Published in final edited form as:
J Cogn Psychother. 2010 November 1; 24(4): 329–343. doi:10.1891/0889-8391.24.4.329.

Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in Type 2 Diabetes

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Abstract

Depression is one of the most common psychological problems among individuals diabetes, and it is associated with worse treatment adherence and clinical outcomes. As part of a program of treatment research aimed at integrating interventions for depression and treatment nonadherence, five depressed patients with suboptimally controlled type 2 diabetes were treated with 10-12 sessions of individual cognitive behavioral therapy for adherence and depression (CBT-AD) in a case-series design. The intervention was delivered in a hospital setting by a collaborative team consisting of a psychologist, a nurse educator, and a dietitian. Post-treatment, all participants demonstrated a decrease in depression severity and demonstrated improvements in diabetes self-care. Four of the five demonstrated improved glycemic control. These preliminary results provide evidence for the acceptability, feasibility, and potential utility of CBT-AD for patients with type 2 diabetes and depression.

Keywords

CBT; Depression; Diabetes; Adherence; Compliance

INTRODUCTION

Depression is a common condition facing individuals with a medical illness in general and diabetes in particular. Patients with diabetes are estimated to be 160-200% more likely to experience depression as the general population (Adriaanse, Dekker, Heine, Snoek & Beekman, 2008; Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001; Egede, 2005; Fisher, Skaff, Mullan, Arean, Glasgow, & Masharani, 2008). When depression is present in these patients, even at subclinical levels, it is consistently associated with worse diabetes control and increased risk of complications of diabetes (Lustman, Anderson, Freedland, 2000; deGroot, Anderson, Freedland, Clouse, & Lustman, 2001). Most strikingly, depressed diabetes patients have been shown to face 2.3 times the risk of mortality as patients with type 2 diabetes who are not depressed (Katon et

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al., 2005). This is of concern because Type 2 diabetes is one of the largest public health problems facing the United States today, affecting approximately 8% of the US population (Centers for Disease Control and Prevention, 2008).

Nonadherence to the diabetes treatment regimen may be one pathway through which depression is associated with worse diabetes outcomes. A recent meta-analysis of depression and treatment nonadherence in 47 independent samples of patients with diabetes documented a consistent association between depression and nonadherence, with effect sizes near the medium range for the relationship between symptoms of depression and most diabetes self-care behaviors (Gonzalez et al., 2008). The relationship between depression and diabetes treatment adherence is important because the ability to treat and manage type 2 diabetes is largely dependent upon patient adherence to a set of complex self-care behaviors (Anderson, 1995). These adherence behaviors include 1) adherence to medications that control hyperglycemia and the metabolic conditions associated with type 2 diabetes, such as hypertension and hyperlipidemia, 2) adherence to dietary recommendations aimed at lowering blood glucose by reducing body weight and improving diet composition, 3) increasing physical activity to improve insulin sensitivity and facilitate weight loss, 4) self-monitoring of blood glucose levels to measure fluctuations in glucose and the impact of behavioral factors on glucose levels (e.g., medication, exercise, diet), and 5) proper preventive foot care to reduce the risk of podiatric complications.

Generally speaking, individuals with diabetes, like individuals with other chronic illnesses, in general, exhibit suboptimal adherence to medical recommendations, with patients with diabetes exhibiting the second lowest adherence rate of the 17 chronic illnesses (see meta analysis by DiMatteo, 2004; Rubin, 2005; Hernandez-Ronquillo, Tellez-Zenteno, Garduno-Espinosa, & Gonzalez-Acevez, 2003; Kirk, Mutrie, Macintyre, & Fisher, 2003). Misconceptions about diabetes and its treatment are prevalent and associated with worse diabetes control (Mann, Ponieman, Leventhal, & Halm, 2009) and concerns about negative effects of treatment, which are often unfounded, are associated with nonadherence to antihyperglycemic and antihypertensive treatments and worse diabetes and hypertension control in patients with diabetes (Aikens & Piette, 2009). These maladaptive cognitions could be especially important in explaining the link between depression and nonadherence as previous work in HIV/AIDS has shown that negative mood states are associated with more concerns about negative effects of treatment (e.g., concern about side-effects, feeling that having to take medicines is disruptive; Gonzalez et al., 2007).

To date, randomized controlled trials of treatments for depression in diabetes patients have been largely successful in improving depression but have had mixed results for diabetes control (For a review see Markowitz, Gonzalez, Wilkinson, & Safren, In Press). One randomized clinical trial of cognitive behavioral therapy (CBT) was successful in improving both depression and diabetes control but, surprisingly, self-care (as indexed by glucose monitoring) decreased in the experimental condition (Lustman et al., 1998). Other depression interventions have also failed to positively impact diabetes self-care (e.g., Lin, Katon, Rutter, et al., 2006). The lack of a consistent effect on diabetes control may result from a missed opportunity to integrate the treatment of depression with cognitive and behavioral strategies to improve diabetes treatment adherence. Given the relationship between depression and poorer treatment adherence, the association between negative mood states and maladaptive beliefs about treatment, and the importance of beliefs about illness and treatment in guiding health behavior, it is likely that interventions for depressed patients struggling with diabetes self-management that employ strategies to simultaneously target depression and adherence behavior may have the strongest impact on hyperglycemia and diabetes outcomes. Cognitive interventions that target beliefs about treatment and illness

that may interfere with treatment adherence are likely to be important in maximizing self-care outcomes.

Cognitive-behavioral therapy for adherence and depression (CBT-AD), originally developed for patients with HIV, integrates cognitive behavioral therapy (CBT) for depression with a CBT intervention designed to promote medical adherence. In the first session of CBT-AD, beliefs about illness and treatment are elicited from patients and special attention is paid to cognitions related to the specific treatment regimen of each patient. Subsequently, cognitive restructuring techniques are employed to challenge maladaptive cognitions. Behavioral strategies and problem-solving approaches are also employed to support successful adherence. CBT-AD has been successful in improving adherence and depression in a randomized controlled trial of patients with depression and HIV that compared the full intervention with a brief intervention focused on adherence alone (Safren et al., 2009). Additionally, CBT-AD has been successful in two case series studies in HIV, one with gay men and the other with HIV-infected injection drug users enrolled in methadone treatment (Safren et al., 2001, Soroudi et al., 2008).

Unlike HIV self-management, which primarily consists of medication adherence, diabetes self-care is composed of several additional important adherence behaviors necessary to control disease progress (e.g., glucose monitoring, diet, exercise, foot care), requiring adaptation of the original intervention. The purpose of the present case series study was, therefore, to examine the degree to which CBT-AD could be applied to the set of adherence behaviors required to manage type 2 diabetes. This intervention is part of a phased approach to psychotherapy research, which includes first conducting studies of feasibility and acceptability in order to obtain an estimate of potential clinical utility, thereby laying the groundwork for a randomized controlled trial that examines the efficacy of CBT-AD for diabetes.

METHODS

Study Design

Two men and three women with diabetes and depression were screened, found eligible for participation, and received the cognitive behavioral therapy intervention for adherence and depression (CBT-AD). Initial assessment of patients for this study occurred between January 2007 and June 2007. All patients received one visit with a nurse diabetes educator, two visits with a dietician, and 10 to 12 sessions of cognitive behavioral therapy for adherence and depression (Safren, Gonzalez, & Soroudi, 2007a, 2007b– described below).

The nurse diabetes educator worked with each patient to set specific directions and goals for the treatment regimen, related to medications, self-monitoring of blood glucose, and foot care. At the initial dietitian visit, the dietitian conducted a comprehensive assessment of past and current diabetes self-management behaviors related to weight loss, diet, physical activity, blood glucose testing results, patterns of hypoglycemia and usual treatment of hypoglycemia. The dietitian then used her diabetes specific knowledge to help each participant set two tailored nutrition goals and one activity goal that were selected based on likelihood of impacting glucose control and each individual's self-confidence in his or her ability to achieve them. At the second visit (6-8 weeks later), the dietitian and participant evaluated progress with these nutrition and activity goals and collaborated to decide on whether to continue working on the same goals, build on them or revise them.

A letter was sent to each patient's provider of choice, usually the primary care physician, regarding any psychiatric diagnoses for which the patient met criteria at baseline. Adherence to hypoglycemic medications and blood glucose testing were electronically monitored over

the course of the study. Patients completed a post-intervention assessment four months after baseline.

Description of CBT-AD in Diabetes

The core modules in CBT-AD are summarized briefly below, and a more detailed description of CBT-AD can be found elsewhere (Safren et al., 2007a, 2007b). Although the modules are presented in a specific sequence, the treatment is designed to provide the clinician with the flexibility to adapt the treatment to the patient's needs. The number of sessions spent on each module is designed to be flexible as well, in order to address areas that are particularly salient to the patient or difficult for the patient to implement.

The intervention is organized into a one-session intervention focused on adherence (Safren et al., 2001), followed by four modules focused on adherence and depression (CBT-AD; Safren et al., 2007a, 2007b). The first session, referred to as "Life-steps" (Safren et al., 2001), is a stand-alone, one-session intervention designed to improve adherence to medical recommendations for the effective management of chronic illness. Life-steps begins with a discussion of their illness, including cognitions related to illness and self-care behaviors. It then consists of eleven informational, problem-solving, and cognitive-behavioral steps that target a range of self-care behaviors, enabling the therapist to identify problem areas for the patient, analyze deficits in adherence, and suggest solutions for addressing barriers to self-care. One important aspect of the intervention is to try to help patients change their cognitions about self-care behaviors in that we elicit positive reasons for being adherent (e.g. "I want to be healthy for my children") and actively think such thoughts when engaging in adherence behaviors instead of focusing on potential cognitive barriers (e.g. "This illness limits me", "Taking these medicines remind me that I am sick"). By the end of the session the therapist and participant collaboratively establish goals for the patient.

After Lifesteps, nine to eleven sessions of CBT-AD focus on addressing deficits in self-care and teaching specific cognitive behavioral skills to treat symptoms of depression. Each therapist determined whether the tenth and eleventh sessions were necessary on a case-by-case basis, depending on patient needs and the therapist's assessment of patient progress. At the beginning of each treatment session, the patient completed the BDI and several adherence questionnaires, and the patient's glucometer and pill cap were read electronically. The therapist then addressed remaining deficits in self-care and established new goals as necessary.

The first module of the intervention (two sessions) introduces the patient to the nature of cognitive behavioral therapy and transitions into motivational interviewing for behavior change. The second module (one session) focuses on behavioral activation and activity scheduling with mood monitoring. Monitoring of blood glucose levels and tracking dietary and physical activity behaviors that influence glucose levels is another key component of this module. The third module (five sessions) focuses on thought monitoring and cognitive restructuring. Elicitation of maladaptive cognitions, identification of distortions, and training in cognitive restructuring target both thoughts relevant to depression and those relevant to diabetes treatment adherence and self-care. A common cognitive strategy used with all patients was to challenge patients' tendencies to engage in self-blame or avoidance in regard to glucose monitoring (e.g., 'my glucose values are always bad so I'd rather not know' or 'I don't want another reminder of how I've failed with my diabetes') and to restructure these cognitions toward an approach to self-monitoring that was based in curiosity and hypothesis-testing rather than judgments of good versus bad numbers. For example, patients were encouraged to think about what factors (e.g., diet, exercise, adherence to medications) might explain personal variations in glucose values rather than exclusively focusing on the fact that values were too high. The fourth module (two sessions) focuses on problem-solving

as a skill to aid in the decision-making process. Problem-solving can be used to address any remaining issues related to depression and self-care behaviors that have not been resolved at this point. The fifth module (two sessions) involves instruction in relaxation training, including diaphragmatic breathing and progressive muscle relaxation.

Participants

All participants were recruited from the Massachusetts General Hospital Diabetes Clinic. In order to participate, patients were required to be between the ages of 18 and 70, carry a diagnosis of type 2 diabetes that remained suboptimally controlled despite use of an oral hypoglycemic (Hemoglobin A1c [HbA1c] > 7.0), and meet criteria at baseline for major depressive disorder or dysthymia. Patients were excluded if they met criteria for any untreated major mental illness that would interfere with their ability to participate or provide informed consent (e.g., psychosis, bipolar disorder, eating disorder, mental retardation, dementia). Patients were excluded if they were currently receiving, or had ever received, cognitive behavioral therapy for depression. Patients using an insulin pump were also excluded due to differences in the self-care behaviors required by this device, as compared to self-injected insulin. Patients were required to have been stable on any medication prescribed for diabetes or depression for two months before beginning the study in order to establish accurate baseline values for depression and glucose control.

Assessments

Clinician-administered assessments of diagnosis and severity—In order to assess depression severity at baseline and after treatment, the following clinician-administered measures were completed by an assessor who was not the client's therapist (an independent assessor).

Psychiatric diagnosis: The Mini International Neuropsychiatric Inventory (MINI; Sheehan et al., 2003) was used to establish baseline diagnoses for all patients. The MINI is a valid, structured psychiatric diagnostic tool that has been shown to reliably detect DSM-IV psychiatric disorders through the administration of questions regarding specific symptoms of various diagnoses.

Depression: The Montgomery-Asberger Depression Rating Scale (MADRS; Montgomery & Asberg, 1979), a structured ten-item interview, was utilized to measure specific symptoms of depression and to provide a rating of severity of depression over the past seven days. The scale has acceptable reliability, validity, and sensitivity to change (MADRS; Montgomery & Asberg, 1979). The MADRS was chosen over other clinical assessments of depression such as the Hamilton Depression Rating Scale (Hamilton, 1960) because of its emphasis on symptoms of depression that are not somatic in nature.

Clinical Global Severity of Depression: The Clinical Global Impression (CGI; Guy, 1976; 1 = not ill to 7 = extremely ill) was utilized to provide a comprehensive rating of depression. The CGI is a valid and reliable measure of the severity of global impairment and distress related to depression, with a score of 3 or higher signifying that the patient meets criteria for the disorder in question.

Participant Self-Report Measures

Beck Depression Inventory: Participants completed the self-reported Beck Depression Inventory (BDI; Beck et al., 1961) during the pre- and posttreatment assessments, as well as during each of the eight weekly therapy sessions. Approximate BDI cutoff scores of severity of depression include: 1-13 = minimal; 14-19 = mild; 20-28 = moderate; and 29-63 = severe

depression. The BDI has a strong history of psychometric reliability and validity and is widely used in a variety of clinical populations. While a revised version of the BDI has been published (BDI-II; Beck, Steer, Brown, 1996), we chose the earlier version because it assessed symptoms over a one-week period rather than the two-week period assessed by the BDI-II.

Adherence Questionnaires: A self-report questionnaire regarding medication adherence was utilized at each study visit to supplement the electronic pill cap. This self-report measure asked patients to document the names and dosing schedules for each of their diabetes medications and to record the number of missed doses since the last study visit (Chesney et al., 2000). These self-reports were used to supplement electronically monitored medication adherence (see below). Patients also completed a questionnaire regarding their own ability to adhere to diabetes self-care behaviors at each visit (Summary of Diabetes Self-Care Activities Scale; Toobert, Hampson, & Glasgow, 2000). This questionnaire is widely used in diabetes research and measures adherence to recommendations for self-care within the following domains: general diet, specific diet, exercise, glucose monitoring, foot care, and medication. Each subscale is scored to reflect the number of days over the past week on which adherence to each domain was adequate. For the medication subscale, this reflects the number of days that the participant did not miss a dose of a diabetes medication, including insulin, if applicable. Based on a review of seven studies, the authors found that the questionnaire had acceptable psychometric properties, with adequate internal reliabilities for all subscales except the specific diet subscale, which often had a low inter-item correlation. Evidence for validity for the diet and exercise scales was also obtained by significant correlations between subscales and various established measures food consumption and physical activity. Sensitivity to change was also established, although estimates ranged rather widely from small to large effects (Toobert et al., 2000).

Adherence Monitoring Devices

Electronic pill cap: Each patient was given a Medication Event Monitoring System (MEMS; AARDEX Inc.) cap, which registers each time the patient's medication bottle is opened. Electronic pill caps have been validated in studies of medication adherence in type 2 diabetes (e.g., Mason, Matsuyama, & Jue, 1995; Matsuyama, Mason & Jue, 1993; Rosen et al., 2003). Self-report was utilized to supplement MEMS data. Patients were oriented to the use of the MEMS cap during the baseline visit. At that time, a study staff member and the participant collaboratively chose one oral hypoglycemic to place in the bottle based on frequency and difficulty (per patient report) of dosing. Patients were instructed to continue taking their medication as usual during the first two weeks of the study, and adherence levels for this period were utilized to calculate one-week baseline medication adherence. Medication adherence was calculated as a percentage by dividing the number of prescribed doses by the number of doses taken. MEMS caps were read at weekly visits and at the post-treatment assessment. A "corrected" MEMS score was used if participants could recall times when they took pills but did not use the bottle (i.e. "pocketed doses"); those doses were counted as taken doses, a technique found to increase the accuracy of electronic medication monitoring among patients with HIV (Liu et al., 2001, 2006; Llabre et al., 2006). In each session, patients were provided with feedback regarding any pattern of missed doses, and the therapist and patient together utilized problem-solving techniques as needed to improve medication adherence. Dosing time and frequency were downloaded via device-specific software.

Glucometer: One Touch Ultra meters (LifeScan, Inc) were used in this study to provide a measure of daily glucose control and frequency of self-monitoring of blood glucose. Glucose monitoring has been found to correlate with other aspects of diabetes self-care

(Goodall & Halford, 1991; Kurtz, 1990). Patients were oriented to the glucose monitor during the baseline visit. Each patient was instructed to test two times per day until he or she met with the nurse diabetes educator, at which time the nurse adjusted testing recommendations based on clinical judgment. Weekly and baseline glucose adherence was established by calculating the number of times the patient tested divided by tests prescribed. At weekly sessions, patients were provided with feedback regarding any pattern of missed tests and fluctuations in glucose values. The therapist and patient together utilized problem-solving skills to improve glucose testing adherence and to attempt to identify and address behaviors that contribute to hyperglycemia. Testing frequency, timing, and blood glucose values were downloaded utilizing device-specific software.

Laboratory Tests

Assessment of Diabetic Control: During the baseline and post-treatment assessments, patients provided a blood sample in order to measure Hemoglobin A1c (HbA1c), which assesses the patient's average glucose level over the past 3 months. This value was obtained with the glycosylated hemoglobin assay, which provides the most objective and reliable information about long-term glucose control in diabetic patients (Nathan, Singer, Hurxthal, & Goodson, 1984; Singer, Coley, Samet & Nathan, 1989). Based on data from two large clinical trials, patients who are able to maintain an HbA1c of less than 7% have been found to have lower risks of complications than patients with higher HbA1c values (The Diabetes Control and Complications Trial Research Group [DCCTRG], 1993; United Kingdom Prospective Diabetes Study Group [UKPDSG], 1998a, b).

RESULTS

Baseline Patient Characteristics

A brief description of each of the five participants who met criteria for participation and completed treatment follows. For all participants, one-week corrected MEMS and glucometer adherence are presented. We do not report complete personal information in order to protect participant confidentiality. Only medications relevant to glycemic control and psychological functioning are mentioned. Although we report baseline medication adherence based on MEMS caps data and adherence to glucose monitoring based on downloaded values, it is important to note that these are not true baseline values. Baseline medication and glucose testing adherence were calculated after the patient had begun the study, based on use of these devices between the baseline assessment and the visit with the nurse educator. During this time, all patients were instructed to take their medications as prescribed and to monitor their blood glucose at least twice a day, or more, if instructed to do so by their health-care provider. Therefore, because participants knew they were being observed during this period, the baseline levels reported below may be higher than true baseline values and were often higher in comparison to baseline self-reports.

Case 1 was a White non-Hispanic male in his mid-60's with a baseline HbA1c of 7.1% and a Body Mass Index (BMI) of 38.4. At baseline, the patient met criteria for dysthymia and major depressive disorder, current (CGI of 3, mildly ill), with a MADRS score of 18 (moderate severity). In addition to one oral hypoglycemic, the patient reported taking insulin and an antidepressant. One-week baseline corrected medication adherence was 93%, and adherence to glucose testing was 64%. The patient was diagnosed with diabetes approximately 11 years prior to enrollment. This patient reported being married, having completed college, and working full-time. The patient reported diet and exercise as the areas of self-care he found most difficult to master. He exhibited a moderate degree of self-blame and use of 'should-statements' about his diabetes self-care. The patient reported a low level

of motivation to change and reported little confidence in his ability to maintain changes over time.

Case 2 was a Hispanic male in his mid-50's with an HbA1c of 9.5% and a BMI of 37.8. At baseline, the patient was diagnosed with major depressive disorder-current, recurrent (CGI of 4; moderately ill) with a MADRS score of 20 (moderate). At baseline, the patient reported taking insulin in addition to one oral hypoglycemic. Baseline medication adherence was 100%, and baseline glucose testing adherence was over 100%. The patient reported having been diagnosed with diabetes 15 years prior to enrollment. The patient reported completing some high school, living with his wife and family, and working full-time. The patient reported cognitions related to feeling overwhelmed with diabetes self-care, especially diet and insulin adherence. Prior to enrolling, he reported that he was often nonadherent to medications and glucose monitoring. This patient reported a great deal of maladaptive cognitions about his ability to manage diabetes and live a healthy life. His cognitions about diabetes were fatalistic: he believed there was very little he could do that would make a difference in his illness and expected to die a horrible death from diabetes. He felt ashamed of his lack of adequate diabetes control and engaged in a great deal of self-blame and 'should-statements.' Other cognitions included thoughts that having diabetes meant that he was a 'weak person' and reported that he believed diabetes was a punishment for past behavior. He often avoided glucose monitoring and other self-care behaviors because they reminded him of his diabetes and perceived failings in self-control.

Case 3 was a non-Hispanic White male in his early 40's with a baseline HbA1c of 12% and a BMI of 41.9. The patient met criteria for major depressive disorder-current, recurrent and dysthymia (CGI of 5; markedly ill) at baseline, with a MADRS of 27 (moderate). The patient also met diagnostic criteria for panic disorder with agoraphobia and obsessive compulsive disorder (obsessions only) at baseline. The patient reported taking three oral hypoglycemic medications but no insulin or psychiatric medications. Baseline medication adherence was 57%, and baseline glucometer adherence was 0%. The patient was diagnosed with diabetes 2 years before study enrollment, and he reported completing college, being married, and being self-employed. This patient reported a number of maladaptive cognitions about diabetes including self-blaming cognitions about his inability to have enough 'will-power' to control his diet and be consistent with glucose monitoring and medications. Attempts at better self-care were seen as unlikely to be enough to make an appreciable change in outcome (e.g., all-or-nothing thinking). He was also quite resistant to begin insulin therapy, despite considerable efforts from his providers to convince him that insulin therapy would be necessary to achieve a lower HbA1c. He reported that he feared becoming hypoglycemic on insulin and had concerns that the injections would be painful and would leave marks on his skin.

Case 4 was a non-Hispanic White female in her mid-40's with a baseline HbA1c of 8.1% and a BMI of 38.3. At baseline, the patient was diagnosed with major depressive disorder, current, single episode (CGI of 4; moderately ill), with a MADRS of 30 (moderate). The patient reported taking medication for depression, an oral hypoglycemic, and insulin. Baseline MEMS adherence was 93%, and baseline glucose testing adherence was 48%. The patient reported being diagnosed with diabetes approximately seven years before study enrollment, completing high school, living with her family, and working full-time. The patient reported that glucose monitoring and diet were the areas of self-care she wished to target in treatment. Her cognitions about glucose monitoring were particularly maladaptive and are illustrative of her overall avoidant approach to diabetes. Some thoughts included the notion that while glucose monitoring would give her useful information about her diabetes that knowing her glucose levels would only make her feel more depressed. At baseline she reported several maladaptive thoughts related to diabetes self-care, including the cognition

that she was unable to make any difference in her diabetes, that she was being punished for an unhealthy lifestyle during her youth, and that she was unable to make changes in her depression and diabetes because she was weak and lazy.

Case 5 was a White non-Hispanic female in her mid-40's with a baseline HbA1c of 7.4% and a BMI of 39.2. At baseline, the patient was diagnosed with major depressive disorder-current, recurrent (CGI of 5, markedly ill), and Generalized Anxiety Disorder, with a MADRS score of 29 (moderate). The patient reported taking an oral hypoglycemic, two types of insulin, and an anti-depressant at baseline. The patient's oral medication adherence was 100% at baseline, insulin adherence was less than 100%, and glucose testing was 19%. The patient reported being diagnosed with diabetes approximately 14 years prior to enrollment, completing college, living with family, and working full-time. This patient reported that attending medical appointments, following a healthful eating plan, exercise, and glucose testing were difficult areas of self-care for her. She also exhibited important maladaptive cognitions about her diabetes treatment regimen. She had little belief in her ability to make changes in her diabetes or depression and often used avoidance and denial to cope with these conditions.

Outcome of Case Series

We first report general trends in outcome data, and then present a qualitative overview of patient progress during therapy, based on patient self-ratings and therapist assessments of patient progress. All five patients completed the treatment, including pretreatment and post-treatment assessments, demonstrating evidence for the feasibility and acceptability of our intervention and assessment procedures. Objective measures of medication adherence demonstrated improvements for most patients in the study. Three patients demonstrated improvements in glucose testing between baseline and post, while two did not. All patients except one experienced a decrease in HbA1c between baseline and post. Two patients experienced a decrease in HbA1c from above 7 to below 7, the treatment goal for most patients. All patients experienced a decrease in MADRS score between baseline and post. Only one patient was still classified as clinically depressed at the post assessment, according to the MINI. BDI scores were slightly less responsive with one patient showing an increase and one patient showing no change from pre- to post-assessment. The three remaining patients reported decreases on the BDI. In addition, all five of the patients experienced a decrease in CGI. Cases 1, 4, and 5 experienced a drop of one point in the CGI, and cases 2 and 3 experienced a drop of 3 points in the CGI (see Table 1). Based on patient self-report measures concerning adherence to multiple self-care activities for diabetes, all patients improved in at least 3 of the following areas: general diet recommendations, specific diet recommendations, exercise, blood glucose testing, foot care, and medication (see Table 2).

Because the improvements demonstrated by patients in the study were not always quantifiable, we also present a summary of treatment progress here. Case 1 reported struggling with his goal of increasing healthy eating habits and exercising regularly at baseline. At post, he was able to increase the frequency of walking and the servings of fruits and vegetables consumed each day, and to decrease the servings of high fat foods or red meat he ate each week by completion of treatment. His cognitions about diabetes and his self-care routine had changed, resulting in a reported a sense of mastery over diet and exercise by the end of treatment. He was also making continued use of behavioral activation and mood monitoring strategies. This patient experienced improvements in all measures of adherence and depression during treatment.

Case 2 reported increases in self-rated adherence to medication, glucose monitoring, diet, and exercise, with a significant increase in activity between baseline and post. This patient experienced a slight decrease in glucose testing frequency between baseline and post;

however, his baseline frequency of testing was quite high and much higher than his self-reported glucose testing prior to enrollment (see discussion below). Activity scheduling and mood monitoring, as well as cognitive restructuring, were particularly useful strategies for this patient. By post, he was much more engaged in his diabetes management, attended medical appointments more regularly, and reported a remarkable shift in his sense of self-efficacy for diabetes management. Upon completion of treatment, he reported that the program had, “saved his life.” This patient improved in all objective measures except for glucose testing.

Case 3 improved on all measures of adherence and depression between baseline and post and agreed to begin insulin therapy, which he had refused in the past. His acceptance of insulin therapy was directly related to the use of cognitive restructuring techniques to challenge maladaptive beliefs about the risks of insulin and the meaning of taking insulin (e.g., If I have to take insulin, that means I failed at managing my diabetes on my own). This patient experienced a striking decrease in HbA1c, most likely due to beginning insulin therapy and being adherent to his prescribed insulin regimen. He was quite responsive to cognitive restructuring and was able to challenge and replace maladaptive cognitions about himself and diabetes with more adaptive cognitions. He exhibited less self-blame and less avoidant coping over the course of treatment.

Case 4 experienced a less dramatic decrease in depression than the other patients in the trial and was the only patient who experienced an increase in HbA1c over time. This patient was an unusual case because she experienced several major stressful life events during the course of treatment (spouse suffered a severe health event during treatment, she lost her job, they separated, patient’s house was foreclosed upon, she moved in with a relative because of financial hardship). We cannot be sure that these factors had any influence on this patient’s outcomes and, despite these events, this patient experienced improvements in all measures except HbA1c. She requested and was referred to continued psychotherapy after study completion due to the difficulties she was experiencing in her home life.

Case 5 was diagnosed with depression and generalized anxiety disorder at baseline but did not meet criteria for either diagnosis at post. Her MADRS score decreased by 15-points from baseline to post-intervention. In contrast, this patient’s BDI score increased from baseline to post-intervention. Although this patient experienced slight decreases in objective measures of medication and glucometer adherence between baseline and post, she reported overall improvements in glucose testing, medication adherence, and foot care at post by treatment completion, as measured by the SDSCA (see Table 2). This patient demonstrated an unusually variable level of glucose testing adherence during treatment, maintaining a level of testing higher than baseline throughout much of treatment. This patient tested 50% or more of the recommended times for 9 of 12 treatment sessions and tested more than 85% at 4 of these visits. This patient also attended her first appointment in 9 months with her diabetes physician while participating in the study, an issue she reported struggling with in the past. This patient experienced improvements in HbA1c and interviewer-assessed depression between baseline and post-intervention.

DISCUSSION

This study provides preliminary evidence for a successful adaptation of CBT-AD, originally developed for patients with HIV, to its application to type 2 diabetes. CBT-AD appears to have been acceptable to all patients (based on successful participation and positive feedback) and may have been helpful in producing improvements in diabetes self-care and depression. All participants experienced an improvement in depressive symptoms (as measured by the MADRS), and four of five patients demonstrated improvements in both

depression (MADRS) and glycemic control (HbA1c). Although only three of five patients experienced an increase in glucose testing adherence (measured by glucometer) between baseline and post, with the caveat that the baseline data for this measure was collected post-enrollment and may have been inflated since participants were instructed to test their glucose regularly and were made aware that study staff would be examining glucometer data in the study. If self-report for glucose testing at baseline (covering the week prior to enrollment) is considered instead, all participants reported improvement in glucose testing. Four of five patients demonstrated either an increase in medication adherence between baseline and post or maintenance of 100% adherence from baseline to post (based on baseline MEMS cap data collected after enrollment). If self-report data, which reflected medication adherence prior to enrollment at baseline, are considered instead, all patients reported either a maintenance or improvement in medication adherence. Finally, all five patients reported difficulty with self-care behaviors related to diet. Since the nutrition interventions provided were selected based on potential to impact glycemic control and each participant's perceived self-efficacy to achieve them, this may be an important consideration as to why patients not only reported improvements in diet and activity behaviors, but also as to why this intervention improved both depression and glycemic control in most patients.

The results of this study must be considered within the context of its design. First, as a case series study, with only five participants, generalizability is limited. Second, as participants were not randomized, the degree to which depression would have improved based on this particular intervention, or over time without intervention, is unknown. Furthermore, while we sought to use objective measures for glucose testing and medication adherence, these data were compromised by a lack of a 'true baseline adherence score.' Baseline values for these measures were collected post-enrollment and consent and thus may have been unrealistically high because of the effects of enrollment in the study, especially considering that patients were aware of the outcome measures the treatment targeted. Baseline self-report values for these variables suggest that adherence was lower prior to enrollment. Decreases in mean glycemic control, measured by HbA1c, for most patients suggest overall improvement in self-care behaviors. It is worthy to note that, because the HbA1c test captures average glucose levels over a 3-month period, the approximate length of the intervention, our post-treatment measure may under-estimate longer-term effects of the treatment on HbA1c. Finally, our use of the BDI rather than the BDI-II may also be seen as a limitation in that the BDI is less consistent with the diagnostic criteria for major depressive disorder than the BDI-II. However, it should be noted that the correlation between the two measures has been reported to be high at .93 (Beck, Steer, Brown, 1996).

Despite these limitations, the results of this case series study suggest that the treatment was feasible and acceptable to patients. Patients successfully completed all study visits and procedures and unstructured feedback from patients suggested that they universally appreciated the opportunity to participate. Anecdotal evidence suggests that diabetes treatment providers (who were often in contact with the study investigators) noted improvements in their patients and were grateful for the opportunity to refer patients for care. Preliminary evidence suggests that CBT-AD was useful in helping patients improve both adherence to diabetes self-care activities and depression. These findings are particularly promising given the high rates of depression in patients with type 2 diabetes (Adriaanse et al., 2008, Ali et al., 2006; Anderson et al., 2001; Egede, 2005), the association of depression with worse treatment adherence (Gonzalez, et al., 2008) and diabetes outcomes (Lustman, Anderson, Freedland, 2000; deGroot, Anderson, Freedland, Clouse, & Lustman, 2001).

The integration of adherence training with cognitive behavioral techniques in CBT-AD is based on the belief that the strategies employed in CBT for depression (e.g., activity scheduling and mood monitoring, cognitive restructuring) have important applications in

facilitating successful treatment adherence in patients with chronic illness (e.g., increasing physical activity, correcting maladaptive beliefs about the illness and treatment). Our intervention addresses diabetes and depression as related conditions that may have a bi-directional influence on each other. For example, negative thinking, which is common in depression, would lead to worse self-care behaviors, making the medical illness worse, allowing for more negative thinking because one's illness is worse. Each session of the treatment focuses on the difficulties that the patient is having with diabetes management, the symptoms of depression that the patient is experiencing, and how these two problems influence each other. The strategies employed in our modular treatment are presented to the patient as equally applicable to the difficulties of diabetes management as to the symptoms of depression.

In order for the cognitive therapist to be successful in integrating work on diabetes treatment adherence with work on depression, it is necessary that the therapist have a high level of familiarity with the treatment recommendations for each patient specifically and with the medical and behavioral management of diabetes in general. Background reading on diabetes would be essential as would direct communication with the patient's treatment team to discuss treatment goals. We see a team approach that involves dietitians, nurses, physicians, and mental health specialists in the management of depressed diabetes patients as being the ideal. It is important for the therapist to recognize that a certain level of distress may arise simply from the burden of managing diabetes and from dealing with the changes in important roles that arise from having diabetes. Therefore, it is important to not make the mistake of only thinking about how distress may be interfering with diabetes management as it is just as likely that problems with diabetes management may lead to increased distress. To be successful with our program, the therapist should be equally comfortable with providing psycho-education, using monitoring to identify patterns, training in problem-solving skills and stress-management skills, and using cognitive techniques to address problems with self-care and treatment adherence as to address problems with depression and negative mood states. Targeting depression and treatment nonadherence simultaneously requires a constant re-evaluation and adjustment of the balance between the focus on diabetes and the focus on depression within and across sessions. A careful initial assessment of the patient's perceptions about the relationship between their problems with depression and their problems with diabetes treatment adherence can greatly inform the planning for and sequencing of treatment sessions.

This case series represents a first step in a program of psychotherapy efficacy research on CBT-AD and provides direction for clinicians who may be interested in employing such strategies in patients with diabetes (more detail can be found in Safren et al., 2007 a, 2007b). Our case series also provides guidance for continued research on integrated behavioral treatments for the common problems of depression and treatment nonadherence in patients with diabetes. The results of our study provide support for the hypothesis that integrating the treatment of depression with CBT-informed strategies to improve skills and motivation for self-care and treatment adherence may maximize the effects of psychological treatments on health outcomes for diabetes patients struggling with depression. This possibility is currently under evaluation in a randomized clinical trial.

Acknowledgments

Supported by NIH 1R01 MH078571

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J Cogn Psychother. Author manuscript; available in PMC 2013 May 10.

Table 1

Changes in adherence and depression between baseline and post assessment.

Case Number	**1**		**2**		**3**		**4**		**5**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
Diabetes Measures										
HbA1c	7.1	6.8	9.5	8	12	7.7	8.1	9.1	7.4	6.5
MEMS (%)	93	100	100	100	57	71	93	100	100	86
Glucose Monitoring (%)	64	>100	>100	79	0	100	48	71	19	14
Depression										
MADRS	18	10	20	3	27	5	30	24	29	14
CGI	3	2	4	1	5	2	4	3	5	4
BDI	13	9	7	2	22	6	23	23	11	15

Note: MEMS and Glucose Monitoring figures refer to % of prescribed medication taken and glucose tests completed over the past week. Greater than 100% adherence reflects that the patient monitored glucose or took medication more often than prescribed.

J Cogn Psychother. Author manuscript; available in PMC 2013 May 10.

Table 2

Changes in patient self-assessment of adherence to self-care activities.

Case Number	**1**		**2**		**3**		**4**		**5**	
Diabetes Self-Care Activities	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
General Diet	3.5	4.5	1	2	0	6.5	2	3.5	0	0
Specific Diet	1.5	3.7	4.5	5	2.3	6	2	2.7	1.3	0.3
Exercise	0.5	3	0	2.5	0	7	0	2.5	0	0
BG Testing	5	7	0.5	5.5	0	7	4.5	3	0	1
Foot care	5.6	5.6	3.5	6	2.8	5.6	7	7	4.4	4.8
Medications	6.7	6.7	6.7	7	4	5	6	7	6	6.3

Note: All data in this table represent the mean number of days per week that the patient was adherent to each type of diabetes self-care activity (based on Summary of Diabetes Self-Care Activities questionnaire).