chicago, IL) using a standardized protocol. All patients were seated for 5 min with both feet on the floor and with their arm supported. Blood pressure was measured twice and averaged. HbA_{1c} was measured by finger stick using the Siemens Medline DCA Vantage 2000 HbA_{1c} Reagent Kit.

The study used previously validated psychosocial measures, with all outcome data collected at baseline and 12-month follow-up. These measures included the PHQ-9 (17), a nine-item self-report measure intended for use in primary care settings to assess symptoms of depression, and its associated two-item screening instrument at the time of patient screening for inclusion (18). The study used the DDS-17 (4), a 17-item self-reported measure that is designed to indicate a respondent's level of current emotional distress related to diabetes management, and its associated two-item screening instrument at the time of patient screening for inclusion (19). Scores for the PHQ-9 were summed; scores for the DDS-17 were summed and divided by 17 (i.e., mean score). The DDS-17 also has four subscales, including the RRD subscore, which is an average from five items that assess distress associated with specific treatment and monitoring activities. This RRD subscore was the specific distress end point targeted for evaluation in the current study given prior publications regarding its relationship to glycemic control and given that the intervention was targeted at regimen-related mood and behaviors. The study also used previously validated health behavior measures with data collected at baseline and 12 months. The Summary of Diabetes Self-Care Activities (SDSCA) measure, a validated instrument by Toobert et al. (20), was used to assess diabetes-specific self-care behaviors. Medication adherence behavior was assessed using a validated self-report scale originally developed by Morisky et al. (21) and later modified.

Data Analysis Plan

The primary outcome measure was change in mean HbA_{1c} from baseline to 12-month follow-up. Sample size determination was previously described (9); a sample size of n = 140 was estimated to be sufficient to provide 92% power to detect a difference in change in HbA_{1c} of 0.7 $\pm$ 1.3% (effect size estimate; Cohen D = 0.58) (value based on a similar randomized trial by Bogner et al. [22]) between the two arms. All data were collected by project staff via in-person interviews/assessments at baseline and 12 months and entered into a REDCap database. For participants included in the intent-to-treat analysis but with one or more missing data points, multiple imputation was used to estimate missing values. Multiple imputation was preferred because it can be superior to other missing data approaches (i.e., mean replacement or last observation) and removing patients with missing data from the study (i.e., listwise), which would result in a significant loss of the study sample. All variables with $<$20% of randomly missing data were kept and imputed using the following variables: randomization group, baseline HbA_{1c}, age, duration of disease, and insulin use. To reduce bias from missing data and improve the precision of estimates, a sensitivity analysis was also performed.

The principal outcome measure, change in HbA_{1c}, and secondary continuous outcome measures (e.g., changes in RRD score, PHQ-9 score, weight, and blood pressure) from baseline to 12 months of follow-up were compared (intervention

group vs. usual care group) using a Student *t* test or ANOVA as appropriate. Pearson correlation coefficient was used twice: *1*) to examine the similarity between improvement in the RRD outcome and improvement in HbA_{1c} across 12 months and *2*) to examine the similarity between improvement in medication adherence and improvement in HbA_{1c} across 12 months. A sensitivity analysis was conducted by creating tertiles for the magnitude of response in RRD from baseline to 12 months and then comparing the proportion of patients in each treatment arm who achieved the largest improvement. An exploratory post hoc analysis examined, in a multivariate linear regression model that included data from intervention group patients only, the relationship between change in RRD and change in HbA_{1c} while controlling for changes in PHQ-9 score, self-care activities (SDSCA), and medication adherence. All analyses were conducted using SPSS version 22 (IBM, Armonk, NY).

RESULTS

A total of 139 adult patients with T2D completed the 12-month study and provided data for analysis. Table 1 provides a summary of patient characteristics in the intervention and usual care groups. Patients were generally middle-aged and predominantly African American, with 22% having class 2 obesity and 28% class 3 obesity. Mean HbA_{1c} values were quite elevated (overall mean across both arms = 9.6% [81 mmol/mol] ± 2.0%), and 52% of patients used insulin at baseline. Internal consistency of the self-report instruments in this sample was good, with Cronbach α values as follows: DDS-17 = 0.78, PHQ-9 = 0.82, SDSCA = 0.76, and medication adherence = 0.71. Mean age, HbA_{1c}, weight, systolic blood pressure, RRD score, PHQ-9 score, and self-care activities (SDSCA) score as well as percent female and percent African American were not significantly different at baseline. However, there was a difference in self-reported medication adherence scores at baseline, with the intervention group reporting modestly lower scores (poorer adherence). At baseline, 49% of patients across both groups reported an RRD score of 3 or higher, suggesting increased RRD symptoms, and another 25% had milder symptoms, with a baseline score between 2 and 3. Likewise, ~39% of patients reported a PHQ-9 score of 10 or higher, suggesting increased depressive symptoms, and another 10% had milder symptoms, with a score between 8 and 10. At the 6-month reassessment, a decline of 1 or more in RRD score and a decline of 2 or more in PHQ-9 score were observed in 26% of intervention group patients assigned to the small-changes lifestyle intervention compared with 56% of intervention group participants assigned to the cognitive behavioral treatment.

Changes from baseline to 12-month follow-up in the primary and secondary outcome measures are shown in Table 2. For the primary physiological outcome, at the 12-month follow-up, the intervention group had a greater reduction in HbA_{1c} compared with usual care (−0.92 vs. −0.31), which approached significance (P = 0.06) (Fig. 2). For all psychological outcomes, there were significant differences between groups across time. Specifically, there were significantly greater improvements in RRD (−1.12 ± 1.05 vs. −0.31 ± 1.22; P = 0.001), depressive symptoms (PHQ-9; −3.39 ± 5.00 vs. −0.90 ± 6.17; P = 0.01), self-care behaviors (SDSCA; 1.10 ± 1.30 vs. 0.58 ± 1.45; P = 0.03), and medication adherence (1.00 ± 2.0 vs. 0.17 ± 1.0; P = 0.02) in intervention patients compared with usual care patients. The proportion of patients with an improvement in RRD symptom scores in the upper tertile at the 12-month follow-up was substantially greater in the intervention arm (47%) than in the usual care arm (28%) (χ^2 = 11.2; P = 0.004).

Notably, there were no differences in the mean changes in these psychological and behavior outcomes by race or sex (data not shown). There were also no significant differences in the pattern of mean changes for these psychological and behavioral outcomes when analyzed using only the subset of patients (n = 120) who had complete data, and no imputation of data was required. There was no significant difference in the percentage of patients in each arm who saw a diabetologist during the study period. A total of 17 (25%) patients in the intervention arm versus 12 (17%) patients in the usual care arm were seen by a diabetologist during the study period (χ^2 = 1.6; P = 0.21). Of the 17 patients in the intervention arm, 9 patients (53%) were seen as a direct result of the offer by the investigators to primary care providers; the remaining 8 patients were referred by their primary care provider without reference to the study. Intervention arm patients engaging with their behavioral provider completed, on average, 10.2 ±

Table 1—Baseline characteristics of the study population

Parameter	Usual care arm (n = 72)	Intervention arm (n = 67)	Total (n = 139)	P value
Age (years)	53 ± 9	51 ± 9	52.6 ± 9.6	0.208
% African American	67	77	73.7	0.368
% Female	76	79	77.7	0.703
HbA_{1c} (%)	9.4 ± 1.7	9.8 ± 2.1	9.6 ± 2.0	0.261
Mean HbA_{1c} (mmol/mol)	79	84	81	
Systolic blood pressure (mmHg)	138 ± 18.7	134 ± 19.3	136 ± 19.0	0.298
Weight (lb)	232 ± 56	217 ± 57	225 ± 56.9	0.110
RRD score	2.9 ± 1.2	3.2 ± 1.3	3.1 ± 1.3	0.144
PHQ-9 score	8.8 ± 6.1	9.7 ± 5.9	9.3 ± 6.1	0.361
Self-care activities score (SDSCA)	3.4 ± 1.3	3.2 ± 1.2	3.3 ± 1.3	0.411
Medication adherence score	5.7 ± 1.7	5.0 ± 2.0	5.4 ± 1.9	0.036

Data are means ± SD unless otherwise indicated.

Table 2—Mean change in outcome measures from baseline to 12-month follow-up

	Usual care arm (n = 72)			Intervention arm (n = 67)			
Parameter	Baseline	12-month follow-up	Change	Baseline	12-month follow-up	Change	P value change by arm
HbA_{1c} (%)	9.35 ± 1.7	9.04 ± 2.2	−0.31 ± 2.0	9.88 ± 2.1	8.96 ± 2.1	−0.92 ± 1.8	0.06
HbA_{1c} (mmol/mol)	79	75	4	84	74	10	
Systolic blood pressure (mmHg)	138 ± 18.7	141 ± 18.8	3.2 ± 22.3	134 ± 19.3	133 ± 22.4	−0.5 ± 19.4	0.35
Weight (lb)	232 ± 56	230 ± 55	−2.0 ± 17	217 ± 57	213 ± 57	−5.3 ± 13	0.21
RRD score	2.9 ± 1.2	2.6 ± 1.3	−0.3 ± 1.2	3.2 ± 1.3	2.1 ± 1.2	−1.1 ± 1.0	0.0001
PHQ-9 score	8.8 ± 6.1	7.9 ± 7.0	−0.9 ± 6.2	9.7 ± 5.9	6.3 ± 5.9	−3.4 ± 5.0	0.01
Self-care activities score (SDSCA)	3.4 ± 1.3	3.98 ± 1.3	0.58 ± 1.4	3.2 ± 1.2	4.3 ± 1.4	1.1 ± 1.3	0.03
Medication adherence score	5.7 ± 1.7	5.89 ± 1.8	0.17 ± 1.9	5.0 ± 2.0	6.0 ± 1.8	1.0 ± 2.0	0.02

Data are means ± SD unless otherwise indicated.

6.2 sessions; 93% of these visits were face-to-face encounters and 7% of visits used telephone contact. However, there was not a significant relationship between the number of behavioral sessions completed and the improvement in scores on psychological measures or HbA_{1c} (data not shown).

The decline in HbA_{1c} from baseline to 12-month follow-up was significantly correlated with the decline in RRD (r = 0.3; P = 0.0001) and with the increase in medication adherence (r = −0.23; P = 0.007). Moreover, exploratory post hoc multivariate analyses in intervention group patients only revealed that improvement in RRD (β = 0.30 [95% CI 0.07–0.98]; P = 0.02) and improvement in self-care activities (SDSCA score; β = 0.28 [95% CI 0.05–0.73]; P = 0.03) remained significantly associated with improvement in HbA_{1c} even when controlling for improvement in PHQ-9 score and improvement in medication adherence. Similar to the primary and secondary outcomes, there were no differences based on race or sex for the preset outcomes (data not shown).

CONCLUSIONS

The current study demonstrated that an integrated care model involving the delivery of tailored CBT plus lifestyle counseling to patients with T2D and comorbid depressive or distress symptoms is feasible in the context of a busy primary care practice. Further, patients in the intervention arm experienced an average decrease in HbA_{1c} of almost 1.0. Although this reduction did not reach statistical significance, this reduction is clinically significant, particularly for patients living within a rural geographical region with historically high rates of diabetes morbidity and mortality (23). Given that symptoms of depression are a risk factor for poor medication adherence (24), the results of this study are particularly relevant as findings demonstrated significant reductions in all psychological measures, including symptoms of depression and distress, as well as improvements in lifestyle management behaviors and medication adherence. Taken together, the current study is among one of the only randomized trials demonstrating that a tailored, integrated care model can result in improvements in both behavioral and glycemic outcomes in a rural primary care setting. However, despite the improvement in HbA_{1c}, mean values remained substantially above target at the 12-month follow-up, and more aggressive pharmacologic treatment may be needed as psychological symptoms are reduced. Therefore, continuing to develop treatment models that integrate both medical and behavioral care in order to maximize treatment outcomes is critical.

One of the unique features of the current study was the tailored treatment delivery based on symptom severity at baseline. By focusing on the level of distress and/or depressive symptoms at the beginning of the study, patients were able to receive treatment tailored to their individualized needs instead of a "one size fits all" treatment. The ability to focus treatment on small behavioral lifestyle changes, PST for intermediate concerns, or CBT for greater symptom severity allowed care providers to target symptoms and concerns that were most pressing for each individual. This is consistent with recent research by Fisher et al. (25) who found a significant moderating effect of baseline characteristics (e.g., emotion regulation, diabetes distress, and cognitive skills) on treatment outcomes, indicating the importance of tailored treatment. An additional strength of the current study was the ability to reevaluate patients and refocus treatment based on their own personal progress, which allowed for continued

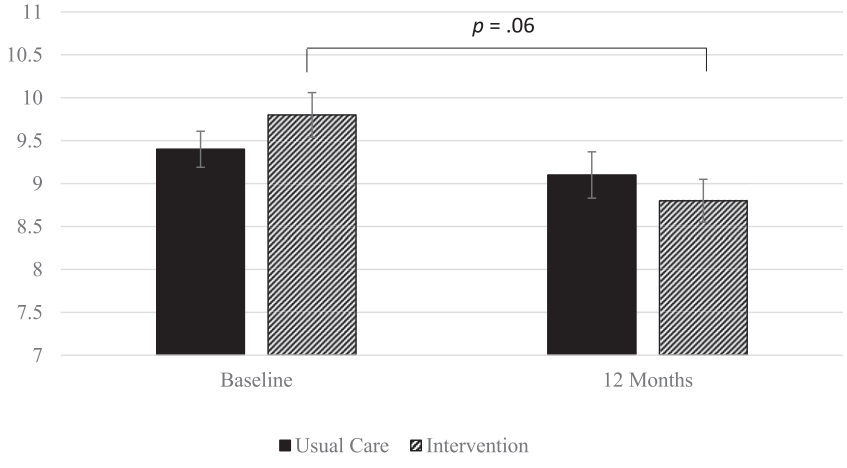

Figure 2—Average HbA_{1c} at baseline and 12-month follow-up in intervention and usual care arms.

growth and support as their individual needs and symptoms changed throughout the year-long treatment. Additionally, the integration of a behavioral health treatment within the context of patients' own primary care clinic may have reduced the stigma and increased patient willingness to engage in treatment with mental health providers such as psychologists. Patients also received support throughout treatment from members of their own community through the care of the CHWs. Prior literature has detailed the benefits of CHW involvement in health treatments, including increasing patient trust and knowledge of community culture and resources as well the effectiveness of CHW-delivered interventions for glycemic control (26,27). In fact, recent research by Spencer et al. (28) found that the improvements in glycemic control and reductions in distress after a CHW intervention can be maintained up to 18 months.

Another significant finding of the current study was confirming the important role that emotional stress plays in impacting physical health outcomes. The study showed that almost twice as many subjects in the intervention arm had improvement in RRD scores at the 12-month follow-up in the upper tertile compared with the control arm. Consistent with the recent recommendations of routine distress screenings for patients with diabetes from the American Diabetes Association (10), our study showed that reductions in RRD were significantly correlated with improvements in HbA_{1c}. We hypothesized that this reduction in RRD might operate through improved self-care behaviors (e.g., diet). In fact, we did find that reductions in RRD were associated with an improvement in the self-care behaviors score across time. These findings are consistent with results from Hessler et al. (7), which demonstrated a relationship over time between self-care activities and glycemic control during an online behavioral health intervention. Further, the findings of the current study are particularly relevant given the similar outcomes experienced by both men and women, and African American and Caucasian individuals. This result suggests that treatment matching based on symptom severity across multiple domains can have favorable outcomes in multiple populations and has significant implications for the treatment of T2D in primary care.

Similar to the relationship between diabetes-related distress and HbA_{1c}, reductions in symptoms of depression were significantly associated with improvements in HbA_{1c}. It is hypothesized that this might operate through similar mechanisms related to improvements in self-care behaviors and medication adherence. In fact, as of 2018, both the American Diabetes Association (29,30) and Diabetes Canada (31) now recommend regular screening for depression and other psychiatric illnesses in all patients with diabetes. Because behavioral comorbidities appear to play a significant and independent role in diabetes self-management, the authors urge researchers and providers to give serious consideration to the addition of even a basic screener for depression and distress (e.g., PHQ-2 or DDS-2) into their routine medical care as a starting point for consideration of additional supports/intervention.

Although there are several strengths to the current study, there are several notable limitations that warrant discussion. With regards to study sample, the study population was composed of two-thirds African American individuals and one-third Caucasian individuals, thus limiting the generalizability of the present findings to other racial and ethnic groups. In addition, the sample only included patients with T2D. Therefore, it is unknown how a similar treatment approach would perform in additional populations of patients with glycemic control concerns such as patients with type 1 diabetes or gestational diabetes. It should also be noted that the current study was conducted in a rural primary care clinic and may not be generalizable in other settings. Further, the model of care that was provided within this study may not be reproducible in settings where health psychologists, psychology graduate students, or CHWs are not available to deliver the various components of the intervention. Although the flexibility and tailored nature of the treatment provided within the intervention group is a strength of the current study, such flexibility may be difficult to reproduce and reduces the internal validity of the study. As such, we suggest that future work should focus on identifying the specific treatment components that result in successfully tailoring treatment and developing manualized guidelines for tailoring treatment in this population. Another limitation is that there is a potential for attention bias because patients in the intervention group received up to 16 additional behavioral visits compared with the control group. Future studies could match for contacts in order to determine treatment effect versus attention effect. In addition, the use of screening instruments for depression has been suggested to include false positives (32). Lastly, for pragmatic reasons, patients in the current study were included with both clinically significant diabetes-related distress and/or depressive symptoms. As such, we cannot determine whether the interventions studied are relatively more effective for diabetes-related distress and/or depressive symptoms.

In conclusion, findings from the current study showed that receiving a severity-tailored CBT intervention with lifestyle counseling resulted in significant improvements in RRD, depressive symptoms, self-care behaviors, and medication adherence as well as clinically significant reductions in HbA_{1c}. This study demonstrated that an integrated care model in the context of a busy primary care setting is feasible and can result in significant improvements in both behavioral and glycemic outcomes. Given the complexities and interacting relationships of glycemic control, engagement in diabetes self-care activities, and mental health concerns, these findings emphasize the need for a more integrated approach involving providers from multiple disciplines as well as CHWs. Although the results of the current study are promising, more in-depth follow-up studies are needed in order to examine the independent effects on distress versus depressive symptoms. Moreover, a larger powered trial across a longer period of time is needed, examining not just mental and physical health outcomes but also health services utilization and costs.

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