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# The Effect of a Computerized Cognitive-Behavioral Stress Management Intervention On Psychological Factors and Diabetes Management

Cathy A. Bykowski
*University of South Florida*, cbykowsk@mail.usf.edu

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by

Cathy A. Bykowski

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of the requirements for the degree of
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Co-Major Professor: Paul B. Jacobsen, Ph.D.
Co-Major Professor: Kristen Salomon, Ph.D.
Thomas H. Brandon, Ph.D.
Michael T. Brannick, Ph.D.
Jack Darkes, Ph.D.

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DEDICATION

This doctoral dissertation is dedicated in memory of my father, Richard A. Rosowski. For my entire life he demonstrated the importance of continued education and striving to attain my goals and dreams. He taught me that I would encounter obstacles and hardships but that perseverance and hard work would allow me to achieve more than I ever imagined. His character and unending support inspired me to pursue my doctorate. His diagnosis of diabetes provided me with personal knowledge of the ways in which it affects both physical and psychological health and a drive to improve our understanding of that relationship and the quality of life for those affected. This work is a small reflection of the profound impact that he has had on my life and a promise to continue to evolve in a way that would make him proud.

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ABSTRACT

Diabetes is associated with increased psychological distress which, in turn, is associated with poorer diabetes outcomes. This study examined the impact of a nine-week Internet-based cognitive-behavioral therapy intervention that targeted stress and mood in people with diabetes. It was hypothesized that the intervention would decrease psychological distress and improve diabetes outcomes and adherence to diabetes treatment regimens. Participants with type 1 and type 2 diabetes were randomly assigned to the intervention ($n$ = 103) or a waiting-list control group ($n$ = 74). ANCOVAs demonstrated significant group effects for the reduction of perceived generalized stress ($F$ (1, 105) = 7.06, $p$ = .01; $d$ = .84), diabetes-related distress ($F$ (1, 105) = 13.45, $p$ < .01; $d$ = .54), depression ($F$ (1, 90) = 7.06, $p$ < .01; $d$ = .40), anxiety ($F$ (1, 89) = 6.78, $p$ = .01; $d$ = .41), and negative affect ($F$ (1, 103) = 13.02, $p$ < .01; $d$ = .56). There were also significant group effects for the reduction of psychological fatigue ($F$ (1, 98) = 7.34, $p$ = .01; $d$ = .40), cognitive symptoms ($F$ (1,95) = 6.40, $p$ = .01; $d$ = .48), hyperglycemic symptoms ($F$ (1, 95) = 11.16, $p$ <.01; $d$ = .41) and hypoglycemic symptom ($F$(1, 98) = 6.16, $p$ = .02; $d$ = .53). Further, there were significant indirect effects of the intervention on the above diabetes symptoms, through psychological distress. There was no effect of the intervention on hemoglobin A1c ($F$(1.43) = 0.28, $p$ = .60), though this analysis was underpowered. The intervention also had no effect on adherence to diabetes treatment regimen. This study provides evidence of a convenient and effective way to reduce psychological distress and

improve symptoms in those with diabetes. It also provides evidence of reduced psychological distress as a mechanism for improving diabetes outcomes.

## Chapter One

## Introduction

Over 29 million Americans, 9.3% of the country's population, have Diabetes Mellitus, an endocrinological disease that reduces the pancreas' ability to produce or effectively use insulin, the hormone needed to regulate glucose (Centers for Disease Control and Prevention, 2014; Hampson et al., 2001). Uncontrolled diabetes substantially increases the risk for a variety of serious medical complications that affect the eyes, kidneys, nerves, and cardiovascular system (Goldstein et al., 2004; Landell-Graham, Yount, & Rudnicki, 2003) and it is the seventh leading cause of death in the United States (Centers for Disease Control and Prevention, 2014). There is also evidence that psychological distress is more prevalent in people with diabetes (Anderson, Freedland, Clouse, & Lustman, 2001; Eaton, 2002; Fenton & Stover, 2006; Lustman, Griffith, Clouse, & Cryer, 1986; Scott et al., 2007). Further, researchers have demonstrated that those with diabetes who are also experiencing psychological distress have worse adherence and glycemic control, more medical complications, higher hospitalization rates, and die at an earlier age (Anderson et al., 2001; Ciechanowski, Katon, & Russo, 2000; de Groot, Anderson, Freedland, Clouse, & Lustman, 2001; de Groot, Jacobson, Samson, & Welch, 1999; Egede, 2006; Gilmer et al., 2005; Grandinetti et al., 2000; Lustman & Clouse, 2005; Lustman et al., 1986; Niemcryk, Speers, Travis, & Gary, 1990; Wrigley & Mayou, 1991). Reducing psychological distress in people with diabetes may lead to improvements in their physical and

psychological health, though the mechanisms involved in this relationship are not well understood.

**Diabetes Mellitus & Glycemic Control**

Diabetes Mellitus is a disease of the endocrine system that affects the pancreas' ability to produce or effectively use insulin, the hormone needed to regulate glucose in the body (Hampson et al., 2001). There are two types of diabetes, which are differentiated by their patterns of onset, etiology, and treatment regimens (de Groot et al., 1999). Type 1 diabetes is the result of autoimmune destruction of the pancreas' beta cells, which usually occurs early in life. The lack of beta cells eliminates the body's ability to produce insulin, requiring patients to rely completely on exogenous forms of insulin for survival. Patients with type 1 diabetes must monitor blood glucose levels and regulate the levels by injecting insulin several times each day (Van Tilburg et al., 2001).

Type 2 diabetes is usually diagnosed later in life, subsequent to the pancreas becoming unable to produce enough insulin or the body's inability to effectively use the insulin to control glucose levels (American Diabetes Association, 2010; Van Tilburg et al., 2001). A patient with type 2 diabetes must enhance the body's ability to use insulin and supplement the pancreas' production of insulin with the aid of oral medication and, sometimes, insulin injections. However, many type 2 diabetics are able to regulate their glucose levels by following a healthy diet plan (Van Tilburg et al., 2001).

The primary goal in the treatment of diabetes is achieving good glycemic control, i.e., reducing blood glucose to a healthy level that is then maintained (Goldstein et al., 2004; Qaseem et al., 2007). This is accomplished through successful diabetes management, which may include a healthy diet, exercise, oral medications and/or insulin injections and careful monitoring of

glucose (American Diabetes Association, 2010). Hemoglobin A1c (A1c) provides a reliable index of glucose regulation over a period of two to three months (Goldstein et al., 2004; Lustman, Griffith, Freedland, & Clouse, 1997). A1c describes the amount of glucose that is bound to red blood cells (RBCs) over the course of their lifespan, which is typically 90-120 days (Goldstein et al., 2004). As RBCs reach the end of their lifespan they will have less influence on the A1c value and the newest RBCs will have the greatest influence. Thus, A1c is a weighted average of glucose control, with the glucose concentrations of the previous month contributing about 50% to the A1c value (Rohlfing et al., 2002). A high A1c level is indicative of poor glycemic control. It is generally recommended that A1c be as low as possible without causing hypoglycemic complications, for most diabetics this is less than 7% (American Diabetes Association, 2010; Qaseem et al., 2007). Prolonged poor glycemic control results in diabetic complications, such as retinopathy, neuropathy, and nephropathy, and increased mortality (Katon et al., 2005). Decreasing A1c by 1% decreases the risk of some complications by as much as 33% to 40% (Centers for Disease Control and Prevention, 2008; Lustman, Anderson, et al., 2000). Therefore, it is important to understand the factors that influence the maintenance and deterioration of glycemic control.

**Diabetes & Psychological Distress**

Psychological distress is more common in people with diabetes than in the general population (Anderson et al., 2001). This was demonstrated in a study that examined 114 individuals with type 1 and type 2 diabetes. In this sample, 71% of the diabetes patients met criteria for a psychiatric diagnosis at some point in their lifetime. The most common diagnoses were major depressive episode (33%) and generalized anxiety disorder (41%; Lustman et al., 1986). Similarly, in an international sample of over 42,000 people, diabetes was associated with

depression, anxiety, and comorbid depression and anxiety (Scott et al., 2007). A meta-analysis of 20 studies concluded that people with diabetes were twice as likely to have depression as non-diabetics (Anderson et al., 2001). Women with diabetes are particularly at risk for depression (Anderson et al., 2001). Cross-sectional studies have indicated that 44% of women with Type 2 diabetes report a depressed mood and 34% report a history of diagnosed depression (Whittemore, Melkus, & Grey, 2004); this is substantially higher than the 10% to 25% lifetime prevalence that is found in community samples (American Psychiatric Association, 2000). Even individuals that do not meet criteria for a psychological disorder experience high levels of distress. In fact, the diagnosis of diabetes often provokes stress related to difficulties following the intense diabetes management regimen and the possibility of short-term (e.g., hypoglycemic episodes) and long-term complications (e.g., neuropathy; Gonder-Frederick, Cox, & Ritterband, 2002).

Diabetes patients who meet criteria for a psychological diagnosis describe their overall physical functioning as poor (Ciechanowski, Katon, Russo, & Hirsch, 2003). They also report more symptoms of diabetes (Ciechanowski et al., 2003; Lustman et al., 1986) and more distress related to the symptoms (Lustman et al., 1986). One meta-analysis of 27 studies found a significant association between depression and diabetes complications, including retinopathy, nephropathy, neuropathy, macrovascular complications and sexual dysfunction (de Groot et al., 2001). In addition, diabetics with depression have more risk factors for cardiovascular disease (Katon, Simon et al., 2004), including higher rates of obesity and smoking (Katon, Simon, et al., 2004).

Psychological distress is also related to poorer glycemic control. Multiple studies have demonstrated higher A1c levels in diabetics who are depressed (de Groot et al., 1999; Grandinetti et al., 2000; Lustman & Clouse, 2005) and anxious (Lustman et al., 1986; Niemcryk

et al., 1990). Diabetics with dangerously high A1c requiring hospitalization complain of more depression and tension (Wrigley & Mayou, 1991). They also report more stressful life events (e.g., moving houses, job loss) and chronic stressors (e.g., marital problems, caring for an ill loved one), compared to diabetics who do not require hospitalization (Wrigley & Mayou, 1991). Similarly, severe personal stressors such as problems with a spouse or child or death of a parent, have been associated to deteriorating glycemic control (Lloyd et al., 1999). A longitudinal study of type 1 diabetics demonstrated that negative stress (e.g., interpersonal conflicts, death of friend) was related to reduced glycemic control over time (Lloyd et al., 1999).

**The Link Between Diabetes & Psychological Distress**

The causal relationship between diabetes and psychological distress is still not well understood. Some research suggests a "consequence model," which posits that the experience of having diabetes (e.g., coping with adherence to medical recommendations or diabetes related medical symptoms) may create psychological distress (Kovacs, Goldston, Obrosky, & Bonar, 1997; Palinkas, Barrett-Connor, & Wingard, 1991; Sacco & Bykowski, 2010). However, other evidence supports an "antecedent model," which suggests that psychological distress contributes to poor glycemic control (Lustman, Clouse, Ciechanowski, Hirsch, & Freedland, 2005; Musselman, Betan, Larsen, & Phillips, 2003; Surwit & Schneider, 1993; Van Tilburg et al., 2001). With regard to the antecedent model, research has focused on two primary paths through which psychological distress may influence glycemic control. These involve physiological and behavioral consequences of distress.

Psychological distress, such as stress and depression, has been implicated in hypothalamic-pituitary-adrenal (HPA) axis activation (Black, 2006). When the body is under stress, the hypothalamus in the brain releases corticotropin-releasing hormone (CRH). This

hormone stimulates the production of corticotropin (ACTH) from the anterior pituitary gland, which causes the adrenal cortex to release cortisol into the body (Black, 2006; Rosmond, 2005). Cortisol inhibits insulin secretion as well as its ability to regulate glucose (Rosmond, 2005), increasing circulating glucose levels and leading to poor glycemic control.

The behavioral pathway emphasizes the importance of adherence to a rigorous diabetes treatment regimen. Psychological stress is one of the four factors that have been identified as predictors of successful self-care behaviors in patients with type 2 diabetes, along with patient characteristics, the doctor-patient relationship, and the social context (Albright, Parchman, Burge, & the RRNeST Investigators, 2001). Those who experience distress may feel that self-care behaviors important to diabetes management may be too difficult or they may not be motivated to perform the necessary tasks (Lloyd, Smith, & Weinger, 2005). Researchers have found that diabetes patients with high levels of depression or stress tend to have poorer diets, participate in less physical activity (Albright et al., 2001; Lin et al., 2004), and are more likely to smoke (Ciechanowski et al., 2003; Lin et al., 2004) than those who report less distress. In addition, depressed patients are more likely to be non-adherent to diabetes medications as well as lipid-lowering and anti-hypertensive medication (Lin et al., 2004). People with higher levels of depressive symptomatology skip their medication more often than those with fewer depression symptoms (Ciechanowski et al., 2000). This lack of adherence and increase in unhealthy behaviors has harmful effects on diabetes management, leading to poor glycemic control (Peyrot, McMurry, & Kruger, 1999).

**Can Reducing Psychological Distress Improve Glycemic Control?**

Given that depression and other forms of psychological distress have been associated with decreased glycemic control, researchers have begun to ask whether treating psychological distress can lead to better glycemic control (Katon, Von Korff, et al., 2004; Lustman & Clouse, 2002; Surwit et al., 2002). There are various forms of treatments for psychological distress that have been shown to be efficacious, including psychopharmacological treatments (e.g., selective serotonin reuptake inhibitors, tricylclic antidepressants), cognitive–behavioral therapy (CBT), and relaxation training (Lambert & Ogles, 2004). Many of these interventions have been examined in people with diabetes. One recent meta-analysis of 30 studies concluded that interventions that target psychological distress significantly reduce A1c in people with diabetes ($d$ = 0.18; 95% CI [0.03, 0.33]), an effect that is equivalent to approximately a 0.32% decrease in A1c (Bykowski, Sacco, & Mayhew, 2011). Although the effect of psychological distress interventions is relatively small, a decrease in A1c by 1% reduces the risk of some serious medical complications by as much as 40% (Centers for Disease Control and Prevention, 2008). Thus, psychological distress interventions could possibly reduce the risk of diabetes complications by as much as 10%.

While a lack of power in this meta-analysis limited the ability to detect significant differences between studies that targeted different types of distress, the 11 intervention studies that targeted stress interventions had a mean effect size that was higher than the effect size for interventions that targeted depression, poor coping, binge eating, and general distress (Bykowski, Sacco, & Mayhew, 2011). These stress management interventions included group (Aikens, Kiolbasa, & Sobel, 1997; Attari, Sartippour, Amini, & Haghighi, 2006; Henry, Wilson, Bruce, Chisholm, & Rawling, 1997; Karlsen, Idsoe, Dirdal, Hanestad, & Bru, 2004; Tsujiuchi et al.,

2002; van Rooijen, Rheeder, Eales, & Becker, 2004) and individual (Feinglos, Hastedt, & Surwit, 1987; Lane, McCaskill, Ross, Feinglos, & Surwit, 1993; McGinnis, McGrady, Cox, & Grower-Dowling, 2005; McGrady, Graham, & Bailey, 1996; McGrady & Horner, 1999) interventions that utilized relaxation exercises (e.g., progressive muscle relaxation, guided imagery) and/or cognitive-behavioral techniques to alleviate stress in people with type 1 and type2 diabetes.

These intervention studies hypothesized that the reduction of distress leads to improved glycemic control. Unfortunately, this mechanism was not tested in most of the studies. Some researchers focused only on the effect of the intervention on glycemic control and did not examine post-intervention distress, and the majority of those that included post-intervention psychological assessments did not examine the relationship between these assessments and changes in A1c. These methodological limitations do not allow for conclusions about whether a reduction in distress mediates the improvement in glycemic control.

However, there is some evidence that intervention-induced reductions in psychological distress may mediate reductions in A1c. In their study on the effect of acceptance and commitment therapy, Gregg, Callaghan, Hayes, & Glenn-Lawson (2007) found that post-intervention acceptance mediated the effect of the treatment on A1c. Similarly, a path analysis by Lustman and colleagues (1997) indicated that treatment with nortriptyline led to a change in BDI scores, which led to a change in A1c. In another study, Lustman and colleagues (Lustman, Griffith, Freedland, Kissel, & Clouse, 1998) described lower A1c in participants who were no longer depressed following 10 weeks of CBT, compared to those who remained depressed. However, this was not replicated in a study of fluoxetine (Lustman, Freedland, Griffith, & Clouse, 2000), in which the glycemic control indices of participants who responded to treatment

with fluoxetine (i.e., had lower BDI scores) were not different from those of non-responders. Finally, while Kendardy et al. (2002) did not find a difference in binge eating frequency between the control and intervention groups after 10 weeks of CBT, they did note that a reduction in binge eating frequency was related to a reduction in A1c.

The mechanisms by which distress reduction lead to improved glycemic control have also been largely ignored. As noted earlier, antecedent models suggest a behavioral pathway that emphasizes the negative effect of distress on adherence to a rigorous diabetes treatment regimen. If distress inhibits self-care behaviors (Lloyd et al., 2005), alleviating distress may improve the self-care behaviors, which ultimately should improve glycemic control. Unfortunately, only one intervention study has provided evidence in support of this pathway. Post-intervention adherence mediated the effect of acceptance and commitment therapy on lower A1c (Gregg et al., 2007). Therefore, additional research should aim to clarify the role of the behavioral pathway in the relationship between distress and glycemic control.

In summary, there is evidence that interventions aimed at alleviating psychological distress may also improve diabetes management and glycemic control in individuals with diabetes. This is not surprising given the strong association between psychological distress and glycemic control (Lustman, Anderson et al., 2000). However, the mechanisms that drive the effect are rarely studied, leaving many questions about whether distress reduction is responsible for improved diabetes outcomes and whether this effect is mediated by improved adherence. Preliminary data thus support the utility of including psychological distress interventions as part of a comprehensive diabetes management program; however, further elucidation of the mechanisms will provide more information about how and why they are useful.

This study examined the relationship between psychological distress and diabetes outcomes, including diabetes symptoms and glycemic control. It evaluated the antecedent model, which posits that psychological distress leads to poor diabetes outcomes. It was hypothesized that psychological distress interventions would reduce psychological distress, which would improve diabetes outcomes in people with diabetes. Further, improved adherence was expected to mediate the effect of the intervention on diabetes outcomes.

**Barriers to Psychotherapy**

Despite the evidence that psychotherapy is effective at reducing various types of psychological distress (Lambert & Ogles, 2004), these interventions are underutilized. There are many reasons for the discrepancy between the number of people that would benefit from psychological services and the number that seek or receive services. Perhaps the most salient reason for most potential clients is the stigma associated with mental disorders (Cuijpers, van Straten, & Andersson, 2008). Individuals may be afraid of what others will think or of how they might be judged because they are participating in psychotherapy. People may also have negative feelings about therapists and they may be uncomfortable or unwilling to talk to a stranger about their personal problems (Cuijpers et al., 2008). These societal and personal issues prevent many people from engaging in psychotherapy, despite their need for services.

There may also be logistical problems that do not make psychotherapy possible for some individuals. For example, for individuals that live in rural or underdeveloped areas, the nearest therapist may be too far away. Other clients may not have the ability to procure transportation to a therapist (Cuijpers et al., 2008). It may also be difficult or impossible for clients to take the time off of work to see a therapist or to find child care (Cartreine, Ahern, & Locke, 2010). People who have comorbid health problems may also have physical limitations that make

traveling to a therapist's office difficult (Cuijpers et al., 2008). In addition, many people do not have the financial resources or medical insurance to cover the cost of psychotherapy (Cartreine et al., 2010).

**Computerized Psychological Distress Interventions**

Technology has provided a way to overcome many of the barriers to psychotherapy. Some therapists have begun to offer computerized psychological interventions. These include interventions that are available as computer programs that are installed on a client's computer (e.g., from a CD-ROM) or accessed via the Internet. These interventions are often client-driven, with little to no contact with a therapist. Many are based on cognitive-behavioral therapy (CBT). CBT is ideal for this type of therapy because the structure and presentation of CBT are easily presented in text and CBT interventions are effective for many types psychological disorders (Cuijpers et al., 2008; Spek et al., 2007).

Computerized CBT (CCBT) can yield benefits for both the therapist and client. The decrease in therapist contact allows more time to see clients and results in shorter waiting lists (Cuijpers et al., 2008; Marks et al., 2003; Spek et al., 2007). One clinic that incorporated CCBT into its practice noticed shorter waiting lists for face-to-face therapy and increases in the number of clients they were able to treat. The therapists at this clinic spent less time per patient but the benefits to the patients were similar to those of face-to-face therapy (Marks et al., 2003).

Clients also benefit from the anonymity that CCBT provides (Spek et al., 2007; Tate & Zabinski, 2004). The ability of clients to access the intervention from their homes can overcome the shame that is a result of the stigma that is often associated with psychotherapy (Cuijpers et al., 2008; Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006; Tate & Zabinski, 2004). Participants tend to be less self-conscious and more likely to disclose information about

themselves via the computer, as compared to face-to-face interactions (Marks et al., 2003; Tate & Zabinski, 2004). In fact, clients who have used computer-aided self help have admitted that they revealed sensitive information to the computer that they would not have told a person (Marks et al., 2003). There may also be a reduced tendency for clients to respond in a certain way due to social desirability (Tate & Zabinski, 2004), making assessment more accurate and therapy more productive.

Clients also appreciate the convenience that these interventions provide. They save time because they do not have to spend time traveling to the therapist's office and do not have to schedule appointments at a time convenient for both the client and therapist (Cuijpers et al., 2008; Griffiths et al., 2006; Spek et al., 2007; Tate & Zabinski, 2004). Some studies have identified the constant availability of the intervention to be among the most important assets of the therapy. In fact, research on CCBT interventions finds that the majority of participants access the programs during traditionally non-clinic hours (Tate & Zabinski, 2004). CCBT also provides a way for clients who are isolated (due to location or medical limitations) to access therapy (Griffiths et al., 2006) and reduces the cost of psychotherapy, increasing the availability of psychotherapy in low socioeconomic groups (Marks et al., 2003).

The qualities of CCBT interventions also provide advantages over traditional, face-to-face psychotherapy. The interactive and audiovisual capabilities may increase clients' motivation to use the program. In addition, clients may feel empowered by the ability to go through the information on their own (Ritterband et al., 2003) and work at their own pace to assure that they understand the concepts that are presented (Cuijpers et al., 2008). The client also has the ability to go back to the program and review important information (Spek et al., 2007). Another therapeutic benefit to CCBT is that it provides an easy way to implement routine

assessments of client progress, information that is valuable to both the client and therapist (Cuijpers et al., 2008).

Some negative aspects of CCBT, such as poor compliance and increased attrition, have been identified in various research studies (Ritterband et al., 2003). It may be easier for a client to disengage from a web-based therapy program than to cancel an appointment with a "real person" (Spek et al., 2007; Tate & Zabinski, 2004). In addition, fully automated programs are limited in that they may not be able to address all concerns that are important to clients (Cuijpers et al., 2008; Tate & Zabinski, 2004) and cannot detect subtle, nonverbal cues that indicate that the client is misunderstanding a concept (Cuijpers et al., 2008). Others have suggested that having clients interact with a machine may be impersonal or dehumanizing (Spek et al., 2007; Wright & Wright, 1997). Despite these potential disadvantages, many clients report that they are satisfied with these types of treatments (Marks et al., 2003).

**Efficacy of CCBT**

While CCBT is a relatively new treatment, several studies have shown it to be a feasible and efficacious treatment for many types of disorders. Several qualitative and quantitative reviews have supported the use of CCBT for the treatment of depression and anxiety (Spek et al., 2007). A meta-analysis of randomized controlled trials (RCT) examining the efficacy of CCBT for the treatment and/or prevention of depression and anxiety identified twelve studies with an overall moderate effect size ($d$ = 0.51). The five studies of CCBT for the treatment/prevention of depression had a fairly small effect size that was still significant ($d$ = 0.22). However, the seven RCTs for the treatment/prevention of anxiety had a large overall mean effect size of $d$ = 0.96 (Spek et al., 2007).

Another meta-analysis of Internet or computer-based treatments for anxiety also demonstrated the efficacy of the treatment over waitlist and placebo control groups (Reger & Gahm, 2009). These computerized programs resulted in improvements in anxiety, depression, general distress, dysfunctional thinking, and functioning in individuals with panic disorder, phobias, PTSD, and other anxiety symptoms. Further, the Internet- or computer-based treatments yielded improvements that were similar or better than traditional face-to-face therapy provided by a therapist (Reger & Gahm, 2009).

The growing literature that supports that use of CCBT for the treatment of anxiety and depression has influenced the treatment recommendations from the National Institute for Health and Clinical Excellence in the United Kingdom. They have recently added several CCBT programs (i.e., "Beating the Blues" and "FearFighter") to their recommendations for the treatment of panic disorder and generalized anxiety disorder in primary, secondary, and community care and depression in primary and secondary care. It is considered a valid alternative to initial interventions in primary care, which is step 2 of a stepped-care approach (National Institute for Health and Clinical Excellence, 2006). CCBT is one of the low-intensity interventions that is suggested for individuals with persistent, subthreshold depressive symptoms, or mild to moderate depression. These recommendations are for individuals with and without a chronic medical condition (National Institute for Health and Clinical Excellence, 2009).

Few published studies have examined the effects of Internet-based stress management programs. A search identified only two published studies, however, both provide encouraging results. Zetterqvist and colleagues (Zetterqvist, Maanmies, Strom, & Andersson, 2003) conducted an RCT of an Internet-based stress management program in 63 participants that registered via a website. The program included six modules that were each composed of three

sections: relaxation, additional exercises, and information. The relaxation section explained progressive relaxation, conditioned relaxation, differential relaxations, cue-controlled relaxation, and applied relaxation. Participants were able to hear the instructions on the website, download an audio-recording, or print the written instructions for the exercises. They were told to practice the techniques throughout the week. Each week they signed on to a website to report the frequency and duration of their relaxation practice. The additional exercises section contained information on problem solving, time management, and cognitive and behavioral responses to stress. Participants were told to apply what they had learned to a topic in their life and complete an exercise form, which was submitted to a database. Completion of the relaxation practices and exercise form was necessary to receive access to the next module. The information sections were optional and included information on sleep management, eating habits, exercise, stress at work, positive activities, and setting limits. The participants were given access to the program coordinators for help with technical difficulties or for further feedback on stress management issues (Zetterqvist et al., 2003). Results included a significant group by time interaction effect, which indicated that, compared to the control group, the intervention group improved more on scores of stress, depression and anxiety (Zetterqvist et al., 2003).

A second RCT examined the effectiveness of an Internet-based CCBT program for stress management in 309 employees of a major technology company (Billings, Cook, Hendrickson, & Dove, 2008). This study employed the *Stress and Mood Management* program, which is an interactive website that provides education about managing stress, preventing mood problems, and identifying and seeking treatment for anxiety and depression if necessary. The program used cognitive-behavioral techniques such as goal setting, problem-solving, identifying and challenging negative thoughts, relaxation, and time management. There are multiple self-

assessments that allow the user to determine which parts of the program are most relevant to them. Participants were granted access to the entire program and worked through it at their own pace. They were encouraged to explore the content areas that were most relevant to them and to return to the program as necessary within a three-month period. Self-report questionnaires completed at the end of three-month period indicated that the program was underutilized. Only 3% of the participants in the intervention group accessed the stress management material four or more times and 65% viewed the material only once. The depression, anxiety, and treatment material were accessed even fewer times. Despite the minimal contact with the program, the intervention group experienced a significant reduction in stress compared to the wait-list control group. However, there were no group differences in depression, anxiety, and mood (Billings et al., 2008).

In summary, CCBT interventions provide a way to overcome many barriers to treatment and are effective for a wide range of problems (Ritterband, Andersson, Christensen, Carlbring, & Cuijpers, 2006). The data in support of CCBT for the treatment of anxiety and depression are quite strong (Cuijpers et al., 2008; Kaltenthaler, Parry, Beverly, & Ferriter, 2008; Reger & Gahm, 2009; Spek et al., 2007). There have been few studies of CCBT stress management programs but the two that were identified have shown improvements in stress, even when the majority of participants did not access the program more than once (Billings et al., 2008; Zetterqvist et al., 2003)..

**Can a Stress Management CCBT Intervention Improve Diabetes Management?**

The increased prevalence of psychological distress in individuals with diabetes has been well-established (Anderson et al., 2001), as has the impact of distress on diabetes management and glycemic control (Lustman, Anderson, et al., 2000). Intervention studies have demonstrated

that treatments designed to alleviate psychological distress also improve glycemic control in people with diabetes (Bykowski, Sacco, & Mayhew, 2011). However, many people do not seek psychological services due to the stigma associated with mental illness, lack of time, insufficient finances, or various other reasons (Cartreine et al., 2010; Cuijpers et al., 2008). Internet-based CCBT interventions have overcome many of these barriers and have demonstrated efficacy in alleviating psychological distress (Billings et al., 2008; Cuijpers et al., 2008; Kaltenthaler et al., 2008; Reger & Gahm, 2009; Spek et al., 2007; Zetterqvist et al., 2003). Internet-based diabetes education and self-management interventions have been shown to be effective at improving glycemic control and self-management over a one year period (Lorig, Ritter, Laurent, & Plant, 2006; McMahon et al., 2005). However, there are few Internet-based CCBT interventions that have been employed to treat psychological distress in people with diabetes. Given the impact that these interventions can have on controlling diabetes, it is important to examine the use of Internet-administered interventions as an adjunct to a comprehensive diabetes management program.

One group of researchers has addressed this need through a randomized trial of a web-based well-being intervention for adults over the age of 60 diagnosed with type 1 or type 2 diabetes for least one year (Bond, Burr, Wolf, & Feldt, 2010). The objective of the intervention was to improve diabetes self-management and psychosocial well-being. Behavioral and motivational strategies were used to emphasize the patient's role in maintaining health, highlighting the importance of setting goals and using problem-solving skills to overcome obstacles to goals and improve self-efficacy. Participants were educated in diabetes management, diet, exercise, and interventions to deal with the physical and emotional demands of diabetes. This program also included a great deal of interaction with a study nurse and other

participants via instant messaging, chat, email, and a bulletin board. Participants also utilized a study website to enter blood glucose readings, exercise programs, weight changes, blood pressure and medication data. The nurse reviewed the information provided by the patients and provided feedback when necessary to resolve problematic changes. All participants also participated in a weekly online discussion group that provided educational material to the group and promoted peer support and social interaction. Following the six-month intervention, the treatment group demonstrated less depression, improved quality of life, increased self-efficacy, and increased social support compared to a treatment-as-usual control group. In addition, the treatment group showed significantly more improvement in A1c, HDL, total cholesterol, weight, and systolic blood pressure (Bond et al., 2007).

While this study shows great promise for incorporating a well-being intervention into a more traditional diabetes self-management program, it also leaves many unanswered questions. The intervention was very intense, including various components (access to a library of diabetes-related articles and websites, online advice, counseling and encouragement, tailored self-management instruction, weekly chat/discussion groups, access to an Internet bulletin board, and the ability to submit daily glucose readings and other data to the study nurse). This intervention also included substantially more interaction (among participants and between participants and the study nurse) than more traditional Internet-based therapies, making it difficult to determine the "active ingredient" in the intervention. Another concern is the generalizabilty of these results to other elderly diabetics. Participants were not required to have any computer experience prior to the study and Internet access and/or computers were provided to those who did not have access on their own. They were also trained in the use of the computer if necessary. It is also

not clear if an improvement in the psychosocial factors mediated the improvement in the physical factors (Bond et al., 2007).

Besides the Bond et al. (2007) study, only one other study of a psychosocial Internet intervention for patients with diabetes can be identified (van Bastelaar, Pouwer, Cuijpers, Riper, & Snoek, 2011). This research aimed to decrease depression as well as diabetes-specific emotional distress. The researchers hypothesized that these improvements would translate to improvements in diabetes self-management and glycemic control. Depressed patients with type 1 or type 2 diabetes were randomly assigned to an eight-week web-based course or a 12-week waiting list control group. Participants logged into the study website once per week and received weekly emails from study coaches to remind them to log into the site, to encourage them to continue, and to provide feedback on homework assignments. The Internet-based CCBT program included topics such as managing poor test results, blood glucose fluctuations, negative emotions, communication with health care professionals, talking about diabetes with others, the burden of diabetes self-management, and coping with diabetes-related worries. Participants also had access to an Internet-based group forum moderated by study coaches, which allowed participants to share experiences, provide support, and discuss issues related to depression and diabetes. At the end of the intervention and at one month post-intervention, participants in the intervention group reported less diabetes-related distress and fewer depression symptoms. However, A1c did not significantly differ between the groups (van Bastelaar et al., 2011).

**The Current Study**

The current study tested the efficacy of a nine-week CCBT stress and mood management program in people with diabetes. The program provided education about managing stress, preventing mood problems, and identifying and seeking treatment for anxiety and depression if necessary. The program began with the stress management material, which is applicable to most adults. It then presented CBT techniques for managing depression and anxiety. The program ended with information on identifying when depression and anxiety require more intense treatment and explained treatment options. The goal was that this program would provide diabetics with resources to manage stress. In addition, given the high prevalence of anxiety and depression in this population, it is important to educate patients on ways to deal with these feelings, either on their own or with the help of a clinician.

The primary goal of this study was to determine whether an online stress management intervention could reduce psychological distress in people with diabetes. A secondary goal was to explore the antecedent model, which posits that psychological distress leads to poor glycemic control through its adverse effect on adherence. Thus, the effects of the program on glycemic control, adherence, and other diabetes outcomes were also explored. This research aimed to provide further insight into the ability of psychological distress reduction interventions to improve diabetes outcomes by improving adherence. The following hypotheses were examined:

1. CCBT-SM will lower psychological distress in the intervention group, compared to the control group. Perceived generalized stress, diabetes-related distress, symptoms of anxiety and depression, and mood will improve after participation in this program.
2. Participation in CCBT-SM will result in improved glycemic control and fewer diabetes symptoms in the intervention group, compared to a waiting-list control group. Due to

changes in the protocol during the study, this hypothesis became exploratory in nature (see below).

3. The mechanism through which CCBT-SM will improve diabetes outcomes is by lowering distress and improving mood. Perceived generalized distress, diabetes-related distress, depression symptoms, anxiety symptoms, and mood will be examined as mediators of the ability of the CCBT-SM intervention to decrease diabetes symptoms and improve A1c.
4. Reducing psychological distress will improve adherence and adherence will mediate the effect of the intervention on diabetes outcomes.

During the course of the study some changes to were made to the methods to counteract difficulties with recruitment and retention of participants. Obtaining A1c from medical records proved to be a large barrier to the participation of many patients, so this requirement was removed from the study. Thus, the hypothesis related to the effect of the intervention on A1c (number 2 above) became exploratory. The number participants with valid A1c at pre- and post-intervention did not provide enough power for adequate analyses. In turn, the focus of the other hypotheses was shifted to other diabetes outcomes, specifically diabetes symptoms.


Figure 1. The indirect effect of CCBT-SM on glycemic control via a reduction in psychological distress.


Figure 2. The indirect effect of CCBT-SM on glycemic control via an increase in adherence.

## Chapter Two:

## Methods

The study protocol was approved by the Institutional Review Board at the University of South Florida.

### Participants

**Recruitment.** Recruitment was open to individuals in the United States. Brochures and flyers were distributed to physicians, physician assistants, nurse practitioners, and diabetes educators nationwide via face-to-face meetings, email exchanges, and relevant newsletters and list servs. The researcher explained the rationale and procedure of the study to the healthcare practitioners and asked them to distribute the literature to their patients with diabetes. The literature included information about the study and directed interested individuals to the study website.

Participants were also recruited via the Internet and email campaigns. Advertisements were placed on diabetes-relevant webpages and newsletters as well as on Facebook support pages. The research study was also listed on two clinical trial recruitment websites. All advertising directed participants to the study website.

The study website outlined the purpose of the intervention and the requirements of participants. The website included a link to the research summary/consent form. Interested participants were asked to read the form and then complete an information sheet to enroll in the

study. Participants were provided a phone number and email address to contact a researcher if they had any questions or concerns.

In addition to those who submitted an online enrollment form, a small number of participants were recruited using HealthStreet, a community engagement program operated by the University of Florida. Individuals with type 2 diabetes who were registered with HealthStreet and indicated that they would be interested in research were contacted by HealthStreet personnel, given a brief description of the study and asked if they would be interested in participating. The contact information for those who were interested was provided to the study researchers ($n$ = 30). The individuals were then contacted and provided with additional information about the study and screened to determine eligibility.

**Eligibility criteria.** Participants were required to be adults (over the age of 18). Initially the study was limited to those who self-reported that they had been diagnosed with type 2 diabetes. However, due to low rates of recruitment, enrollment was opened to those who self-reported that their doctor had diagnosed them with type 1 or type 2 diabetes.

There were no psychological criteria for eligibility. The intervention was designed to benefit the general population, so participants were not required to demonstrate feelings of stress, anxiety, or depression. However, participants who endorsed suicidal ideation on the pre-intervention questionnaire ($n$=5) were excluded from the study and encouraged to receive individual treatment. Initially the study required that participants have a minimum A1c of 6.5, which is a typical cutoff for the diagnosis of diabetes. However, this limited the number of interested individuals who were eligible to participate. To improve recruitment, this requirement was lifted and there were no requirements regarding current diabetes management.

Participants were required to have access to a computer with an Internet connection. It was also necessary for the computer to have the ability to play sounds via speakers or headphones. The CCBT-SM program required the use of Adobe Reader and Macromedia Flash Player. These programs were available for free download if they were not already installed.

The study website used for advertising and recruitment tracked the number of visits to the site to provide an indication of the number of people who were curious about the study but decided not to enroll. In addition, the researchers tracked the number of people who requested a telephone call but were ineligible to participate or who decided not to participate after receiving the telephone call.

**Sample size.** The effect sizes that have resulted from similar studies suggest a moderate effect of stress management interventions on reducing psychological distress and A1c. The Zetterqvist et al. (2003) online stress management intervention that was tested in healthy adults resulted in a medium effect size ($d = 0.62$) for the reduction in perceived stress. However, this study included therapist contact and was highly structured, requiring the submission of homework assignments to be granted access to the next module. It is not clear how this type of structure may affect the effect size. A meta-analysis of non-Internet based work-related stress-management programs indicated that interventions that used CBT ($d = .68$), relaxation ($d = .35$) and a combination of CBT and relaxation ($d = .51$) had an medium effect on post-test measures of stress (van der Klink et al., 2001). Another meta-analysis of psychological distress interventions for people with diabetes found a medium effect size for stress management interventions ($d = 0.43$), but a small effect size ($d = 0.18$) for distress interventions in general (Bykowski, Sacco, & Mayhew, 2011). The majority of this data suggest that a medium effect size could be expected.

An a priori power analysis using G*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) indicated that with a total sample size of 107 participants, a multiple regression analysis would detect the effect of an intervention with the expected medium effect size ($f^2$= .15) and α = .05. Previous studies of Internet-based treatments have experienced attrition rates that range from 12% to 56%, with more recent studies having lower rates of attrition (Zetterqvist et al., 2003). Given this large range of attrition rates, this study planned for attrition that is between these extremes, approximately 34%. Based on this data, the researchers planned to randomize at least 142, approximately 71 participants in each group.

At the completion of data collection, after consulting with members of the dissertation committee, it was decided that analysis of covariance (ANCOVA) would be a more appropriate statistical test of the proposed hypotheses. An a priori power analysis using G*Power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) indicated that a total sample size of 128 participants would be necessary for an ANCOVA to detect the effect of an intervention with the expected medium effect size ($f$ = .25) and α = .05. Given that the sample size was based on the original power analysis and the obtained sample was 108 participants, the ANCOVA analyses may be underpowered.

**Procedure**

The procedure for enrollment in the study was modified to improve recruitment and retention of participants. Initially, individuals who visited the study website and were interested in participating in the study clicked on a link that directed them to an online form where they entered contact information. Once the researchers received the information, the individual was contacted via telephone to review the study requirements and determine eligibility. Individuals who were eligible and wished to participate were then mailed (via the US Postal Service) a

consent form and an authorization for the release of healthcare information form. The release form stated that the participant allowed the release of their A1c levels by their physician to the researcher. They were asked to complete and return the forms in a self-addressed stamped envelope. A copy of the consent form was kept on file and the release form was faxed to the participant's physician at the beginning and end of their participation in the study. Once a valid A1c was obtained from the physician, the participant was sent a welcome email and link to the first questionnaire.

This procedure faced several obstacles, including difficulties reaching participants by telephone, the amount of time lost waiting for the forms via the postal service, and requiring participants to complete forms and mail them back. Thus, the procedure was streamlined. The link from the study website was amended to include an automated screening form. Those who were eligible were then automatically directed to a study summary/consent sheet. A waiver of documentation of consent was obtained from the institutional review board because the study presented no more than minimal risk. This allowed for consent to be acknowledged online immediately after individuals decided to participate. Once the consent was read and acknowledged, eligible participants were directed to an online form to collect their contact information. Completed forms were automatically sent to the researcher via email and the information was logged in a secure database. Once the researcher received the online contact form and acknowledgement of consent, the individual was mailed (via the US Postal Service) the release of information form and emailed a letter welcoming them to the study with a link to the first questionnaire. They were asked to complete and return the release form in a self-addressed stamped envelope. A copy was kept on file and faxed to the participant's physician at the beginning and end of their participation in the study.

The welcome email contained a link to the pre-intervention questionnaire (Q1), which was presented via Surveygizmo.com. After participants completed the pre-intervention questionnaire, they were randomly assigned to the intervention or control group, via a random number generator. Random assignment was initially 1:1 but after substantial attrition in the intervention group, it was changed to 2:1 (intervention : control) for the last third of the assigned participants. If a participant indicated suicidal ideation on the pre-intervention questionnaires, they were excluded from the study and encouraged to seek individual psychotherapy from a mental health provider. The researcher provided referrals to national websites that aid in finding mental health services.

The treatment period and wait-list control period lasted nine weeks. Following the fourth and ninth weeks, participants were sent an email and asked to complete the mid- and post-intervention questionnaires (Q2 and Q3) via Surveygizmo.com. Approximately two to three months after the participants completed the nine-week intervention (or waiting list) period, the researchers requested the most recent A1c from the participant's physician. At that point, the participants in the waiting list group were invited to participate in the intervention.

Initially participants did not receive compensation for their participation. To improve recruitment, the protocol was revised so that the final two-thirds of participants were compensated for their time with gift cards to an online retailer. They received a five-dollar gift card for each questionnaire completed and a bonus five-dollar gift card if they completed the entire study.

**Treatment Groups**

**CCBT-SM.** The intervention group participated in "*Stress & Mood Management,*" a web-based program designed to educate adults about managing stress, preventing mood

problems, and identifying and seeking treatment for anxiety and depression if necessary. The program was centered on an interactive website that utilized graphics, animation, audio, and video to present the information in an engaging manner. It used cognitive-behavioral techniques such as goal setting, problem-solving, identifying and challenging negative thoughts, relaxation, and time management. The program was designed by researchers at the Center for Workforce Health and is available for employers to purchase and make available to their employees as part of a wellness program. Users have access to the entire program and are encouraged to return to the program as necessary and to work through it at their own pace. While this is the most convenient way to make the program available in a work-place setting, it tends to result in underutilization, making the program less effective. The current study added structure to the program so that participants were encouraged to access it at least once each week and complete specific modules during each visit.

Each participant in the intervention group received a unique username and password that was used to access the program and track use of the program and completion of tasks. Each week participants received an email reminding them to complete a specified part of the program. They were told where to start and stop the program that week and were provided with a screen-shot of the last screen they should see each week. They were instructed to end the program when they arrive at that screen. The email also included a link to a web-based questionnaire. The questionnaire was referred to as a "self-check" that asked three multiple-choice questions about the week's presentation, which were designed to help participants to remember the key points of the program. They were provided with immediate feedback about the accuracy of their answers and provided with an explanation of the correct answer. The "self check" also included an open-ended question that asks them to indicate what information was most interesting, surprising, or

useful to them this week, to encourage participants to apply what they learned during the session to their lives. In addition to the "self-check" the questionnaire asked participants to use a checklist to indicate which, if any, stress management techniques were used over the previous week.

The self-check was electronically submitted to the researchers once it was completed, which indicated that the participant had finished the program for the week. If a participant did not submit their weekly self-check, they were sent an email to remind them to do so. If they did not respond to the email, they were phoned by the researcher and sent another email. The program also collected usage data to track the amount of time spent by each participant on each web-page; however these data were not available to the researchers until the end of the study.

The program was divided into eight modules. Participants were instructed to allow at least 30 minutes to complete the modules, which were approximately 15 to 30 minutes long. See Table 1 for a detailed description of the information covered in each lesson. Each week the participants were given a homework assignment that was related to the week's lesson. Assignments included self-monitoring stress responses, practicing relaxation techniques, and completing thought records (see Table 1 for specific information about each week's homework assignment). In some modules the assignment is specifically mentioned in the program. However, there are several modules that did not have an integrated homework assignment. Therefore, a homework assignment was created by the researcher to supplement these modules. The weekly reminder email always described the homework for the week. The only contact with the researchers was through the weekly emails and reminder emails/telephone calls, which were standardized. Researchers did not provide any additional therapy or counseling to the participants. Appendix A includes the homework assignments created for this study.

**Waiting list control.** The control group was put on a waiting list to participate in the study after a nine-week period. These participants received an email halfway through the treatment period to provide a reminder of their participation in the study and ask them to complete the mid-intervention questionnaires (Q2). They received another email after nine weeks asking them to complete the post-intervention questionnaire (Q3) and reminding them to provide another A1c measurement. The control group was invited to participate in the intervention after they completed the post-intervention questionnaire.

**Measures**

Participants completed each of the questionnaires described below at pre-, mid-, and post-intervention (Q1, Q2, and Q3, respectively). The demographic information was only collected pre-intervention, as the responses were not expected to change during the intervention. A1c was collected only at pre- and post-intervention.

**Perceived generalized stress.** The Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983) is a 14-item measure that assesses the degree to which respondents perceive situations in their lives as stressful. Respondents used a Likert scale ranging from 0 (never) to 4 (very often) to indicate how often they have experienced feelings of stress (e.g., "In the last month, how often have you felt nervous and stressed?" "In the last month, how often have you felt that things were going your way?"). The score is obtained by reversing the scores on the seven positive items and summing across all items; a higher score indicates that the person perceives more stress. The measure has been shown to have good internal consistency ($\alpha$ = .84 - .86) and test-retest reliability after two days (.85). The internal consistency at baseline in the current study was slightly higher than previously reported ($\alpha$ = .90). The PSS is correlated with number of life events ($r$ = .17 to .39) and impact of life events ($r$ = .24 to .49). The measure

predicts symptoms of depression and social anxiety as well as physical stress-related symptoms better than other commonly used life events scales (Cohen et al., 1983).

**Diabetes-related distress.** The Problem Areas in Diabetes (PAID) Scale (Polonsky et al., 1995) was used to measure emotional distress associated with diabetes. The scale consists of 20 emotional problems that are often reported by people with diabetes. The self-report measure asks respondents to indicate the degree to which each item is a problem for them using a Likert Scale that ranges from 0 (not at all) to 4 (serious problem). The items address areas such as worry ("worrying about the future and possibility of serious complications"), anger ("feeling angry when you think about living with diabetes"), and interpersonal problems ("feeling that friends/family are not supportive of diabetes management efforts;" Polonsky et al., 1995). The ratings are summed and multiplied by 1.25 so that the total score ranges from 0 to 100, with higher scores indicating more diabetes-related stress (Welch, Jacobson, & Polonsky, 1997). The PAID has demonstrated high internal reliability ($\alpha = .95$) and significant correlations with measures of general psychological distress ($r = .63$) and glycemic control ($r = .30$; Polonsky et al., 1995). The internal consistency at baseline in the current study was also high ($\alpha = .94$).

**Affect.** Affect was assessed via the Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988). The 20-item scale consists of ten positive affect items (PA: attentive, interested, alert, excited, enthusiastic, inspired, proud, determine, strong, and active) and ten negative affect items (NA: distressed, upset, hostile, irritable, scared, afraid, shamed, guilty, nervous, and jittery). Respondents are provided with a Likert scale ranging from 1 (very slightly or not at all) to 5 (extremely) and asked to indicate to what extent they have felt this way during the past few weeks. The authors have demonstrated that the scale has good internal consistency (.87 for both NA and PA) and acceptable test-retest reliability after an 8-week period

(.58 for PA; .48 for NA). It also has good convergent (.92 for both) and divergent validity (-.10 for PA, -.18 for NA) as well as item validity (Watson et al., 1988). The internal consistency at baseline in the current study was high for both positive affect (α = .91) and negative affect (α = .89).

**Depression**. The presence and severity of depression symptoms was assessed via the nine-item depression measure from the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PHQ-9). The PHQ-9 is a brief measure of depressive symptoms that allows a health care provider to determine whether a primary care patient meets criteria for Major Depressive Disorder (MDD) and also offers a measure of severity of symptoms. The scale consists of the nine DSM-IV criteria for MDD and respondents are asked to indicate whether they experience each symptom "not at all," "several days," "more than half the days," or "nearly every day." These responses are scored 0, 1, 2, 3, respectively and summed. Scores from 5 - 10 indicate mild depression, 11 - 15 indicate moderate depression, 16 – 20 indicate moderately severe depression and above 20 indicate severe depression. Respondents who indicate that they experience five symptoms more than half the days or nearly every day, with one of the symptoms being "little interest or pleasure in doing things" or "feeling down, depressed, or hopeless" are designated as meeting criteria for MDD. Criteria for suicidal ideation are met if respondents indicate any presence of "thoughts that you would be better off dead, or of hurting yourself in some way." The PHQ-9 has been shown to have high internal consistency (α = .86 - .89) and test-retest reliability (.84) and has shown to be a sensitive and specific diagnostic tool that is highly correlated with diagnoses made by mental health professionals as well as with indices of functional impairment (.33 - .73) and health care utilization (.24 - .55; Kroenke, Spitzer, & Williams, 2001; Spitzer, Kroenke, Williams, & The

Patient Health Questionnaire Primary Care Study Group, 1999). There was high internal consistency at baseline in the current study (α = .87).

**Anxiety.** The presence and severity of symptoms of generalized anxiety disorder were assessed via the GAD-7 (Spitzer, Kroenke, Williams, & Lowe, 2006). This seven-item scale asks respondents to indicate how often over the previous 2 weeks they experienced each of seven symptoms of anxiety (e.g., "feeling nervous, anxious, or on edge," "being so restless that is hard to sit still"). Respondents respond to each symptom "not at all," "several days," "more than half the days," or "nearly every day." The responses are scored from 0 to 3 and summed, resulting in a total score that ranges from 0 to 21, with high scores indicating high levels of anxiety. A score greater than 10 suggests a diagnosis of Generalized Anxiety Disorder. Scores from 6 – 10 indicate mild anxiety, 11 – 15 indicate moderate anxiety and scores greater than 15 indicate severe levels of anxiety. The scale has been shown to have good internal consistency (Cronbach α = .92) and test-retest reliability (.83). The scale is significantly correlated with functional impairment (.30 - .75) and symptom-related difficulty (.63). It is also highly correlated with the Beck Anxiety Inventory ($r$ = .72) and the anxiety subscale of the Symptom Checklist-90 ($r$ = .74) and independent diagnoses of anxiety made by mental health professionals conducting a clinical interview (Spitzer et al., 2006). There was high internal consistency at baseline in the current study (α = .90).

**Adherence.** The degree to which the participants were engaging in activities to manage their diabetes was measured via the revised version of the Summary of Diabetes Self-Care Activities (SDSCA; Toobert, Hampson, & Glasgow, 2000). The SDSCA is a multi-dimensional measure that consists of 11 core items that assess diet, exercise, blood sugar testing, foot care, and smoking over the previous seven days. Fourteen additional questions provide further

information about self-care recommendations, diet, medications, foot care, and smoking. In a summary of seven studies that used the scale, the inter-item correlations for the core items were generally acceptable (mean = .47). A moderate level of test-retest reliability over a three to four month period was also demonstrated (mean $r$ = .40). The dietary and exercise sub-scales were also significantly correlated to other measures of compliance to dietary (e.g., food records, Food Habits Questionnaire) and exercise (e.g., Physical Activity Scale for the Elderly, Stanford 7-Day Recall) recommendations. The 14 additional items were recently added to provide more information to clinicians and researchers but there is no data regarding the reliability and validity of these items (Toobert et al., 2000). The internal consistency at baseline in the current study was high for the general diet (α = .93), exercise (α = .91), blood glucose testing (α = .85) but low for foot care (α = .54) and specific diet subscales (α = .36).

**Diabetes symptoms.** The Diabetes Symptom Checklist-Revised (DSC-R; Arbuckle et al., 2009) assessed the number and severity of diabetes-related symptoms that the participants are experiencing. This scale was initially developed as a tool for clinicians to assess symptoms and track changes due to treatment. The 34-item scale assesses hyperglycemic (e.g., thirst, dry mouth), hypoglycemic (e.g., moodiness, irritability), psychological-cognitive (e.g., sleepiness, difficulty concentrating), psychological-fatigue (e.g., lack of energy, overall sense of fatigue), cardiovascular (e.g., shortness of breath, palpitations), neurological-pain (e.g., pain in the legs and calves), neurological-sensory (e.g., numbness in hands and feet), and ophthalmologic (e.g., blurred vision, deteriorating vision) symptoms. Participants are asked whether they have experienced each symptom in the past 4 weeks. If they have experienced a particular symptom, they are asked to indicate how troublesome the symptoms is, using a 5-point Likert scale (1 = not at all; 5 = extremely). Responses are summed to obtain an overall score as well as sub-test

scores for each domain, with higher scores indicating more diabetes symptom burden. Subtest scores are divided by the number of items in the domain to allow for comparison of scores across domains. All subscales have been shown to have good internal consistency (Cronbach α = .69 - .87; Arbuckle et al., 2009). The internal consistency at baseline in the current study was high for total score (α = .94) as well as the subscales (α = .69 - .87). The DSC-R subscales have small to moderate correlations with SF-36 scores of perceived health status (-.22 to -.69). Higher DSC-R scores are associated with higher A1c and higher BMI. Further, changes in DSC-R scores after one year were consistent with patients' reports of perceived health changes (Arbuckle et al., 2009).

**Glycemic control.** Glycemic control was assessed via hemoglobin A1c, an index of glucose regulation over a period of about two to three months (Lustman, Griffith, Freedland, & Clouse, 1997b). A high A1c level is indicative of poor glycemic control. It is generally recommended that A1c be as low as possible without causing hypoglycemic complications; for most diabetics this is less than 7% ("Executive summary: Standards of medical care in diabetes--2009," 2009; Qaseem et al., 2007).

A1c was obtained from the participants' medical records. Participants were asked to sign a release of information form when they enrolled in the study. The researcher forwarded the release form to participant's physician and the physician was asked to provide the researcher with the patient's A1c values within a specified time period. Initial A1c was valid if measured no more than 90 days before completing Q1 or no more than 30 days after completing Q1. Final A1c was valid if measured no more than 30 days before completing Q3 or no more than 90 days after completing Q3. These time periods reflect the characteristic of A1c as a weighted average of glucose control over the past 90 -120 days, with the most recent 30 days having a greater

effect on the measurement. Thus, these periods are assumed to give the best approximation of A1c before and after the intervention period.

**Demographic information and treatment history.** Participants were asked to complete a survey that was designed for this study. Questions included demographic information such as age, race, gender, education, and marital status. They were also asked about their diabetes history, such as how long since diagnosis, what they are doing to control their diabetes (e.g., diet, medication, insulin, etc), and their overall sense of their ability to manage diabetes. Participants were asked to indicate whether they have ever sought psychological counseling or medication, whether they are currently receiving counseling or medication, and whether they would consider seeking services in the future if they thought it was necessary.

**Data Analysis**

**Preliminary analyses**. The characteristics of the participants in the intervention and control groups were compared to determine whether random assignment was successful. T-tests and $\chi^2$ analyses were conducted to determine whether the groups significantly differed on demographic and diabetes-specific characteristics (number of males/females, ethnic proportions, age of participants, length of time since diabetes diagnosis, etc.). Those who completed the study and those who withdrew were also compared to determine the effect of attrition on the sample.

**Outcome analyses**. The efficacy of CCBT-SM was tested using Analysis of Covariance (ANCOVA). Pre-study (Q1) scores on the outcome measures (PSS, PAID, PHQ-9, GAD-7, PANAS, A1c, DSC-R, and SDSCA) were entered into the model as covariates with intervention group as the fixed factor and post-study (Q3) scores as the dependent variable. The significance of the *F*-value for group was used to determine whether the intervention significantly influenced the Q3 scores, controlling for the Q1 scores.

The data for the mid-study questionnaire (Q2) were not used in the outcome analyses. This questionnaire was administered halfway through the intervention/waiting period to potentially counteract the effect of attrition. The data was to be used to increase the power of the study if there was substantial attrition after the halfway point. However, including the questionnaire only allowed for the inclusion of data from five participants in the intervention group. In the control group there fewer people who completed Q2 than Q3. Because the data in the middle of the intervention does not speak to the efficacy of the entire intervention and it did not significantly increase the sample size, it was decided to not include it in the final analyses.

**Mediation analyses.** It was hypothesized that there would be an indirect effect of the intervention on glycemic control and diabetes symptoms through a reduction in psychological distress (see Figure 1) and there would be an indirect effect of the intervention on diabetes symptoms through an increase in adherence (see Figure 2). The Bootstrapping Method was used to test these hypotheses, employing the SPSS macro provided by Hayes (2013). This method provides an estimate of indirect effect that makes no assumption about the shape of the distribution of the indirect effect. The bias-corrected bootstrapped 95% confidence interval (BCa CI) is estimated using 1000 bootstrapped samples. The indirect effect is determined to be significant if the BCa CI around the estimate does not include 0. The mediation effect size was measured using the ratio of the indirect effect to the total effect ($P_M$), which is loosely interpreted as the proportion of the total effect that is mediated. This is one of the most widely used effect sizes for mediation (Preacher & Kelley, 2011).

Table 1

Outline of the CCBT-SM Intervention

| Week / Time | Topics Covered | Homework |
|---|---|---|
| Week 1<br><br>16 – 20 minutes | Overview<br>• How to use this Program (1:11)<br>• About this Program (1:35)<br>Stress Management<br>• Introduction (1:36)<br>• Assess Your Stress (0:17)<br>o Self-Assessment<br>• The Stress Response<br>o This Thing Called stress (0:39)<br>o Primitive vs. Modern (1:23)<br>o Fight or Flight (1:12)<br>o A Vicious Cycle (1:15)<br>o What Next? (1:17)<br>• Identify Stressors<br>o Introduction (1:40)<br>o Stress Symptoms (0:45)<br>o Recognize Symptoms (0:23)<br>o Personal Stressors (1:51) | Identify Your Personal Stressors Worksheet (original) |
| Week 2<br><br>10 minutes | Avoid Negative Coping<br>• The Trap (1:22)<br>• Alcohol – A Legal Drug (1:16)<br>• The Drug Trap (1:22)<br>• Self-Assessment (0:16)<br>• Positive Alternatives (0:55)<br>• Tips for Cutting Down (1:00)<br>• Managing Social Drinking (0:59)<br>• A Healthy Lifestyle (0:35) | Identify Your Personal Stressors (original) & Negative Coping Worksheet (additional) |
| Week 3<br><br>16 – 20 minutes | Make Positive Choices<br>• Introduction (1:19)<br>• Adopt Mental Strategies (1:02)<br>o The Mental Lens (1:27)<br>o Choosing Optimism (1:34)<br>o Optimism vs. Pessimism (2:55)<br>o Avoid Negative Thinking (1:46)<br>o Changing Negative Thinking (1:20)<br>o Embrace Positive Thinking (1:36)<br>o Finding Humor (1:17)<br>o Stress Hardiness (1:24) | Embrace Positive Thinking Worksheet (additional) |

Table 1 (continued)

| Week / Time | Topics Covered | Homework |
|---|---|---|
| Week 4<br><br>10 minutes | Make Positive Choices<br>• Adopt Behavioral Strategies (0:16)<br>○ Physical Activity (1:41)<br>○ Stress Emergencies (0:52)<br>○ Relaxation Practice (0:32)<br>○ Breathwork (1:12)<br>○ Progressive Relaxation (1:03)<br>○ Guided Imagery (1:25)<br>○ Meditation (1:23) | Practice the relaxation exercises (mp3s) (original)<br><br>Use worksheet to track effect of relaxation on tension (additional) |
| Week 5 | Mid-Intervention Questionnaire | Continue to practice the procedures learned over the past 4 weeks; use worksheets that were most useful |
| Week 6<br><br>15 minutes | Make Positive Choice<br>• Adopt Behavioral Strategies<br>○ Social Support (1:44)<br>○ Time Management (2:42)<br>• Take Charge (Assertiveness & Problem-Solving)<br>○ Introduction (2:20)<br>○ Take Charge at Work (2:09)<br>○ Take Chare at Home (1:23)<br>○ Take Charge Against Terrorism (1:30)<br>○ Go For It – Review of stress management (1:48) | Problem solving Worksheet (additional) |
| Week 7<br><br>25 - 30 minutes | Managing Depression<br>• Introduction (0:57)<br>• Are You Feeling Depressed (0:48)<br>○ Assess Yourself (0:14)<br>• The Nature of Depression<br>○ Major Depressive Disorder (1:11)<br>○ Dysthymia (0:37)<br>○ Bipolar Disorder (1:09)<br>• The Impact of Depression<br>○ Introduction (0:41)<br>○ Emotions and Moods (0:46)<br>○ Thinking (0:49)<br>○ Physical Functioning (0:52)<br>○ Behaviors (0:49) | Download the Thought Record (original)<br><br>and/or<br><br>Lists Worksheet (additional) |

Table 1 (continued)

| Week / Time | Topics Covered | Homework |
|---|---|---|
| Week 7 (Continued) | • Managing Your Mood<br>○ Introduction (1:49)<br>○ Get Your Mind Right (0:28)<br>▪ Mental Lens (1:11)<br>▪ Harmful Thinking (1:12)<br>▪ Identify Harmful Thinking (0:47)<br>▪ 3 Types of Harmful Thinking (1:03)<br>▪ Choosing Optimism (1:47)<br>▪ Optimism vs. Pessimism (2:55)<br>▪ Challenging Harmful Thinking (0:56)<br>▪ Embracing Positive Thinking (0:47)<br>○ Get Your Body Right – exercise, sleep (1:01)<br>○ Get Your Actions Right – activity schedule (0:56)<br>○ Connecting with Others (0:55)<br>The Time is Now (0:51) | |
| Week 8<br><br>35 minutes | Managing Anxiety<br>• Introduction (1:01)<br>• What is Anxiety<br>○ Introduction (0:51)<br>○ Crossing the Line (1:13)<br>○ Assess Yourself (0:20)<br>• Types of Anxiety Disorders<br>○ Introduction (1:14)<br>○ Specific Phobia (1:12)<br>○ Social Phobia (1:09)<br>○ Panic Disorder (1:21)<br>○ Generalized Anxiety Disorder (1:11)<br>○ Obsessive-Compulsive Disorder (1:14)<br>○ Post-Traumatic Stress Disorder (1:19)<br>• Strategies that Work<br>○ Introduction (1:33)<br>○ Getting Your Body Right (0:42)<br>▪ Deep Relaxation (0:49)<br>▪ Breathing (1:16)<br>▪ Progressive Muscle Relaxation (1:13)<br>▪ Guided Imagery (1:04)<br>▪ Meditation (1:43)<br>▪ Regular Physical Activity (1:00)<br>▪ Eat Smart (1:24)<br>▪ See Your Physician (0:41)<br>○ Get Your Mind Right (1:28)<br>▪ Threatening Thoughts (1:19)<br>▪ Identifying Threatening Thoughts (0:48)<br>▪ Challenging Threatening Thoughts (0:57) | Thought Record for Challenging Threatening Thoughts (additional) |

Table 1 (continued)

| Week / Time | Topics Covered | Homework |
|---|---|---|
| Week 8 (continued) | ○ Get Your Actions Right (0:46)<br>▪ Expressive Writing (1:04)<br>▪ Overcoming Procrastination (1:08)<br>▪ Facing Your Fears (1:14)<br>▪ One Step at a Time (1:29) | |
| Week 9<br><br>25 – 30 minutes | Treatments that Work<br>• Introduction (1:06)<br>• Where to Start<br>○ Overcoming Stigma (1:17)<br>○ Evaluation and Diagnosis (1:08)<br>• Psychotherapy<br>○ Introduction (2:35)<br>○ Picking the Right Person (1:05)<br>○ Other Important Factors (1:08)<br>○ Cognitive Behavior Therapy (1:15)<br>○ CBT for Depression (1:09)<br>○ CBT for Anxiety (1:32)<br>○ Interpersonal Psychotherapy (0:51)<br>○ IPT for Depression and Anxiety (0:52)<br>○ Psychodynamic Therapy (1:00)<br>○ PDT for Depression and Anxiety (1:14)<br>• Medications<br>○ Introduction (1:06)<br>○ Questions to Ask (0:59)<br>○ Classes of Medications (0:44)<br>○ How They Work (1:13)<br>○ SSRIs (1:22)<br>○ Side Effects of SSRIs (0:58)<br>○ Anti-anxiety Medications (1:22)<br>○ Mood Stabilizers (1:03)<br>• Fit is Key<br>○ Do You Feel Comfortable? (1:06)<br>Resources | No official homework. Participants were encouraged to continue to use the skills they have been learning throughout the program. They were told that this is the last week that they have access to the program and that they are free to review the program as needed over the course of the week. |

*Note.* The outline above contains all of the sections that comprise the CCBT-SM intervention. The length of each module is in parentheses following the title of the section. The sections have been divided to create 8 modules. The homework section indicates whether the assignment was part of the original program (original) or whether it was created for use with this more structured version of the original program (additional). The additional homework worksheets can be found in Appendix A.

## Chapter Three

## Results

### Recruitment

All advertisements and literature related to the study directed interested individuals to the study website. The website received 4949 visits from unique IP addresses. From those visits, 608 individuals expressed interest in the study by completing an enrollment form with their contact information. An additional 30 individuals were recruited directly from HealthStreet.

Of the 638 enrollment forms that were submitted, 6 were determined to be falsified (i.e., the phone numbers and addresses were not valid) and 103 individuals could not be reached after several attempts via email and telephone. Of those who were assessed for eligibility ($n$ = 529), 352 were excluded because they did not meet eligibility criteria, did not complete the screening process, or declined to participate. The remainder ($n$ = 177) were randomly assigned to the intervention or control group. See Figure 3 for additional information regarding recruitment and attrition.

As expected, the attrition rate was high. Due to 39% of participants not completing the final questionnaire, a higher number of participants than expected were randomized ($N$ = 177). Also, the rate of attrition was higher for the intervention group (44%) compared to the control group (20%). To allow for better comparisons, randomization for the last third of the study was done at a 2:1 ratio, with twice as many participants randomly assigned to the to the intervention group ($n$ = 103) compared to the control group ($n$ = 74).

**Sample Characteristics**

The baseline characteristics of the sample are outlined in Table 2. Participants were recruited from 40 states across the US, with the highest percentage (18.6%) from Florida. Participants were primarily women and Caucasian. They ranged in age from 19 to 83 ($M$ = 55.13, $SD$ = 13.9). All but one participant graduated from high school, with more than half achieving a college degree or higher (58.7%).

Approximately two-thirds of the sample reported that they had been diagnosed with type 2 diabetes (66 %) and on average the sample had been living with diabetes for 15.41 years ($SD$ = 12.7). The majority reported they considered their diabetes management to be fair (35.6%) or good (37.3%). Most (89.8%) reported at least one chronic illness other than diabetes.

Slightly more than half of the participants reported that they had undergone some type of psychotherapy (55.9%) and/or taken a psychotropic medication (53.7%) at some point in their lives. However, only about one-third (33.9%) were currently taking a psychotropic medication. The sample's mean score on the PHQ-9 ($M$ = 9.08, $SD$ = 5.6) indicates a mild level of depression, with scores ranging from 0 (no depression) to 26 (severe depression). Similarly, the scores on the GAD-7 indicate a mild to moderate level of anxiety ($M$ = 7.92, $SD$ = 5.2) with a range of 0 (no anxiety) to 21 (severe anxiety). There are no published cut-offs for the PSS. Possible scores range from 0 to 56. The range in the current sample was from 8 to 49 and the mean was 29.23 ($SD$ = 8.0). The amount of diabetes-related distress reported in the sample ($M$ = 46.86, $SD$ = 24.4) indicated high levels of distress.

**Preliminary Analyses**

Statistical comparisons indicated that randomization was successful (see Table 2). There were no significant differences between the intervention and waiting list group on baseline

demographic, diabetes, or psychological characteristics. With the exception of blood glucose testing, this was also the case when comparing only those who completed the study (see Table 3). Those who completed the study in the intervention group reported more frequent blood glucose testing than those who completed the study in the waiting list group.

Table 4 provides comparisons between those who completed the study and those who did not. While those who did not complete the study did not differ from those who did on demographic characteristics, there were some differences in other areas. Those who did not complete the study were more likely to describe their diabetes management as "poor." They also reported higher levels of negative affect and anxiety.

Correlations of A1c with the outcome variables are shown in Table 5. There were no correlations between reported severity of total diabetes symptoms and A1c. However, A1c was correlated with ophthalmological symptoms (at baseline) and sensory symptoms (at final assessment). There were also almost no correlations between A1c and the psychological measures. The one exception is a positive relationship between A1c and diabetes-related distress at baseline (see Table 5). A1c at baseline was also related to adherence to general diet recommendations.

Correlations of psychological outcomes with diabetes outcomes and adherence at baseline are shown in Tables 6 and 7. Correlations of psychological variables with diabetes symptoms were significant at baseline (Table 6) and at the end of the intervention (Table 7). However, there were few significant relationships between the psychological variables and adherence variables. A notable exception is the positive correlations of positive affect with adherence to diet and exercise recommendations (see Tables 6 and 7).

**CCBT-SM Utilization**

The use of CCBT-SM by those in the intervention group was measured in multiple ways. The primary assessment of program engagement was through the weekly "self-checks." These short quizzes were sent to the participants each week in the weekly program email. When the self-check was complete, the researcher received a notification email. Participants who did not complete the self-check in a timely manner were reminded to access the program and complete the self-check (see methods section for further detail). On average participants completed 7.39 (*SD* = 1.2) weekly self-checks and the majority (67.3%) completed all eight.

The program website also contained software that provided information on overall utilization of the program by each participant at the conclusion of the study. On average, participants logged-in to the program 11.8 (*SD* = 6.0) times, visited 100 (*SD* = 34.4) of the program's 124 pages, and spent 335 (*SD* = 236.3) minutes in the program. These numbers are higher than what was expected (i.e., log-ins once per week, total of 140 minutes spent on the program).

**Tests of ANCOVA Assumptions**

The assumptions of ANCOVA were examined. Visual inspection of scatterplots and significant correlations (see Appendix B) indicated linear relationships between all Q1 and Q3 measures for each group. Standardized residuals for the group were not normally distributed for several of the variables (Shapiro-Wilk's test $p > .05$) including negative affect, generalized anxiety, and depression. Transforming the variables resulted in normal distributions but did not change the outcome of the ANCOVAs, thus the untransformed data is reported below. The distributions of standardized residuals were also non-normal (Shapiro-Wilk's test $p > .05$) for several of the diabetes symptom clusters (neurological pain, sensory, cardiac, and

ophthalmological symptoms). Inspection of the data revealed that most participants reported very few or no symptoms in these clusters. The distribution of standardized residuals for adherence to blood-glucose testing recommendations was also non-normal. Multiple transformations of these data were performed but normality was unable to be achieved. Although ANCOVA is robust to non-normality of distributions, these analyses should be interpreted with caution. In addition, the distribution of standardized residuals for adherence to foot care recommendations was positively skewed. There was one obvious outlier in the data of the intervention group. When this value was removed, a normal distribution was achieved. However, the results of the ANCOVA were unchanged. The data-point was determined to be valid, thus this participant's data remained in the dataset.

Equality of error variances was significant for positive affect, anxiety, and hypoglycemia (Levene's test of equality of error variances $p <$ .05). In all cases transforming the data achieved homogeneity of variances but the results of the ANCOVA were not affected. Visual inspection of scatter plots of standardized residuals against predicted values raised some concerns of heteroscedasticity. However, in all cases, transforming the dependent variable achieved homoscedasticity but did not affect the outcome of the ANCOVA. Thus, the untransformed data are reported below.

**Hypothesis 1: Effect of CCBT-SM on Psychological Distress**

The first hypothesis stated that CCBT-SM would lower psychological distress in the intervention group, compared to the control group. Perceived generalized stress, diabetes-related distress, symptoms of anxiety and depression, and mood were expected to improve after participation in CCBT-SM. ANCOVAs were used to examine to this hypothesis.

This hypothesis was supported (see Table 8). Group assignment had a significant effect on all measures of psychological distress (i.e., perceived generalized stress, diabetes-related distress, symptoms of anxiety and depression, and negative affect) at post-intervention when controlling for baseline scores, with the intervention group scoring lower than the control group on all of these measures. There was a medium effect size for diabetes-related distress, anxiety, depression, and negative affect and a large effect for perceived generalized distress. The intervention did not have a significant effect on positive affect.

The ANCOVA testing the effect of the intervention on negative affect must be qualified due to heterogeneity of slopes in this model. That is, the group*covariate (negative affect at Q1) interaction was significant ($F(1,102) = 6.54$, $p = .012$). Examination of plots of the regression lines (see Figure 4) demonstrated that the treatment effect varied across levels of baseline negative affect. Those who started with a low level of negative affect did not benefit from the intervention. However, in those with higher baseline negative affect, the group placement had a greater affect on Q3 negative affect scores.

**Hypothesis 2: Effect of CCBT-SM on Diabetes Symptoms and Glycemic Control**

The second hypothesis stated that participation in CCBT-SM would result in improved glycemic control and fewer diabetes symptoms in the intervention group compared to a waiting-list control group. ANCOVAs were also used to test this hypothesis (see Table 9).

The ANCOVA did not indicate a significant effect of intervention on A1c. However, due to a change in the methods, only 46 participants (less than half of the sample) submitted valid post-intervention A1c results. Thus, this analysis was underpowered.

There was also no effect of intervention on the total severity of diabetes symptoms. However, there were some effects on symptom clusters (see Table 9). The intervention had

significant effects on psychological fatigue, cognitive symptoms, hyperglycemic symptoms, and hypoglycemic symptoms. There were large effect sizes for cognitive symptoms and symptoms of hypoglycemia and small effect sizes for psychological fatigue and symptoms of hyperglycemia. In each instance, the intervention group scored lower on these measures than the control group.

The ANCOVA testing the effect of the intervention on hyperglycemic symptoms must be qualified due to heterogeneity of slopes in this model. That is, the group*covariate (hyperglycemic symptoms at Q1) interaction was significant ($F$ (1,94) = 9.92, $p < .01$). Examination of plots of the regression lines (see Figure 5) demonstrated that the treatment effect varied across levels of baseline hyperglycemic symptoms. Those who started with a fewer hypoglycemic symptoms did not benefit from the intervention. However, in those with more baseline hyperglycemic symptoms, the group placement had a greater affect on Q3 hyperglycemic symptoms.

**Hypothesis 3: Psychological Distress will Mediate the Effect of CCBT-SM on Symptoms**

The third hypothesis stated that the mechanism through which CCBT-SM will improve diabetes outcomes is by lowering distress and improving mood. Because there was not a significant effect of the intervention on A1c, a mediation analysis was not performed for this variable. However, there were significant intervention effects for the symptom clusters of fatigue, cognitive symptoms, hypoglycemic symptoms and hyperglycemic symptoms. Thus, perceived generalized distress, diabetes-related distress, depression symptoms, anxiety symptoms, and negative affect were examined as mediators of the ability of CCBT-SM to decrease these symptoms.

There were significant indirect effects of the intervention on fatigue, cognitive symptoms, hypoglycemic symptoms, and hyperglycemic symptoms through all of the psychological distress measures (see Figure 6 and tables 10-13). Examination of the effect sizes indicates that depression and perceived generalized stress have the largest influence on the relationship between the intervention and diabetes outcomes.

Because these mediation analyses were conducted with data from the same time (Q3), directionality cannot be inferred. That is, it is possible that rather than there being an indirect effect of CCBT-SM on diabetes symptoms through psychological distress (see Figure 6), there is an indirect effect of CCBT-SM on psychological distress through diabetes symptoms (see Figure 7). To better understand these competing models, additional mediation analyses were conducted to compare the size of the indirect effect in each pathway. As can be seen in Tables 14 -17, the reversed models tend to show weaker indirect effects (i.e., the completely standardized indirect effects and effect sizes are smaller). These analyses offer the best support for a path from CCBT-SM to psychological distress to fatigue and hyperglycemic symptoms. When the first model is reversed (that is, the path becomes CCBT-SM to fatigue to psychological distress), all indirect effects are smaller and those with depression and anxiety as outcomes are not significant (see Tables 10 and 14). Similarly, when the path from CCBT-SM to psychological distress to hyperglycemic symptoms is reversed, all indirect effects are smaller and the indirect effects on perceived generalized distress and diabetes-related distress are not significant (see Tables 12 and 16). The pathway from CCBT-SM to psychological distress to hypoglycemic symptoms was among the weakest of those tested. When the pathway is changed to CCBT-SM to hypoglycemic symptoms to psychological distress, the indirect effects are not greatly affected. In the case of anxiety, the size of the indirect effect of hypoglycemic symptoms actually slightly

increases (see Tables 13 and 17). Therefore, it is not clear whether the psychological distress variables mediate the effect of the intervention on hypoglycemic symptoms or if hypoglycemic symptoms mediate the effect of the intervention on psychological distress.

**Hypothesis 4: Adherence will Mediate the Effect of CCBT-SM on Diabetes Outcomes.**

The fourth hypothesis posited that there would be an indirect effect of CCBT-SM on diabetes outcomes through adherence to diabetes management recommendations. There were no significant effects of the intervention on adherence to the diabetes treatment regimen (see Table 18). That is, the intervention did not have a significant effect on adherence to diet, exercise, blood-glucose testing, or foot care recommendations. Therefore, this hypothesis was not tested.

Table 2

Baseline Characteristics of Participants Randomized to the Computerized Cognitive-Behavioral Therapy for Stress Management (CCBT-SM) or the Waiting List Group

| | Total Sample ($N$ = 177) | CCBT-SM ($n$ = 103) | Waiting List ($n$ = 74) | |
|---|---|---|---|---|
| Demographic Variables | | | | |
| Age in years | 55.13 (13.9) | 55.22 (13.3) | 54.99 (14.6) | $t$ (174) = .11, $p$ >.05 |
| Women | 130 (73.4) | 76 (73.8) | 54 (74.0) | $X^2$ (1) = .001, $p$ > .05 |
| Caucasian | 155 (87.6) | 92 (89.3) | 69 (93.2) | $X^2$ (1) = .806, $p$ > .05 |
| Married | 106 (59.9) | 60 (58.3) | 46 (62.2) | $X^2$ (1) = .274, $p$ > .05 |
| College graduate or higher | 104 (58.7) | 56 (54.4) | 48 (66.7) | $X^2$ (1) = 1.96, $p$ > .05 |
| Diabetes-Related Variables | | | | |
| Type 2 | 117 (66.1) | 65 (63.1) | 52 (70.3) | $X^2$ (1) = .986, $p$ >.05 |
| Years since Diagnosis | 15.41 (12.7) | 15.9 (13.8) | 14.72 (10.9) | $t$ (164) = .587, $p$ >.05 |
| Hemoglobin A1c | 7.60 (1.3) | 7.59 (1.1) | 7.61 (1.6) | $t$ (79) = -.041 $p$ >.05 |
| Diabetes symptoms (Total) | 39.25 (28.4) | 39.98 (28.8) | 38.23(28.1) | $t$ (175) = .403, $p$ >.05 |
| Sensory | 0.91 (1.13) | 1.01 (1.2) | 0.76 (1.0) | $t$ (169) = 1.44, $p$ >.05 |
| Psychological Fatigue | 2.21 (1.36) | 2.19 (1.3) | 2.24 (1.4) | $t$ (169) = -.217, $p$ >.05 |
| Cognitive | 1.69 (1.36) | 1.71 (1.3) | 1.67 (1.3) | $t$ (168) = .202, $p$ >.05 |
| Neurological Pain | 0.57 (1.0) | 0.61 (1.0) | 0.51 (1.1) | $t$ (165) = .628, $p$ >.05 |
| Cardiac | 0.75 (0.9) | 0.78 (1.0) | 0.72 (0.9) | $t$ (171) = .408, $p$ >.05 |
| Ophthalmologic | 0.62 (1.0) | 0.60 (0.9) | 0.63 (1.1) | $t$ (168) = -.210, $p$ >.05 |
| Hypoglycemic | 1.67 (1.2) | 1.66 (1.27) | 1.67 (1.2) | $t$ (171) = -.052, $p$ >.05 |
| Hyperglycemic | 1.29 (1.2) | 1.33 (1.3) | 1.24 (1.2) | $t$ (165) = .474, $p$ >.05 |
| Ability to Manage Diabetes | | | | |
| Horrible | 6 (3.4) | 4 (3.9) | 2 (2.7) | $X^2$ (1) = .183, $p$ >.05 |
| Poor | 24 (13.6) | 15 (14.6) | 9 (12.2) | $X^2$ (1) = .212, $p$ >.05 |

Table 2 (Continued)

| | Total Sample ($N$ = 177) | CCBT-SM ($n$ = 103) | Waiting List ($n$ = 74) | |
|---|---|---|---|---|
| Fair | 63 (35.6) | 39 (37.9) | 24 (32.4) | $X^2$ (1) = .554, $p$ >.05 |
| Good | 66 (37.3) | 37 (35.9) | 29 (39.2) | $X^2$ (1) = .197, $p$ >.05 |
| Excellent | 15 (8.5) | 8 (7.8) | 7 (9.5) | $X^2$ (1) = .159, $p$ >.05 |
| Oral Diabetes Medication | 108 (61.0) | 62 (60.2) | 46 (62.2) | $X^2$ (1) = .070, $p$ >.05 |
| Insulin | 106 (59.9) | 62 (60.2) | 44 (59.5) | $X^2$ (1) = .010, $p$ >.05 |
| Chronic Illnesses | 3.97 (2.9) | 4.19 (2.9) | 3.66 (2.7) | $t$ (175) = .12, $p$ >.05 |
| Adherence to Diabetes Regimen | | | | |
| General diet | 4.38 (1.8) | 4.37 (1.9) | 4.42 (1.7) | $t$ (173) = -.171, $p$ >.05 |
| Specific diet | 3.84 (1.6) | 3.85 (1.7) | 3.81 (1.5) | $t$ (172) = .141, $p$ >.05 |
| Exercise | 2.81 (2.3) | 2.773 (2.5) | 2.92 (2.2) | $t$ (174) = -.544, $p$ >.05 |
| Blood glucose testing | 4.98 (2.5) | 5.20 (2.4) | 4.67 (2.6) | $t$ (170) = 1.39, $p$ >.05 |
| Foot care | 4.20 (1.5) | 4.22 (1.4) | 4.17 (1.5) | $t$ (163) = .214, $p$ >.05 |
| Psychological Variables | | | | |
| Perceived Generalized Stress | 29.23 (8.0) | 29.67 (8.2) | 28.63 (7.6) | $t$ (173) = .849, $p$ >.05 |
| Positive Affect | 27.06 (8.2) | 27.02 (8.1) | 27.11 (8.4) | $t$ (171) = -.072, $p$ >.05 |
| Negative Affect | 23.96 (8.1) | 24.49 (8.6) | 23.23 (7.4) | $t$ (175) = 1.01, $p$ >.05 |
| Depression | 9.75 (5.9) | 10.27 (6.23) | 9.01 (5.4) | $t$ (157) = 1.31, $p$ >.05 |
| Anxiety | 7.92 (5.2) | 8.40 (5.3) | 7.24 (5.1) | $t$ (159) = 1.39, $p$ >.05 |
| Diabetes-Related Distress | 46.86 (24.4) | 48.0 (25.6) | 45.3 (22.5) | $t$ (175) = .721, $p$ >.05 |
| History of Psychotherapy | 99 (55.9) | 59 (57.3) | 40 (54.1) | $X^2$ (1) = .182, $p$ >.05 |
| Current Psychotropic Medication | 60 (33.9) | 37 (36.3) | 23 (33.3) | $X^2$ (1) = .156, $p$ >.05 |
| Stress Management in Past Week | 4.13 (4.0) | 4.24 (3.14) | 3.97 (3.0) | $t$ (175) = .571, $p$ >.05 |

*Note*. Values are *M (SD)* or *n* (%) as appropriate.

Table 3

Baseline Characteristics of Participants Who Completed the Study in the Computerized Cognitive-Behavior for Stress Management (CCBT-SM) Group vs. the Waiting List Group

| | Total Sample ($N$ = 108) | CCBT-SM ($n$ = 49) | Waiting List ($n$ = 59) | |
|---|---|---|---|---|
| Demographic Variables | | | | |
| Age in years | 55.05 (14.6) | 57.22 (13.9) | 53.24 (15.0) | $t$ (100) = 1.42, $p$ > .05 |
| Women | 80 (74.8) | 36 (73.5) | 44 (75.9) | $X^2$ (1) = .081, $p$ > .05 |
| Caucasian | 101 (93.5) | 47 (95.9) | 54 (91.5) | $X^2$ (1) = .852, $p$ > .05 |
| Married | 67 (62.0) | 29 (59.2) | 38 (64.4) | $X^2$ (1) = .310, $p$ > .05 |
| College Graduate or Higher | 65 (60.2) | 28 (57.1) | 37 (62.7) | $X^2$ (1) = .346, $p$ > .05 |
| Diabetes-Related Variables | | | | |
| Type 2 | 72 (66.7) | 31 (63.3) | 41 (69.5) | $X^2$ (1) = .467, $p$ > .05 |
| Years Since Diagnosis | 14.48 (11.0) | 16.15 (12.6) | 13.05 (9.4) | $t$ (100) = 1.420, $p$ > .05 |
| Hemoglobin A1c | 7.58 (1.4) | 7.59 (1.2) | 7.56 (1.6) | $t$ (62) = 0.09, $p$ >.05 |
| Diabetes Symptoms (Total) | 36.83 (26.5) | 35.90 (23.6) | 37.61 (28.9) | $t$ (106) = -0.33, $p$ > .05 |
| Sensory | 0.78 (1.1) | 0.91 (1.1) | 0.68 (1.0) | $t$ (102) = 1.07, $p$ >.05 |
| Psychological Fatigue | 2.15 (1.4) | 2.11 (1.3) | 2.19 (1.4) | $t$ (102) = -0.31, $p$ >.05 |
| Cognitive | 1.60 (1.3) | 1.48 (1.2) | 1.69 (1.3) | $t$ (101) = -0.82, $p$ >.05 |
| Neurological Pain | 0.54 (1.0) | 0.44 (0.8) | 0.63 (1.2) | $t$ (99) = -0.88, $p$ >.05 |
| Cardiac | 0.65 (0.8) | 0.59 (0.7) | 0.70 (0.9) | $t$ (102) = -0.69, $p$ >.05 |
| Ophthalmologic | 0.58 (1.0) | 0.59 (0.9) | 0.58 (1.1) | $t$ (104) = -0.04, $p$ >.05 |
| Hypoglycemic | 1.61 (1.2) | 1.49 (1.2) | 1.71 (1.2) | $t$ (102) = -0.94, $p$ >.05 |
| Hyperglycemic | 1.19 (1.1) | 1.22 (1.1) | 1.16 (1.2) | $t$ (101) = .25, $p$ >.05 |
| Ability to Manage Diabetes | | | | |
| Horrible | 4 (3.7) | 2 (4.1) | 3 (3.4) | $X^2$ (1) = .036, $p$ > .05 |
| Poor | 10 (9.3) | 4 (8.2) | 6 (10.2) | $X^2$ (1) = .128, $p$ > .05 |

Table 3 (Continued)

| | Total Sample ($N = 108$) | CCBT-SM ($n = 49$) | Waiting List ($n = 59$) | |
|---|---|---|---|---|
| Fair | 40 (37.0) | 21 (42.9) | 19 (32.2) | $X^2$ (1) = 1.303, $p > .05$ |
| Good | 42 (38.9) | 18 (36.7) | 24 (40.7) | $X^2$ (1) = .175, $p > .05$ |
| Excellent | 9 (8.3) | 4 (8.2) | 5 (8.5) | $X^2$ (1) = .003, $p > .05$ |
| Oral Diabetes Medication | 70 (64.8) | 33 (67.3) | 37 (62.7) | $X^2$ (1) = .252, $p > .05$ |
| Insulin | 66 (61.1) | 31 (63.3) | 35 (59.3) | $X^2$ (1) = .175, $p > .05$ |
| Chronic Illnesses | 3.76 (2.7) | 4.10 (2.8) | 3.47 (2.5) | $t$ (106) = 1.23, $p >.05$ |
| Adherence to Diabetes Regimen | | | | |
| General diet | 4.50 (1.8) | 4.64 (1.9) | 4.37 (1.6) | $t$ (105) = 0.77, $p >.05$ |
| Specific diet | 3.85 (1.6) | 3.90 (1.6) | 3.80 (1.6) | $t$ (104) = 0.34, $p >.05$ |
| Exercise | 2.93 (2.3) | 2.93 (2.5) | 2.93 (2.2) | $t$ (106) = -0.01, $p >.05$ |
| Blood Glucose Testing | 5.04 (2.5) | 5.61 (2.1) | 4.59 (2.6) | $t$ (102) = 2.14, $p =.04$ |
| Foot care | 4.11 (1.5) | 4.08 (1.4) | 4.13 (1.6) | $t$ (96) = -0.14, $p >.05$ |
| Psychological Variables | | | | |
| Perceived Generalized Stress | 28.37 (8.0) | 28.52 (8.8) | 28.25 (7.3) | $t$ (105) = 0.17, $p >.05$ |
| Positive Affect | 27.92 (8.1) | 28.27 (7.3) | 27.62 (8.8) | $t$ (104) = 0.41, $p >.05$ |
| Negative Affect | 22.83 (7.9) | 22.84 (8.8) | 22.83 (7.1) | $t$ (106) = 0.004, $p >.05$ |
| Depression | 9.08 (5.6) | 9.24 (5.8) | 8.94 (5.4) | $t$ (96) = 0.27, $p >.05$ |
| Anxiety | 7.16 (5.2) | 7.36 (5.4) | 7.00 (5.0) | $t$ (93) = 0.33, $p >.05$ |
| Diabetes-Related Distress | 44.36 (24.2) | 43.52 (26.8) | 45.06 (22.0) | $t$ (106) = -0.33, $p >.05$ |
| History of Psychotherapy | 57 (52.8) | 21 (53.1) | 31 (52.5) | $X^2$ (1) = .003, $p > .05$ |
| Current Psychotropic Medication | 31 (29.5) | 16 (32.7) | 16 (26.8) | $X^2$ (1) = .432, $p > .05$ |
| Stress management in Past Week | 4.33 (3.1) | 4.63 (3.2) | 4.08 (3.1) | $t$ (106) = 0.91, $p >.05$ |

*Note*. Values are *M (SD)* or *n* (%) as appropriate.

Table 4

Baseline Characteristics of Participants who Completed the Study and Those who Did Not Complete the Study

| | Total Sample ($N$ = 177) | Non-Completers ($n$ = 69) | Completers ($n$ = 108) | |
|---|---|---|---|---|
| Demographic Variables | | | | |
| Age in years | 5.13 (13.85) | 55.25 (12.7) | 55.05 (14.6) | $t$ (174) =0.10, $p$ >.05 |
| Women | 130 (73.4) | 50 (72.5) | 80 (74.8) | $X^2$ (1) = .0.12, $p$ > .05 |
| Caucasian | 161 (91.0) | 60 (87.0) | 101 (93.5) | $X^2$ (1) = 2.21, $p$ > .05 |
| Married | 106 (59.9) | 39 (56.5) | 67 (62.0) | $X^2$ (1) = 0.53, $p$ > .05 |
| College Graduate or Higher | 104 (58.7) | 39 (56.5) | 65 (60.2) | $X^2$ (1) = 0.23, $p$ > .05 |
| Diabetes-Related Variables | | | | |
| Type 2 | 117 (66.1) | 45 (65.2) | 72 (66.7) | $X^2$ (1) = 0.04, $p$ > .05 |
| Years Since Diagnosis | 15.41 (12.7) | 16.89 (14.9) | 14.48 (11.0) | $t$ (164) = 1.20, $p$ > .05 |
| Hemoglobin A1c | 7.60 (1.3) | 7.74 (1.0) | 7.56 (1.4) | $t$ (79) = 0.490, $p$ > .05 |
| Diabetes Symptoms (Total) | 39.25 (28.4) | 43.03 (31.0) | 36.83 (26.5) | $t$ (175) = 1.42, $p$ > .05 |
| Sensory | 0.91 (1.13) | 1.10 (1.2) | 0.78 (1.1) | $t$ (169) = 1.81, $p$ > .05 |
| Psychological Fatigue | 2.21 (1.36) | 2.31 (1.4) | 2.15 (1.4) | $t$ (169) = 0.72, $p$ > .05 |
| Cognitive | 1.69 (1.36) | 1.84 (1.3) | 1.60 (1.3) | $t$ (168) = 1.20, $p$ > .05 |
| Neurological Pain | 0.57 (1.0) | 0.61 (1.0) | 0.54 (1.0) | $t$ (165) = 0.43, $p$ > .05 |
| Cardiac | 0.75 (0.9) | 0.90 (1.1) | 0.65 (0.8) | $t$ (171) = 1.70, $p$ > .05 |
| Ophthalmologic | 0.62 (1.0) | 0.67 (0.9) | 0.58 (1.0) | $t$ (168) = 0.56, $p$ > .05 |
| Hypoglycemic | 1.67 (1.2) | 1.74 (1.3) | 1.61 (1.2) | $t$ (171) = 0.69, $p$ > .05 |
| Hyperglycemic | 1.29 (1.2) | 1.46 (1.4) | 1.19 (1.1) | $t$ (165) = 1.39, $p$ > .05 |
| Ability to Manage Diabetes | | | | |
| Horrible | 6 (3.4) | 2 (2.9) | 4 (3.7) | $X^2$ (1) = .0.08, $p$ > .05 |
| Poor | 24 (13.6) | 14 (20.3) | 10 (9.3) | $X^2$ (1) = 4.37, $p$ = .04 |
| Fair | 63 (35.6) | 23 (33.3) | 40 (37.0) | $X^2$ (1) = 0.25, $p$ > .05 |
| Good | 66 (37.3) | 24 (34.8) | 42 (38.9) | $X^2$ (1) = 0.30, $p$ > .05 |

Table 4 (Continued)

| | Total Sample ($N = 177$) | Non-Completers ($n = 69$) | Completers ($n = 108$) | |
|---|---|---|---|---|
| Excellent | 15 (8.5) | 6 (8.7) | 9 (8.3) | $X^2$ (1) = 0.01, $p > .05$ |
| Oral Diabetes Medication | 108 (61.0) | 38 (55.1) | 70 (64.8) | $X^2$ (1) = 1.68, $p > .05$ |
| Insulin | 106 (59.9) | 40 (58.0) | 66 (61.1) | $X^2$ (1) = 0.17, $p > .05$ |
| Chronic Illnesses | 3.97 (2.9) | 4.30 (3.2) | 3.76 (2.6) | $t$ (175) =1.24, $p > .05$ |
| Adherence to Diabetes Regimen | | | | |
| General diet | 4.38 (1.8) | 4.22 (1.8) | 4.50 (1.8) | $t$ (173) = -0.98, $p > .05$ |
| Specific diet | 3.84 (1.6) | 3.82 (1.7) | 3.85 (1.6) | $t$ (172) =-0.11, $p > .05$ |
| Exercise | 2.81 (2.3) | 2.63 (2.4) | 2.93 (2.3) | $t$ (174) = -0.84, $p > .05$ |
| Blood Glucose Testing | 4.98 (2.5) | 4.88 (2.5) | 5.04 (2.5) | $t$ (170) = -0.40, $p > .05$ |
| Foot care | 4.20 (1.5) | 4.33 (1.4) | 4.11 (1.5) | $t$ (163) = 0.97, $p > .05$ |
| Psychological Variables | | | | |
| Perceived Generalized Stress | 29.23 (8.0) | 30.59 (7.8) | 28.37 (8.0) | $t$ (173) = 1.81, $p > .05$ |
| Positive Affect | 27.06 (8.2) | 25.70 (8.2) | 27.92 (8.1) | $t$ (171) = -1.74, $p > .05$ |
| Negative Affect | 23.96 (8.1) | 25.72 (8.2) | 22.83 (7.9) | $t$ (175) = 2.34, $p = .02$ |
| Depression | 9.75 (5.9) | 10.84 (6.4) | 9.08 (5.6) | $t$ (157) = 1.83, $p > .05$ |
| Anxiety | 7.92 (5.2) | 9.02 (5.2) | 7.16 (5.17) | $t$ (159) = 2.24, $p = .03$ |
| Diabetes-Related Distress | 46.86 (24.4) | 50.78 (24.3) | 44.36 (24.2) | $t$ (175) = 1.72, $p > .05$ |
| History of Psychotherapy | 99 (55.9) | 42 (60.9) | 57 (52.8) | $X^2$ (1) = 1.12, $p > .05$ |
| Current Psychotropic Medication | 60 (33.9) | 29 (43.9) | 31 (29.5) | $X^2$ (1) = 3.70, $p > .05$ |
| Stress management in Past Week | 4.13 (4.0) | 3.81 (3.05) | 4.33 (3.12) | $t$ (175) = -1.09, $p > .05$ |

*Note*. Values are *M (SD)* or *n* (%) as appropriate.

Table 5

Correlations of A1c with Outcome Variables at Baseline & Final Assessment

| Variable | Baseline A1c & Q1 Correlations ($n$ = 64) | Final A1c & Q3 Correlations ($n$ = 54) |
|---|---|---|
| Perceived Generalized Stress | -.01 | .07 |
| Diabetes-Related Distress | .25* | .23 |
| Depression | -.09 | .14 |
| Anxiety | -.03 | .08 |
| Positive Affect | .20 | -.08 |
| Negative Affect | .01 | .16 |
| Diabetes Symptoms (Total) | .18 | .11 |
| Fatigue Symptoms | .06 | -.01 |
| Cognitive Symptoms | .11 | -.04 |
| Neurological Pain Symptoms | .23 | .23 |
| Sensory Symptoms | .03 | .28* |
| Cardiac Symptoms | .11 | .15 |
| Opthomological Symptoms | .33** | .09 |
| Hypoglycemia Symptoms | -.10 | -.77 |
| Hyperglycemia Symptoms | .20 | .11 |
| General Diet Recommendations | -.39** | -.01 |
| Specfic Diet Recommendatons | -.23 | -.01 |
| Exercise Recommendations | .03 | .17 |
| Glucose Testing Recommendations | -.02 | -.01 |
| Foot Care Recommendation | -.09 | -.13 |

*$p$ < .05. **$p$ < .01.

Table 6

Correlations of Psychological Outcomes with Diabetes Outcomes and Adherence at Baseline

| Variable | Perceived Generalized Stress | Diabetes-Related Distress | Depression | Anxiety | Positive Affect | Negative Affect |
|---|---|---|---|---|---|---|
| Diabetes Symptoms (Total) | .47** | .53** | .67** | .44** | -.32** | .51** |
| Fatigue | .44** | .45** | .63** | .40** | -.34** | .43** |
| Cognitive | .46** | .45** | .62** | .44** | -.38** | .51** |
| Pain | .30** | .31** | .42** | .37* | -.09 | .24* |
| Sensory | .26** | .31** | .42** | .23* | -.18 | .29** |
| Cardiac | .33** | .30** | .45** | .21* | -.21* | .35** |
| Ophthalmologic | .20* | .22* | .27** | .22* | -.07 | .17 |
| Hypoglycemic | .54** | .49** | .56** | .54** | -.35** | .56** |
| Hyperglycemic | .21* | .48** | .42** | .28** | -.11 | .33** |
| Adherence to Recommendations | | | | | | |
| General diet | -.29** | -.21* | -.18 | -.03 | .23* | -.09 |
| Specific diet | -.31** | -.17 | -.22* | -.14 | .26** | -.21* |
| Exercise | -.35** | -.07 | -.24* | -.08 | .28** | -.18 |
| Glucose testing | -.05 | .06 | -.05 | .09 | .16 | .03 |
| Foot care | .03 | -.01 | .03 | .13 | -.01 | .11 |

*$p < .05$. **$p < .01$.

Table 7

Correlations of Psychological Outcomes with Diabetes Outcomes and Adherence at Final Assessment

| Variable | Perceived Generalized Stress | Diabetes-Related Distress | Depression | Anxiety | Positive Affect | Negative Affect |
|---|---|---|---|---|---|---|
| Diabetes Symptoms (Total) | .33** | .46** | .64** | .51** | -.23* | .50** |
| Fatigue | .49** | .39** | .75** | .59** | -.33** | .53** |
| Cognitive | .48** | .47** | .76** | .64** | -.35** | .58** |
| Pain | .26** | .34** | .39** | .39** | -.22* | .39** |
| Sensory | .16 | .38** | .40** | .33** | -.18 | .35* |
| Cardiac | .28** | .39** | .53** | .41** | -.17 | .51** |
| Ophthalmologic | .19 | .32** | .38** | .39** | -.12 | .44** |
| Hypoglycemic | .57** | .42** | .67** | .69** | -.32** | .71** |
| Hyperglycemic | .23* | .42** | .58** | .46** | -.07 | .47** |
| Adherence to Recommendations | | | | | | |
| General diet | -.23* | -.16 | -.13 | -.07 | .32** | -.04 |
| Specific diet | -.14 | -.15 | -.22* | -.14 | .32** | -.09 |
| Exercise | -.15 | -.11 | -.12 | .00 | .23* | -.08 |
| Glucose testing | -.13 | -.13 | -.15 | -.12 | .14 | -.21* |
| Foot care | -.05 | -.04 | -.08 | -.04 | .11 | .01 |

*$p < .05$. **$p < .01$.

Table 8

ANCOVAs Examining the Effect of CCBT-SM on Psychological Distress Variables

| | Baseline | | | | | | Final | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CCBT-SM | | | Waiting List | | | CCBT-SM | | Waiting List | | | | | |
| | *n* | *M* | *SD* | *n* | *M* | *SD* | *M* | *SD* | *M* | *SD* | *F* | *p* | *Cohen's d* | $\eta_p^2$ |
| Perceived Stress | 48 | 28.52 | 8.8 | 57 | 28.53 | 7.2 | 19.96 | 8.9 | 27.26 | 8.5 | 25.3 | <.01 | 0.84 | .199 |
| Diabetes-Related Distress | 49 | 43.52 | 26.8 | 59 | 45.06 | 22.0 | 28.95 | 22.6 | 40.89 | 21.5 | 13.45 | <.01 | 0.54 | .114 |
| Depression | 42 | 9.00 | 5.9 | 51 | 9.06 | 5.4 | 5.95 | 5.5 | 8.04 | 5.1 | 7.06 | .01 | 0.40 | .073 |
| Anxiety | 41 | 7.39 | 5.5 | 51 | 7.18 | 5.0 | 4.44 | 4.7 | 6.57 | 5.5 | 6.78 | .01 | 0.41 | .071 |
| Positive Affect | 47 | 28.09 | 7.2 | 58 | 27.62 | 8.8 | 29.3 | 9.1 | 27.26 | 8.8 | 1.64 | .20 | 0.23 | .016 |
| Negative Affect | 49 | 22.84 | 8.8 | 57 | 23.09 | 7.1 | 17.16 | 7.3 | 21.6 | 8.5 | 13.02 | <.01 | 0.56 | .112 |

Table 9

ANCOVAs Examining the Effect of CCBT-SM on Diabetes Symptoms and A1c

| | Baseline | | | | | | Final | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CCBT-SM | | | Waiting List | | | CCBT-SM | | Waiting List | | | | | |
| | *n* | *M* | *SD* | *n* | *M* | *SD* | *M* | *SD* | *M* | *SD* | *F* | *p* | *Cohen's d* | $\eta_p^2$ |
| Total Diabetes Symptoms | 49 | 35.90 | 23.6 | 59 | 37.61 | 28.9 | 32 | 23.7 | 39.17 | 29.7 | 2.54 | .11 | 0.26 | .024 |
| Fatigue | 48 | 2.14 | 1.3 | 53 | 2.17 | 1.4 | 1.62 | 1.4 | 2.18 | 1.4 | 7.34 | .01 | 0.4 | .070 |
| Cognitive | 41 | 1.44 | 1.2 | 57 | 1.67 | 1.4 | 1.13 | 1.1 | 1.71 | 1.3 | 6.4 | .01 | 0.48 | .063 |
| Neurological | 45 | 0.45 | 0.8 | 51 | 0.64 | 1.2 | 0.24 | 0.5 | 0.39 | 0.9 | 0.26 | .61 | 0.20 | .003 |
| Sensory | 46 | 0.92 | 1.2 | 54 | 0.62 | 1.0 | 0.7 | 1.0 | 0.54 | 0.9 | 0.03 | .85 | 0.17 | .000 |
| Cardiac | 44 | 0.53 | 0.6 | 53 | 0.72 | 0.9 | 0.44 | 0.8 | 0.67 | 1.0 | 0.47 | .50 | 0.25 | .005 |
| Ophthalmologic | 45 | 0.56 | 0.9 | 55 | 0.50 | 1.0 | 0.45 | 0.9 | 0.52 | 1.0 | 0.44 | .51 | 0.07 | .005 |
| Hyperglycemic | 44 | 1.23 | 1.1 | 54 | 1.15 | 1.2 | 0.69 | 0.8 | 1.09 | 1.1 | 11.16 | <.01 | 0.41 | .105 |
| Hypoglycemic | 45 | 1.48 | 1.2 | 56 | 1.73 | 1.2 | 0.78 | 0.9 | 1.32 | 1.1 | 6.16 | .02 | 0.53 | .059 |
| A1c | 21 | 7.35 | 0.9 | 25 | 7.65 | 1.7 | 7.26 | 1.0 | 7.58 | 1.4 | 0.28 | .60 | 0.26 | .007 |

Table 10

The Indirect Effect of CCBT-SM on Fatigue through Psychological Distress Measures

| Mediator | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 7.69** | 0.07* | 0.01 | 0.58* | 0.57 [.31, .93] | 0.20 [.11, .32] | 0.99 |
| Diabetes-Related Distress | 11.27* | 0.02** | 0.29 | 0.56* | 0.26 [.07, .60] | 0.09 [.02, .20] | 0.48 |
| Depression | 2.56* | 0.19** | 0.08 | 0.58* | 0.50 [.02, .97] | 0.17 [.01, .32] | 0.86 |
| Anxiety | 2.51* | 0.16** | 0.10 | 0.50 | 0.40 [.08, .73] | 0.14 [.02, .25] | 0.79 |
| Negative Affect | 4.22** | 0.09** | 0.23 | 0.61* | 0.38 [.12, .73] | 0.13 [.04, .25] | 0.62 |

*Note*. See Figure 6 for diagram of relationship between variables. *a* = the slope of the mediator regressed on the intervention, *b* = the slope of psychological fatigue regressed on the mediator controlling for the intervention, *c'* = the slope of the direct effect of the intervention on psychological fatigue, *c* = the slope of the indirect effect of the intervention on psychological fatigue through the mediator, *ab* = the indirect effect of the intervention on psychological fatigue through the mediator, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

* $p < .05$, ** $p < .01$

Table 11

The Indirect Effect of CCBT-SM on Cognitive Symptoms through Psychological Distress Measures

| Mediator | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 7.66** | 0.06** | 0.17 | 0.61* | 0.44 [.22, .76] | 0.18 [.09, .31] | 0.72 |
| Diabetes-Related Distress | 13.45** | 0.02** | 0.29 | 0.61* | 0.31 [.11, .66] | 0.13 [.05, .26] | 0.51 |
| Depression | 2.91** | 0.17** | 0.12 | 0.60* | 0.48 [.17, .85] | 0.20 [.07, .34] | 0.80 |
| Anxiety | 2.89** | 0.15** | 0.18 | 0.61* | 0.43 [.20, .71] | 0.17 [.08, .28] | 0.70 |
| Negative Affect | 5.05** | 0.08** | 0.26 | 0.67** | 0.41 [.19, .72] | 0.17 [.08, .29] | 0.61 |

*Note*. See Figure 6 for diagram of relationship between variables. *a* = the slope of the mediator regressed on the intervention, *b* = the slope of cognitive symptoms regressed on the mediator controlling for the intervention, *c'* = the slope of the direct effect of the intervention on cognitive symptoms, *c* = the slope of the indirect effect of the intervention on cognitive symptoms through the mediator, *ab* = the indirect effect of the intervention on cognitive symptoms through the mediator, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

* $p < .05$. ** $p < .01$.

Table 12

The Indirect Effect of CCBT-SM on Hyperglycemic Symptoms through Psychological Distress Measures

| Mediator | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 7.66** | 0.02 | 0.18 | 0.34 | 0.16 [.002, .39] | 0.08 [.00, .19] | 0.46 |
| Diabetes-Related Distress | 12.71** | 0.02** | 0.13 | 0.36 | 0.23 [.06, .50] | 0.11 [.03, .22] | 0.63 |
| Depression | 2.33* | 0.11** | 0.12 | 0.37 | 0.25 [.03, .57] | 0.12 [.02, .27] | 0.68 |
| Anxiety | 2.44* | 0.08** | 0.21 | 0.41* | 0.20 [.05, .43] | 0.10 [.02, .21] | 0.49 |
| Negative Affect | 4.53** | 0.05** | 0.14 | 0.39 | 0.25 [.07, .52] | 0.12 [.04, .25] | 0.64 |

*Note*. See Figure 6 for diagram of relationship between variables. *a* = the slope of the mediator regressed on the intervention, *b* = the slope of hyperglycemic symptoms regressed on the mediator controlling for the intervention, *c'* = the slope of the direct effect of the intervention on hyperglycemic symptoms, *c* = the slope of the indirect effect of the intervention on hyperglycemic symptoms through the mediator, *ab* = the indirect effect of the intervention on hyperglycemic symptoms through the mediator, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

* $p < .05$. ** $p < .01$.

Table 13

The Indirect Effect of CCBT-SM on Hypoglycemic Symptoms through Psychological Distress Measures

| Mediator | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 8.41** | 0.06** | 0.11 | 0.63** | 0.51 [.30, .82] | 0.24 [.15, .38] | 0.82 |
| Diabetes-Related Distress | 12.70** | 0.02** | 0.36 | 0.58** | 0.22 [.06, .48] | 0.10 [.03, .22] | 0.38 |
| Depression | 2.89** | 0.13** | 0.19 | 0.55* | 0.36 [.12, .67] | 0.17 [.05, .30] | 0.66 |
| Anxiety | 2.69** | 0.13** | 0.22 | 0.58** | 0.36 [.10, .65] | 0.17 [.05, .29] | 0.63 |
| Negative Affect | 4.93** | 0.09** | 0.16 | 0.60** | 0.44 [.20, .74] | 0.21 [.10, .34] | 0.74 |

*Note*. See Figure 6 for diagram of relationship between variables. *a* = the slope of the mediator regressed on the intervention, *b* = the slope of hypoglycemic symptoms regressed on the mediator controlling for the intervention, *c'* = the slope of the direct effect of the intervention on hypoglycemic symptoms, *c* = the slope of the indirect effect of the intervention on hypoglycemic symptoms through the mediator, *ab* = the indirect effect of the intervention on hypoglycemic symptoms through the mediator, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

$p < .05$. ** $p < .01$

Table 14

The Indirect Effect of CCBT-SM on Psychological Distress through Fatigue.

| Dependent Variable | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 0.58* | 2.85** | 6.03** | 7.69** | 1.65 [0.14, 3.56] | 0.09 [.01, .18] | 0.22 |
| Diabetes-Related Distress | 0.56* | 5.67** | 8.12 | 11.27* | 3.15 [0.42, 7.41] | 0.07 [.01, .16] | 0.28 |
| Depression | 0.58* | 2.81** | 0.92 | 2.56* | 1.64 [-0.04, 3.45] | 0.15 [-.01, .29] | 0.64 |
| Anxiety | 0.50 | 2.05** | 1.49 | 2.51* | 1.02 [0.01, 2.31] | 0.10 [-.01, .21] | 0.41 |
| Negative Affect | 0.61* | 2.89** | 2.47 | 4.22** | 1.75 [0.32, 3.52] | 0.11 [.02, .20] | 0.42 |

*Note*. See Figure 7 for diagram of relationship between variables. *a* = the slope of the fatigue regressed on CCBT-SM, *b* = the slope of psychological distress regressed on fatigue controlling for CCBT-SM, *c'* = the slope of the direct effect of CCBT-SM on psychological distress, *c* = the slope of the indirect effect of CCBT-SM on psychological distress through fatigue, *ab* = the indirect effect of CCBT-SM on psychological distress through fatigue, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

$p < .05$. ** $p < .01$.

Table 15

The Indirect Effect of CCBT on Psychological Distress through Cognitive Symptoms.

| Dependent Variable | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 0.61* | 3.26** | 5.69** | 7.66** | 1.97 [0.67, 4.02] | 0.10 [.04, .20] | 0.26 |
| Diabetes-Related Distress | 0.61* | 7.73** | 8.76* | 13.45** | 4.69 [1.32, 9.32] | 0.10 [.03, .20] | 0.35 |
| Depression | 0.60* | 3.30** | 0.93 | 2.91** | 1.98 [0.41, 3.37] | 0.18 [.03, .30] | 0.68 |
| Anxiety | 0.61* | 2.53** | 1.35 | 2.89** | 1.54 [0.41, 2.82] | 0.15 [.04, .26] | 0.53 |
| Negative Affect | 0.67** | 3.55** | 2.67 | 5.05** | 2.37 [0.94, 4.29] | 0.15 [.06, .26] | 0.47 |

*Note*. See Figure 7 for diagram of relationship between variables. *a* = the slope of cognitive symptoms regressed on CCBT-SM, *b* = the slope of psychological distress regressed on cognitive symptoms controlling for CCBT-SM, *c'* = the slope of the direct effect of CCBT-SM on psychological distress, *c* = the slope of the indirect effect of CCBT-SM on psychological distress through cognitive symptoms, *ab* = the indirect effect of CCBT-SM on psychological distress through cognitive symptoms, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

$p < .05$. ** $p < .01$.

Table 16

The Indirect Effect of CCBT-SM on Psychological Distress through Hyperglycemic Symptoms

| Dependent Variable | *a* | *b* | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 0.34 | 1.57 | 7.13** | 7.66** | 0.53 [-0.02, 1.92] | . 03 [.00, .10] | 0.07 |
| Diabetes-Related Distress | 0.36 | 8.49** | 9.64* | 12.71** | 3.06 [-0.00, 7.26] | .07 [.00, .16] | 0.24 |
| Depression | 0.37 | 2.93** | 1.26 | 2.33* | 1.08 [0.13, 2.43] | .10 [.01, .22] | 0.46 |
| Anxiety | 0.41* | 2.21** | 1.54 | 2.44* | 0.90 [0.15, 2.12] | .09 [.01, .20] | 0.37 |
| Negative Affect | 0.39 | 3.53** | 3.16* | 4.52** | 1.37 [0.26, 3.28] | .08 [.02, .18] | 0.30 |

*Note*. See Figure 7 for diagram of relationship between variables. *a* = the slope of hyperglycemic symptoms regressed on CCBT-SM, *b* = the slope of psychological distress regressed on hyperglycemic symptoms controlling for CCBT-SM, *c'* = the slope of the direct effect of CCBT-SM on psychological distress, *c* = the slope of the indirect effect of CCBT-SM on psychological distress through hyperglycemic symptoms, *ab* = the indirect effect of CCBT-SM on psychological distress through hyperglycemic symptoms, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

$p < .05$. ** $p < .01$.

Table 17

The Indirect Effect of CCBT-SM on Psychological Distress through Hypoglycemic Symptoms.

| Dependent Variable | *a* | | *c'* | *c* | *ab* [BCa 95% CI] | $ab_{cs}$ [BCa 95% CI] | $P_M$ |
|---|---|---|---|---|---|---|---|
| Perceived Generalized Stress | 0.63** | 4.27** | 5.74** | 8.41** | 2.67 [1.09, 4.67] | .14 [.06, .23] | 0.32 |
| Diabetes-Related Distress | 0.58** | 8.00** | 8.08 | 12.70** | 4.62 [1.62, 9.30] | .10 [.04, .19] | 0.36 |
| Depression | 0.55* | 3.31** | 1.07 | 2.89** | 1.83 [0.67, 3.33] | .17 [.06, .29] | 0.63 |
| Anxiety | 0.58** | 3.30** | 0.77 | 2.69** | 1.91 [0.66, 3.53] | .18 [.06, .33] | 0.71 |
| Negative Affect | 0.50** | 5.25** | 1.80 | 4.93** | 3.13 [1.26, 5.47] | .19 [.07, .31] | 0.63 |

*Note*. See Figure 7 for diagram of relationship between variables. *a* = the slope of hypoglycemic symptoms regressed on CCBT-SM, *b* = the slope of psychological distress regressed on hypoglycemic symptoms controlling for CCBT-SM, *c'* = the slope of the direct effect of CCBT-SM on psychological distress, *c* = the slope of the indirect effect of CCBT-SM on psychological distress through hypoglycemic symptoms, *ab* = the indirect effect of CCBT-SM on psychological distress through hypoglycemic symptoms, $ab_{cs}$ = completely standardized indirect effect, $P_M$ = the ratio of the indirect effect to the total effect.

$p < .05$. ** $p < .01$.

Table 18

ANCOVAs Examining the Effect of CCBT-SM on Adherence to Diabetes Regimen

| | Baseline | | | | | | Final | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | CCBT-SM | | | Waiting List | | | CCBT-SM | | Waiting List | | | | | |
| | *n* | *M* | *SD* | *n* | *M* | *SD* | *M* | *SD* | *M* | *SD* | *F* | *p* | *Cohen's d* | $\eta_p^2$ |
| General Diet | 48 | 4.64 | 1.9 | 58 | 4.37 | 1.7 | 4.76 | 1.9 | 4.5 | 1.8 | 0.08 | .78 | 0.14 | .001 |
| Specific Diet | 48 | 3.90 | 1.6 | 57 | 3.84 | 1.5 | 4.15 | 1.5 | 4.18 | 1.4 | 0.14 | .71 | 0.02 | .001 |
| Exercise | 48 | 2.96 | 2.5 | 59 | 2.93 | 2.2 | 3.04 | 2.2 | 2.58 | 2.1 | 2.26 | .14 | 0.21 | .021 |
| Blood Glucose Testing | 46 | 5.61 | 2.1 | 58 | 4.59 | 2.6 | 5.86 | 2.0 | 4.96 | 2.5 | 0.17 | .69 | 0.39 | .002 |
| Foot Care | 42 | 4.06 | 1.4 | 53 | 4.13 | 1.6 | 4.4 | 1.5 | 4.4 | 1.7 | 0.11 | .75 | 0.00 | .106 |

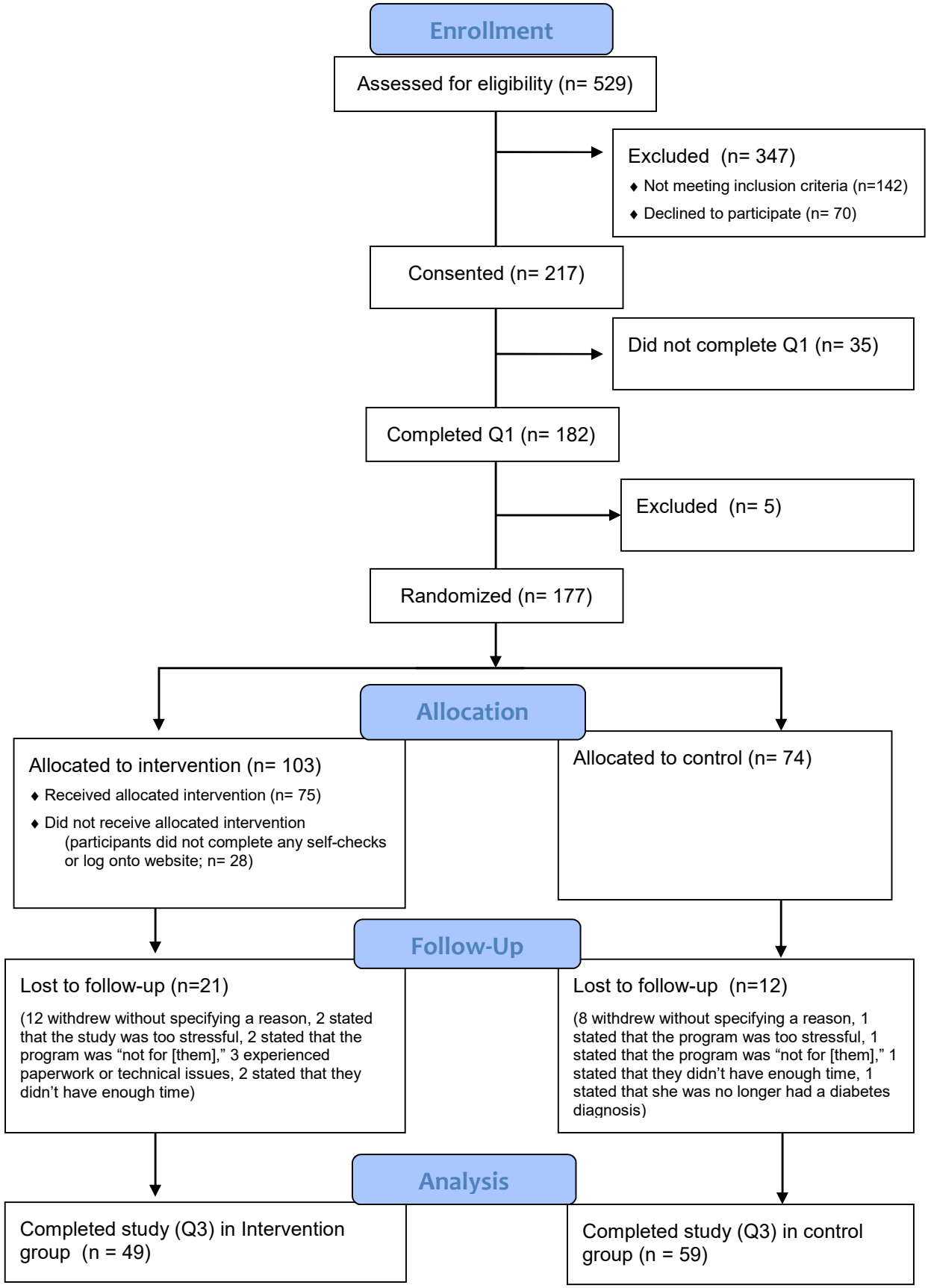


Figure 3. CONSORT diagram of participant flow

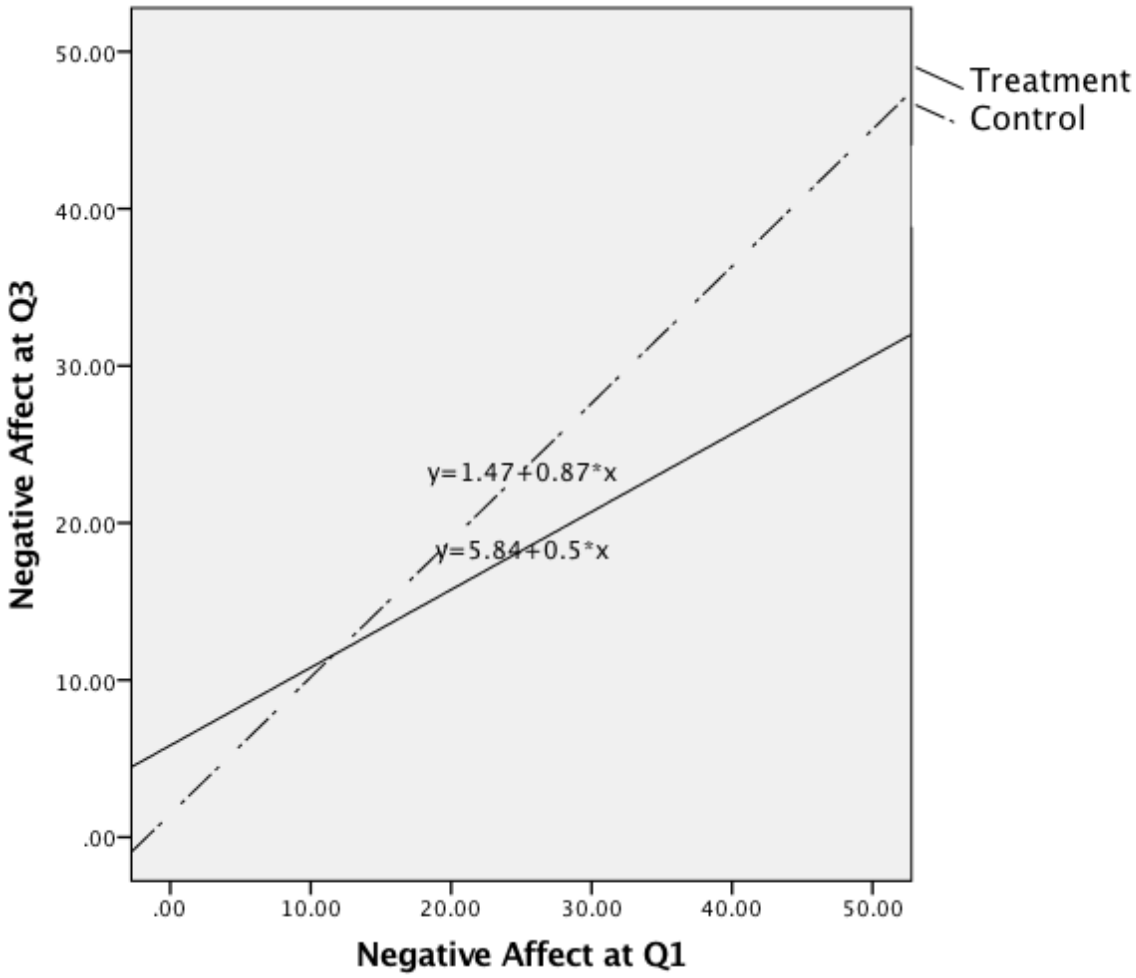


Figure 4. The interaction between baseline negative affect scores and group.

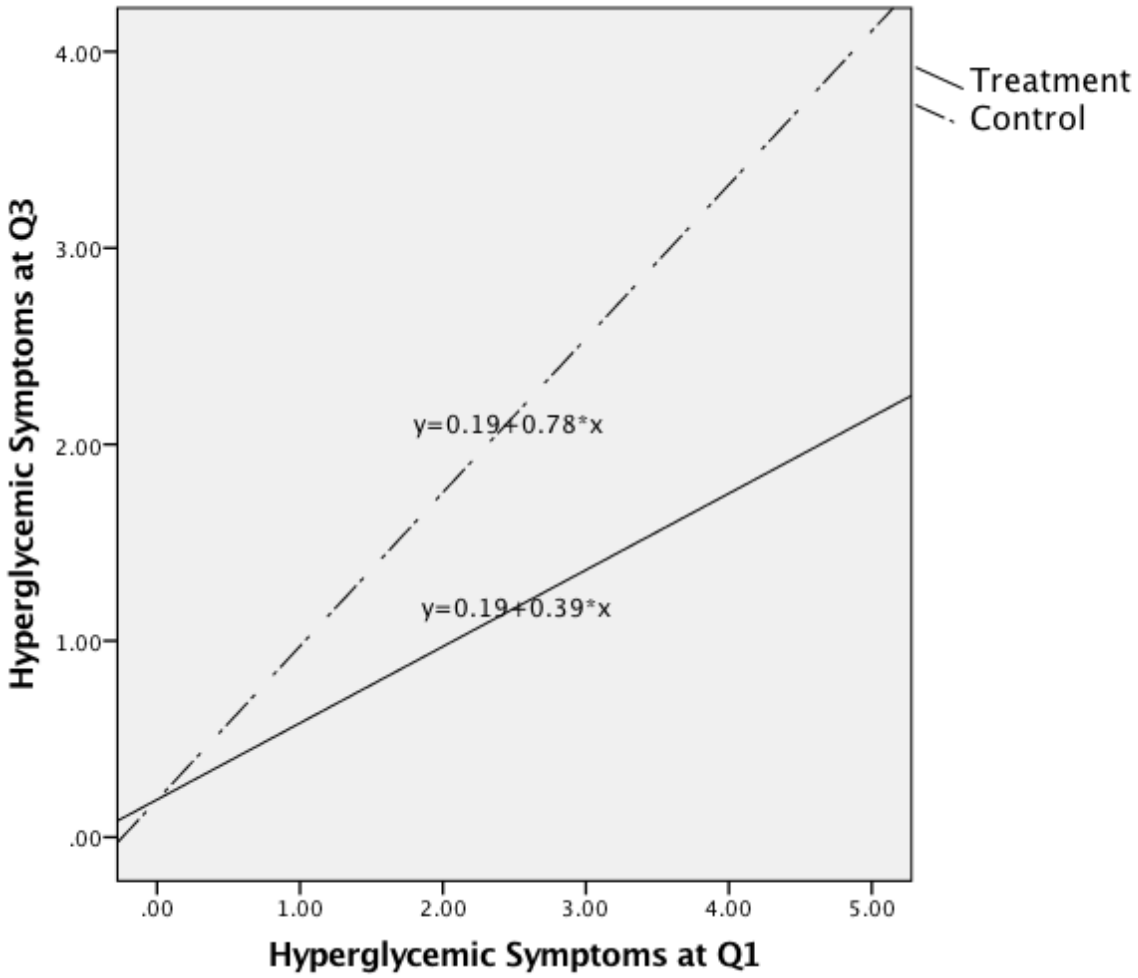


Figure 5. The interaction between baseline hyperglycemic symptoms and group.

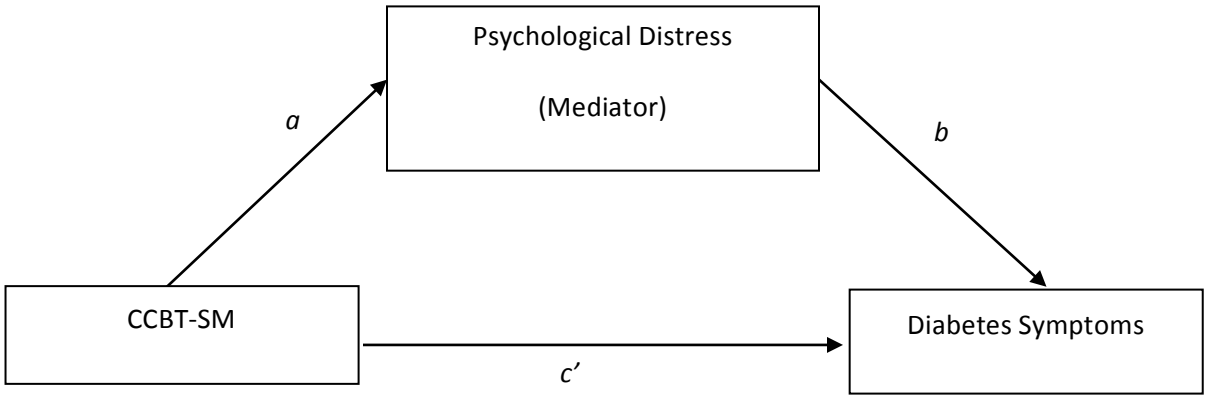


Figure 6. Conceptual Mediation Diagram. *a* = the slope of the mediator regressed on the intervention, *b* = the slope of diabetes symptoms regressed on the mediator controlling for the intervention, *c'* = the slope of the direct effect of the intervention on diabetes symptoms, *c* = the slope of the indirect effect of the intervention on diabetes symptoms through the mediator (Preacher & Kelly, 2001).

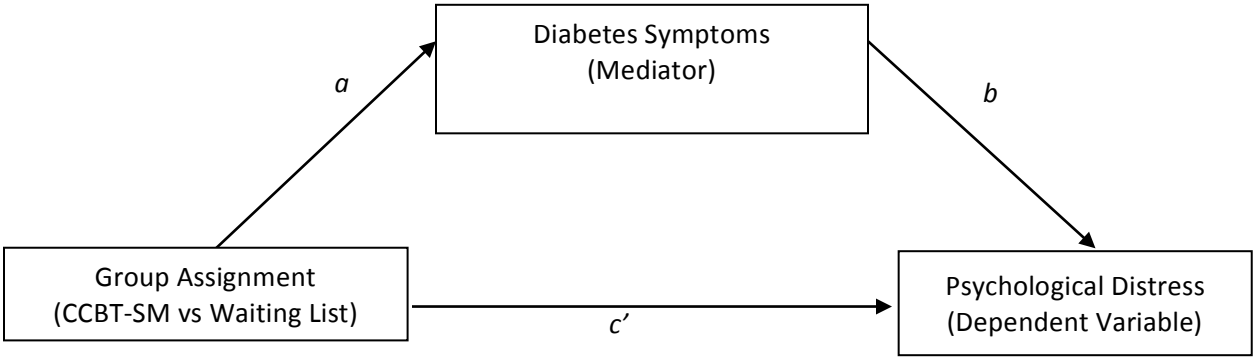


Figure 7. Mediation diagram displaying an alternative explanation of the relationships between group placement, diabetes symptoms, and psychological distress. *a* = the slope of the mediator regressed on group assignment, *b* = the slope of psychological distress regressed on the mediator controlling for group assignment, *c'* = the slope of the direct effect of group assignment on psychological distress, *c* = the slope of the indirect effect of group assignment on psychological distress through the mediator (Preacher & Kelly, 2001)

# Chapter Four

## Discussion

The current study found that an online stress and mood management intervention reduced psychological distress and several types of diabetes symptoms in adults with type 1 and type 2 diabetes. The nine-week program provided participants in the intervention group Internet-based education about managing stress, preventing mood problems, and identifying and seeking treatment for anxiety and depression. Participation in the program led to decreased perceived generalized stress, decreased diabetes-related distress, decreased symptoms of depression and anxiety, and decreased negative affect compared to those who were placed on a waiting list. The intervention also reduced several clusters of diabetes symptoms, including fatigue, cognitive symptoms, hypoglycemic symptoms, and hyperglycemic symptoms. Further, it demonstrated an indirect effect of the intervention on improved diabetes symptoms through psychological distress. However, the program did not have an effect on A1c or adherence to diabetes management recommendations.

### Efficacy of CCBT-SM on Psychological Distress

The CCBT-SM intervention employed in the current study led to a reduction across multiple types of psychological distress, i.e., perceived generalized stress, diabetes-related distress, depression, anxiety, and negative affect. These results contribute to a large body of literature that has shown the efficacy of CBT for alleviating symptoms of depression, anxiety, and stress in the general population (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). It also

adds to a smaller, but growing, body of research on the use of CBT in people with diabetes showing improvements in depression (Henry et al., 1997; Lustman et al., 1998; Welschen et al., 2013), diabetes-related stress (Karlsen et al., 2004), stress, and anxiety (Henry et al., 1997).

The use of CCBT is in this study provides an innovative way to utilize CBT. The Internet-based nature of CCBT-SM provided an alternative to face-to-face therapy that included the primary components of CBT while overcoming barriers to traditional psychotherapy, such as stigma, distrust of therapists, discomfort discussing personal problems, logistical issues, physical limitations, and financial constraints (Cartreine et al., 2010; Cuijpers et al., 2008). The current results are consistent with previous research that has demonstrated the efficacy of Internet or computer-based psychological treatments for the treatment of anxiety, depression, and general distress (Andersson & Cuijpers, 2009; Reger & Gahm, 2009; Spek et al., 2007) and for improvements in stress (Billings et al., 2008; Zetterqvist et al., 2003) in nonmedical populations.

The current study produced effect sizes that were consistent with those seen in meta-analyses of RCTs examining the efficacy of CCBT for depression and anxiety (Andersson & Cuijpers, 2009; Spek et al., 2007). While other studies have noted greater effect sizes of CCBT for anxiety compared to depression (Spek et al, 2007), those seen in the current study were almost identical. Interestingly, Spek et al. (2007) also reported that studies with minimal therapist interaction had an effect size that was smaller than the effect sizes seen in the current study, which also had minimal therapist contact.

This study adds significantly to the scarce literature regarding the use of CCBT in people with diabetes. Few researchers have conducted such studies and the two studies available are very different. In one study, CCBT was employed in a six month RCT of a web-based well-being intervention for adults over the age of 60 diagnosed with type 1 or type 2 diabetes that

targeted both diabetes self-management and psychosocial well-being (Bond et al., 2007). In the second study, CCBT was part of an eight-week web-based course that addressed psychological reactions to diabetes-specific topics in type1 and type 2 diabetics with elevated depression symptoms (van Bastelaar et al., 2011). The results of the current study are consistent with these studies, which reported decreases in depression (Bond et al., 2007; van Bastelaar et al., 2011) and less diabetes-related distress (van Bastelaar et al., 2011). The current study adds additional support for the use of CCBT in people with type 1 and type 2 diabetes. It also suggests that these programs can be effective at reducing distress in this population without addressing diabetes management or diabetes-specific concerns and that this type of intervention is effective for a general adult diabetic population that does not report high baseline levels of depression symptoms.

The current study differs from previous research in several ways. The CCBT-SM intervention used in this study did not include many of the components that have been employed in other studies of CCBT in people with diabetes. There was no contact with a coach or therapist, other than to remind them to log on to the program and complete their self-checks. This was a purely self-guided program and there was no way for participants to contact other participants. In addition, the program focused solely on psychological distress. It did not include any instruction on diabetes management nor did it address diabetes-specific distress. It was up to the patient to apply the lessons to their experience of diabetes.

**Effect of CCBT-SM on Diabetes Outcomes**

The current study did not find an effect of the intervention on the primary indicator of diabetes control, A1c. This is in contrast to other studies of face-to-face CBT interventions that have seen effects on A1c (Henry et al., 1997; Ismail et al., 2008; Karlsen et al., 2004; Lustman et

al., 1998) but consistent with a CCBT study that also did not find an effect of the intervention on A1c (vanBastelaar et al, 2011).

One explanation for the lack of relationship is that the analyses in the current study were underpowered. A recent meta-analysis of 30 studies concluded that stress management interventions have a medium effect on A1c (Bykowski, Sacco, & Mayhew, 2011). Thus, the study was originally powered for a regression analysis expecting a medium effect size, requiring 107 participants. It was later decided that an ANCOVA would be a more appropriate analysis and that would require 128 participants. Unfortunately the acquisition of A1c lab test results from participants was a major barrier to the completion of the project and was eliminated as a requirement for participation. While the researcher strived to collect valid A1c results from all participants, many participants did not have values that were measured at the correct relationship to the study questionnaires. There were several participants who did not have their A1c measured often enough to be included in the study or did not provide the necessary authorization to obtain the A1c from their physicians. As a result, the final sample had only 46 participants with both pre and post-study A1c. Thus, at least three times the current sample size would have been necessary to see the expected effect.

There were also surprisingly few significant correlations between A1c and other outcome variables. Despite the very strong and well-established relationship between A1c and diabetes complications (Krishnamurti & Steffes, 2001), the only significant relationship in the current sample was between A1c and ophthalmologic symptoms at baseline and sensory symptoms at the final assessment. In general, the correlations were in the expected direction, suggesting that the lack of significant relationships were likely due to the small sample size and, consequently, a lack of power in the analyses.

There were several significant correlations between the psychological variables and the symptom clusters at baseline and final assessment, suggesting that there is a relationship between psychological distress and diabetes symptoms. However, there was no effect of the intervention on total diabetes symptoms. The lack of an effect of the intervention on diabetes symptoms may be due to a floor effect in the more severe symptom clusters. At baseline, the sample reported few sensory, pain, cardiac, and ophthalmologic symptoms. Indeed, the distributions of these symptom clusters were so skewed that applying transformations to the data did not result in a normal distribution. In addition, these symptoms represent more advanced diabetes complications that can take years to reverse (Krishanmurti & Steffes, 2001). It is likely that a nine-week period was not enough time to see a noticeable change in these more stable and severe symptoms.

In contrast, participants reported higher rates of psychological fatigue, cognitive symptoms, hypoglycemic symptoms, and hyperglycemic symptoms at baseline, giving these symptoms room to decrease. These clusters are also comprised of more transient symptoms that are more likely to fluctuate over short periods of time (i.e., lack of energy, an overall sense of fatigue, sleepiness/drowsiness, difficulty concentrating, lack of energy, becoming easily irritated or annoyed, thirst, dry mouth). Consistent with these features, these are the areas where the intervention had a significant effect. These symptom clusters are also considered more psychological in nature (Arbuckle et al., 2009) and overlap with symptoms of stress, depression, and anxiety. Thus, while considered to be proximal indicators of diabetes outcomes, they may have been directly targeted by the intervention. It should be noted that no previous studies of CCBT or CBT have examined the effect of the intervention on diabetes symptoms.

**Psychological Distress as Mediator**

The results indicated indirect effects of the intervention on diabetes symptoms through psychological distress. This supports the antecedent model, which suggests that psychological distress contributes to poor diabetes outcomes (Lustman et al., 2005; Musselman et al., 2003; Surwit & Schneider, 1993; Van Tilburg et al., 2001). Taking this a step further, the antecedent model suggests that reducing psychological distress should improve diabetes outcomes, as this study has demonstrated.

Previous research has shown that interventions which induce reductions in psychological distress also result in reductions in A1c (Gregg et al., 2007; Kendardy et al., 2002; Lustman et al, 1997; Lustman et al., 1998). However, previous CCBT interventions for people with diabetes (Bond et al, 2007; van Bastelaar et al., 2011) did not report on mediators or proposed mechanisms. Thus this study provides the first evidence of the antecedent model as it relates to CCBT interventions.

It was acknowledged that the cross-sectional nature of the mediation analyses also allows for the possibility of a consequence model, which posits that the experience of having diabetes (e.g., coping with adherence to medical recommendations or diabetes related medical symptoms) may create psychological distress (Kovacs et al., 1997; Palinkas et al., 1991; Sacco & Bykowski, 2010). To address this alternative explanation of the data, a second set of mediation analyses examined the indirect effect of the intervention on psychological distress through diabetes symptoms. In most cases the indirect effects observed in these consequence model analyses were smaller than those seen in the antecedent model analyses. In some cases the consequence mediation models were not significant, whereas all antecedent mediation models were significant. This pattern suggests that the antecedent model better explains this data and

relationship between the variables. However, it must also be noted that many of the differences between the consequence and antecedent models were small and many of the indirect effects in the consequence models were significant. This was especially true for the models that included hypoglycemic symptoms. Thus, more research into these models must be conducted. It may also be possible that these models do not compete with each other, but actually complement each other in a bidirectional explanation of the relationship.

**Role of Adherence**

One proposed mechanism for the relationship between psychological distress and diabetes outcomes is through a behavioral pathway. The behavioral pathway emphasizes the importance of adherence to a rigorous diabetes treatment regimen. It has been suggested that those who experience distress may feel that self-care behaviors important to diabetes management are too difficult or they may not be motivated to perform the necessary tasks (Lloyd, Smith, & Weinger, 2005). Not adhering to the treatment recommendations, in turn, leads to poorer diabetes outcomes (Centers for Disease Control and Prevention, 2014). The baseline data supported a relationship of adherence to general diet, specific diet, and exercise recommendations with perceived generalized stress as well as adherence to specific diet and exercise recommendations with depression. This pattern is consistent with the results of other researchers who have noted that diabetes patients with high levels of depression or stress tend to have poorer diet and participate in less physical activity (Albright et al., 2001; Lin et al., 2004). However, the current study did not support the effect of CCBT-SM on adherence. The lack of effect of the intervention on adherence to diabetes recommendations is consistent with other RCTs of CBT in diabetics (Ismail et al., 2008; Lustman et al., 1998; van der Ven et. al., 2005).

However, one study did note an indirect effect of acceptance and commitment therapy on A1c through adherence (Gregg et al., 2007).

The hypothesis that adherence would mediate the relationship between CCBT-SM and diabetes outcomes was not tested in the current study. The lack of relationship between CCBT-SM and adherence suggests that this relationship could not explain the relationship between CCBT-SM and diabetes outcomes. Thus it was determined that the mediation analyses would be uninformative in this situation.

**Limitations**

There are several limitations of this study that must be considered. Foremost were the problems with recruitment and attrition that did not allow for the study to be conducted as originally proposed. The original inclusion criteria, which required a minimum A1c of 6.5, eliminated a large number of interested individuals. A concern regarding eliminating this criterion is that it could have resulted in floor effect for A1c. That is, if baseline A1c was low, it might not have had room to decrease. However, the majority (>80%) of the baseline A1c data obtained were still above 6.5%. A larger concern was that, after eliminating the requirement of A1c prior to the start of participation, many participants did not provide A1c at all or within the specified time frame. This significantly reduced the power in the analyses involving A1c, limiting the ability to draw valid conclusions from the data. It is unclear whether the intervention would have had an effect on A1c if the analyses had been appropriately powered. A1c is the primary measure of glycemic control in people with diabetes and the lack of A1c data limits how the intervention relates to diabetes management. Future research should continue to explore the ability of psychosocial interventions to influence A1c using methodology that is better able to answer this question.

A second limitation of the study was the high attrition rate. Less than half of those assigned to the CCBT-SM group completed the study. Others have noted that CCBT is associated with poor compliance and increased attrition (Ritterband et al., 2003) and have suggested that it may be easier for a client to disengage from a web-based therapy program than to cancel an appointment with a "real person" (Spek et al., 2007; Tate & Zabinski, 2004). Those that did complete Q3 logged in to the program more times than expected, spent more time on the program than anticipated, and completed most of the weekly self-checks. This pattern among those who completed Q3 is better engagement than was reported by Billings et al. (2008) in an RCT that used a very similar CCBT-SM program. Thus, it appears that the additional structure of weekly emails, the division of the program into modules, self-checks, homework, and reminders increased adherence to the program. Future research should determine ways to engage and retain participants.

A third limitation is that the results of this study speak only to the ability of the intervention to affect psychological distress and diabetes outcomes over the nine-week course of the study. There were no follow-up assessments; therefore, it cannot be determined whether CCBT-SM had a lasting effect. Future research would benefit by including follow-up assessments that address this issue. Additional follow-ups may also allow for better explanation of the mechanisms. The mediation analyses were conducted using cross-sectional data. Using data from multiple time points may allow for better information regarding the direction of the effects and causality.

A fourth limitation is that this study included both type 1 and type 2 diabetics. While the symptoms and presentation of the conditions are very similar, their onsets, etiologies, and often their treatment regimens are different. It is not clear whether this type of intervention would

have a greater impact on those with one type of diabetes compared to the other. This issue was not examined in the current study due to insufficient power to compare the two groups. Future research should look at whether CCBT-SM is more beneficial to one subset of diabetics.

A fifth limitation of this study was that overall acceptability of the program was not assessed. Critics of CCBT have suggested that it may seem impersonal or dehumanizing (Spek et al., 2007; Wright & Wright, 1997). It is also possible that fully automated programs do not address all concerns that are important to clients (Cuijpers et al., 2008; Tate & Zabinski, 2004) and cannot detect subtle, nonverbal cues that indicate that the client is misunderstanding a concept (Cuijpers et al., 2008). The occurrence of these feelings in the participants was not assessed. It is also assumed that this program was successful at overcoming the barriers to psychotherapy. However, the patient's perceptions of the ability of the program to overcome the issues related to stigma, concerns regarding psychotherapy, and logistical issues were not assessed. Future research would benefit from additional surveys to create a program that is client-friendly and acceptable as well as effective to determine the extent to which patients would choose CCBT over face-to-face therapy.

**Clinical Implications**

Diabetes mellitus affects over 9% of the population of the United States and is the country's seventh leading cause of death (Centers for Disease Control and Prevention, 2014). In addition to the medical complications of uncontrolled diabetes that affect vision, kidney function, and the neurological and cardiovascular systems (Goldstein et al., 2004; Landell-Graham et al., 2003), it also affects psychological health (Anderson et al., 2001; Eaton, 2002; Fenton & Stover, 2006; Lustman et al., 1986; Scott et al., 2007). One study noted that as many as 71% of diabetics experience psychological distress (Lustman et al., 1986) and it has been shown that people with

diabetes are twice as likely to experience depression (Anderson et al., 2001) compared to the general population. Further, those with psychological distress and diabetes report poor overall physical functioning, (Ciechanowski et al., 2003), more symptoms of diabetes (Ciechanowski et al., 2003; Lustman et al., 1986) and more distress related to diabetes symptoms (Lustman et al., 1986). Diabetics who report symptoms of depression also experience higher rates of retinopathy, nephropathy, neuropathy, macrovascular complications and sexual dysfunction (de Groot et al., 2001) and have more risk factors for cardiovascular disease (Katon et al., 2004). Psychological distress has also been associated with worse adherence and glycemic control, more medical complications, higher hospitalization rates, and death at an earlier age (Anderson et al., 2001; Ciechanowski et al., 2000; de Groot et al., 2001; de Groot et al., 1999; Egede, 2006; Gilmer et al., 2005; Grandinetti et al., 2000; Lustman & Clouse, 2005; Lustman et al., 1986; Niemcryk et al., 1990; Wrigley & Mayou, 1991). It is clear that this population is not only more at risk for experiencing distress, but also that the distress is related to negative health outcomes. This study suggests that CCBT-SM offers a way to improve the mental health of diabetics as well as diabetes symptoms.

Given the toll of psychological distress on the health of those with diabetes, the American Diabetes Association has dedicated a section of their Standards of Care stressing the importance of the detection and treatment of distress in routine diabetes care (American Diabetes Association, 2014). However, only about one-third of diabetic patients who experience mental health concerns receive treatment (Ducat, Philipson, & Anderson, 2014). Physicians report several difficulties addressing the social and emotional concerns of their diabetic patients, including lack of expertise for treating these issues, few treatment options, difficulty identifying clinicians for referrals, and many patients who are not open to receiving mental health referrals

(Beverly, Hultgren, Brooks, Ritholz, Abrahmson, & Weinger, 2011). An online intervention can provide a useful tool to physicians and patients who otherwise would not feel comfortable addressing psychological concerns. Thus, the CCBT-SM program used in this study provides a means for more clinics to meet the American Diabetes Association's Standards of Care. This may provide psychological and physical health benefits to a population at greater risk for the development of psychological distress compared to the general population.

**Future Directions**

The results of this study suggest that CCBT-SM may be a useful component of diabetes care. However, this remains a relatively new form of treatment that opens the door to several lines of future research. As with all new interventions, the study must be replicated to ensure that similar results are consistently achieved. Future research would benefit from studying a larger, more diverse sample to ensure adequate power across all analyses. As mentioned above, greater attention should be paid to A1c, which is a primary indicator of diabetes management. However, other diabetes outcomes and physical health outcomes, such as cardiovascular risk factors (i.e., cholesterol, blood pressure, body mass index), markers of inflammation (i.e., CRP), and lifestyle factors (i.e., smoking status) should also be examined. Working with physicians to collect these data in a more systematic way would also provide more reliable information than obtaining the information from medical records as was done in this study.

Future research on a larger, more diverse sample would also allow for the examination of possible moderators of intervention efficacy. Determining whether the intervention is more efficacious for individuals with certain characteristics would be helpful in understanding how the intervention works as well as who would benefit most. For example, the ANCOVA analyses indicated that the intervention reduced negative affect more for those who started with higher

baseline negative affect and the intervention was more effective as lowering hyperglycemia for those with higher baseline hyperglycemia. It is possible that the intervention would have a differential effect on those who started with more or less psychological distress or with better or worse diabetes control. The technology component of CCBT-SM may also make the intervention more effective for those who are more comfortable with technology compared to those who are not as comfortable with it.

Additional research on mechanisms is also necessary. This study examined the behavioral pathway as the possible link between diabetes distress and diabetes outcomes. Unfortunately this pathway was not supported. A physiological pathway, which implicates the HPA axis, has also been suggested as the mechanism driving the relationship between psychological distress and diabetes outcomes (Black, 2006; Rosmond, 2005). Future research would benefit from measuring HPA axis activation, perhaps through cortisol levels. This would provide evidence of the presence or absence of a physiological pathway in the relationship between psychological distress and diabetes outcomes.

CCBT-SM takes advantage of the benefits of technology. Future research should continue to capitalize on the evolution of technology to ensure the program remains relevant and appealing to patients. Allowing users to access the program on smart phones and tablets would likely increase the utilization, as well as employing text message reminders and perhaps incorporating social media components.

This study offers compelling evidence for the use of CCBT-SM in a diabetic population. However, the intervention employed did not address diabetes in any way. The intervention had an affect on the symptoms of diabetes that are more psychological in nature and did not affect adherence or A1c. Future research should explore changes to the program to more specifically

address these outcomes. Numerous studies have shown that online diabetes self-management interventions are effective at improving adherence and diabetes outcomes (Ramadas, Quek, Chan, & Oldenburg, 2011). The combination of those programs with CCBT-SM may provide the most comprehensive and impactful treatment for those with diabetes. The benefits of including such components should be examined.

Because of the lack of diabetes-specific information in the CCBT-SM program used in the study, this same program could be applied to other chronically ill populations as well as the general population. The effectiveness of a generic CCBT-SM could provide primary care and other physicians with a very useful tool in the treatment of distress and improvement of physical health. Future research should determine the program's efficacy in other populations.

In summary, this study provides evidence for the psychological and physical health benefits of CCBT-SM in a diabetic sample. It also supports an antecedent model of understanding the relationship between psychological factors and diabetes outcomes. Further research should continue to explore the effect of the intervention on A1c as well as physiological pathways involved in the relationships.

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## Appendix A

## Original Homework Assignments

## Identifying Negative Coping Strategies

| Stressor | How I Felt (stress symptoms) | How I Reacted | How I Responded | Do you rely on drugs, alcohol, smoking, or other negative behaviors to cope with stress? |
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# Embrace Positive Thinking

| Situation | Identify the Negative Pattern<br>*Let your emotions be your guide.* | Evaluate your assessment of the situation | | | | Notice how you feel after you realistically assess the situation |
|---|---|---|---|---|---|---|
| | | Evidence<br>*What is the factual evidence that supports your belief?* | Alternatives<br>*Are there other ways of looking at the situation?* | Implications<br>*If the negative belief is true, ask yourself how bad is it?* | Usefulness<br>*Does this type of pessimistic thinking serve any positive purpose?* | |
| We are late to Sam's soccer game | I feel like an idiot for making us so late and having to rush; I feel defeated, depressed, anxious, and stressed | I haven't been late before; Sam knows I'm always there for him | Being late isn't idiotic; We're involved in a lot of activities; Sam's brother had a doctors appointment – that was a priority | Being late isn't the end of the world, nothing terrible will happen; Sam will still get to the game in time to play | Worrying is a waste of my time; I will try to enjoy the game | I feel much better now that I have realistically assessed the situation; now I can enjoy the game |
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# Stress Management

## Adopting Behavioral Strategies

Rate your level of tension before and after you do your relaxation exercise.
Use the following Scale:

1 2 3 4 5 6 7 8 9 10

Totally Relaxed
No Tension

Extremely
Tense

| Date & Time | Tension Before Relaxation | Type of Relaxation Exercise | Tension After Relaxation | Comments |
|---|---|---|---|---|
| 12/15/10<br><br>2:00 pm | 8 | ☐ Breathwork<br>✓ Progressive Relaxation<br>☐ Guided Imagery<br>☐ Meditation | 4 | This worked really well today, I felt much better after I relaxed! |
| | | ☐ Breathwork<br>☐ Progressive Relaxation<br>☐ Guided Imagery<br>☐ Meditation | | |
| | | ☐ Breathwork<br>☐ Progressive Relaxation<br>☐ Guided Imagery<br>☐ Meditation | | |
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# Stress Management

## Problem Solving

***Recognize that there is a problem situation.***

***Define the problem.***

***Generate alternative solutions.***

***Take action on alternative(s) selected.***

***Evaluate the effectiveness of the solution chosen.***

# Managing Your Mood – Helpful Lists

This worksheet includes spaces for you to try some of the different types of lists that are recommended in the managing your mood section of the program. You don't have to be depressed to find these lists useful. Try each one for at least one day and see if they are helpful.

## Identify Harmful Thinking

3 times a day, write down the most important emotion-related thoughts you've had since you last wrote. Remember that important thoughts generate feelings and may occur repeatedly.

| Positive Thoughts | Negative Thoughts |
|---|---|

## Make a gratitude list.

Jot down situations that you are pleased about or people you appreciate.

## Make a list of your current accomplishments.

This is the rewarding side of the "To Do List," and most of us never write it!

## Pleasant Activities

Create a list of activities that give you feelings of pleasure or mastery. You can go to this list when you need to get your mind off your troubles or when you find that you are engaging in too many activities that lead to sadness or anger.

## Identify Positive People & Relationships in Your Life

*Loneliness can feed depression, but increasing contact and activities with likeable people can lessen it. If social contact seems hard to maintain, a useful approach is to start with brief outings with "safe" people. Friends and family can serve as a positive source of social support.*

# Managing Anxiety

## Challenging Threatening Thoughts

| Situation | Identify the Threatening Thought<br>*What was I thinking when the anxiety began? Did I have a mental image? What did I think was going to happen?* | Evaluate your assessment of the situation | | | | Notice how you feel after you realistically assess the situation |
|---|---|---|---|---|---|---|
| | | Evidence<br>*What is the factual evidence that supports my belief?* | Alternatives<br>*Are there other ways of looking at the situation?* | Usefulness<br>*How does this type of thinking help me?* | Thinking Errors<br>*Black & White Thinking, Unrealistic Standards, Catastrophic Thinking, Overgeneralizing, Overestimating the likelihood of bad events?* | |
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| Situation | Identify the Threatening Thought<br>*What was I thinking when the anxiety began? Did I have a mental image? What did I think was going to happen?* | Evaluate your assessment of the situation | | | | Notice how you feel after you realistically assess the situation |
|---|---|---|---|---|---|---|
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## Appendix B

## Correlations Between Baseline and Final Assessments

Table B1

Correlations Between Baseline and Final Assessment of all Variables

| Variable | Correlation of Baseline & Final Assessments |
|---|---|
| Perceived Generalized Stress | .49** |
| Diabetes-Related Distress | .70** |
| Depression | .70** |
| Anxiety | .60** |
| Positive Affect | .65** |
| Negative Affect | .64** |
| Diabetes Symptoms (Total) | .71** |
| Fatigue Symptoms | .71** |
| Cognitive Symptoms | .75** |
| Neurological Pain Symptoms | .69** |
| Sensory Symptoms | .73** |
| Cardiac Symptoms | .65** |
| Ophthalmological Symptoms | .59** |
| Hypoglycemia Symptoms | .51** |
| Hyperglycemia Symptoms | .68** |
| A1c | .87** |
| General Diet Recommendations | .70** |
| Specific Diet Recommendations | .70** |
| Exercise Recommendations | .72** |
| Glucose Testing Recommendations | .84** |
| Foot Care Recommendation's | .81** |

**$p < .01$.