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The Effects of Learning Mindfulness Based Stress Reduction on Psychosocial Variables and HbA1c in Adolescents with Type 1 Diabetes

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THE PHYSIOLOGICAL AND PSYCHOLOGICAL EFFECTS OF AN ONLINE

MINDFULNESS BASED STRESS REDUCTION INTERVENTION ON ADOLESCENTS

WITH TYPE 1 DIABETES

A Dissertation

Submitted to the Graduate Faculty of the School of Nursing

Duquesne University

In Partial fulfillment of the requirements for

the degree of Doctor of Philosophy

By

Denise E. Van Sant – Smith

May 2019

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Approved April 5, 2019

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ABSTRACT

THE PHYSIOLOGICAL AND PSYCHOSOCIAL EFFECTS OF AN ONLINE

MINDFULNESS BASED STRESS REDUCTION INTERVENTION ON ADOLESCENTS

WITH TYPE 1 DIABETES

By

Denise E. Van Sant – Smith

May 2019

Dissertation Supervised by Linda Goodfellow, PhD, RN, FAAN

Background: Stress has been shown to increase glucose levels through a sympathetic physiological response resulting in a release of chemicals such as adrenalin and cortisol, a response which results in an even greater need for insulin. Adolescents with Type 1 Diabetes may not be able to change or decrease the amount of stress in their lives but they may be able to change the way they respond to the stress they experience. Mindfulness Based Stress Reduction (MBSR) has been shown to help practitioners change the way they respond to stress and perhaps reduce the psychosocial and physiological effects of stress.

Objectives: To determine if learning MBSR has an influence on psychosocial variables and the physiological variable of HbA1c in adolescents with Type 1 Diabetes and explore the relationships between those psychosocial variables and HbA1c in adolescents with Type 1 Diabetes.

Methods: This between group experimental design measured the effects of a 6-week, online/web-based instructional MBSR training module at three time points (pre intervention, immediately post intervention and 3 months post intervention) on adolescents with Type 1 Diabetes (N = 65) randomly assigned to either the Active Group or Control (Wait) group. The major dependent variables of Mindful Attention Awareness (MAAS-A), Diabetes Quality of Life (DQOLY) were measured at the three time points to examine the effects of MBSR on those variables. The dependent variable of HbA1c was measured at Time 1 and Time 3 to examine the effects of MBSR. Data Collected on Mindfulness, Quality of Life and HbA1c were correlated with MBSR training to examine their relationships. Prior to hypotheses testing, data collected on perceived stress and characteristics of the sample population were examined to ascertain any confounding variables.

Results: 65 individuals participated in the study. Mixed between-within subjects analysis of variance tests were used to determine the effects of MBSR over the two post intervention time points. There was a significant interaction effect of time with group assignment (Active or Control Group) on MAAS-A scores, Wilks' Lambda = 0.44, $F(2, 62) = 38.85$, $p = 0.000$. There were also significant main effects on the score of time and group assignment for MAAS-A. There was a significant interaction effect of time with group on DQOLY scores, Wilks' Lambda = 0.793, $F(2, 62) = 8.08$, $p = 0.001$. There was a significant main effect of time on DQOLY score Wilks' Lambda = .73, $F(2,62) = 11.18$ $p < 0.001$. There was a significant interaction effect of time with group on HbA1c results, Wilks' Lambda = 0.861, $F(1, 63) = 10.13$, $p = 0.001$.

Discussion: These findings suggest that learning MBSR may improve Mindful Attention Awareness, quality of life and lower HbA1c.

DEDICATION

This dissertation is dedicated to my family, for all their love, support and encouragement. I am so grateful to all of you. To Schuyler, I have seen you meet the challenges every day of living with diabetes, the extra work you do and the effort and toll that has taken. This journey has been an effort to make it all just a little bit easier for you and others who bare this burden. To my sweet Jadelynn, I'll never forget how you ran down the sidewalk as I drove out of the neighborhood headed toward Doctoral Week at Duquesne, shouting encouragement and telling me you loved me. To Kevin, there are no words to express how wonderful it has been to have a true partner and friend on this life journey.

ACKNOWLEDGMENT

The completion of this dissertation would not have been possible without the careful guidance of my Chair, Dr. Linda Goodfellow. My sincerest gratitude extends to my committee members, Dr. Fran Cogen and Dr. Jessica DeVido for their advice and efforts on my behalf.   It is no small thing to guide and encourage another – I hope to pay it forward someday – in all your names.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ADA: American Diabetes Association

CGM: Continuous Glucose Meter

DECA: Diabetes Education and Camping Association

DQOL: Diabetes Quality of Life Measurement Questionnaire

HbA1c: Hemoglobin A1c/glycated hemoglobin test

MAAS: Mindfulness Attention Awareness Scale

MBSR: Mindfulness Based Stress Reduction

PNEI: PsychoNeuro-EndocrinImmunology

QOL: Quality of Life

T1D: Type 1 Diabetes

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

The last 30 years has seen a threefold increase in the number of cases of *childhood diabetes*, the majority of that increase is in Type 1 diabetes (T1D). According to government statistics, more than 15,000 children and 15,000 adults are diagnosed each year with 1.25 million Americans currently living with T1D (National Institutes of Health, 2011). The prevalence of T1D in Americans under age 20 rose by 23 percent between 2001 and 2009 (Juvenile Diabetes Research Foundation, 2011). It is estimated that the rate of incidence among children under age 14 will increase by three percent annually worldwide and according to the International Diabetes Federation (IDF), the incidence of T1D among children is increasing with 79,100 developing the condition annually. The diagnosis of T1D has increased in most IDF regions demonstrating the incidence rate increases occurring in many countries (Patterson et al., 2014).

T1D is an autoimmune disease in which the body attacks and destroys the insulin-producing cells of the pancreas. Individuals are rendered dependent on the exogenous delivery of insulin and as such, are required to perform numerous blood glucose checks to evaluate and treat their blood sugar levels over the course of the day and night. The dependence of individuals with Type 1 diabetes on the self-administration of insulin and constant monitoring of blood glucose levels related to diet, exercise, health status, growth and sexual maturity make the management of this condition intensely demanding. The fact that T1D strikes most often in childhood also has significant implications for disease management.

Furthermore, failure to successfully manage blood glucose levels daily results in both short and long term health complications. Subsequently, the demanding management of this disease often creates an environment of immense psychological demands - in addition to the

obvious physiological demands. Those psychological demands are known to exacerbate the condition through the physiological stress response of cortisol release resulting in blood glucose increases (Hou, 2015). This known physiological mechanism of stress response is important to understand and manage to achieve more effective and holistic care goals. The psychology and physiology of an individual are intertwined. Recognition of this relationship and care that addresses both concerns is key to advancing the standards of care for this population.

1.2 Significance of the Problem

The increased prevalence of T1D in adolescents and the intense demands of disease management have brought to the forefront the need for a comprehensive approach, one that encompasses both the physiological and psychological aspects for better management of this chronic condition. This comprehensive approach concerns the creation of a program to assist adolescents with T1D to learn management of their stress through a learned technique of mindfulness. This approach would provide adolescents the opportunity to learn techniques that would aid in the management of the stress related to T1D. The objective of this study was to examine the effects of this comprehensive approach in this population.

1.3 Theoretical Basis for the Study

The conceptual framework that was used to guide this study is a combination of two theoretical models, Engel's biopsychosocial model (Engel, 1977) and Ader's psychoneuroimmunology framework (Ader & Cohen, 1995). The conceptual frameworks represented by these models provide a basis for assessing and reviewing the existing literature. The concepts represented by the models were also essential in the development of the intervention for this research.

1.3.1 Biopsychosocial Model

Dr. George Engel's Biopsychosocial model was developed as a response to the biomedical model which had failed to answer many of the psychological components that can be part of physical illness, especially chronic illness. The Biopsychosocial model acknowledges that health and disease are a result of interactions between social, psychological and biological factors and it asks that practitioners recognize the complex interactions between these factors in their care of patients. It has frequently been used to address treatment of those with cancer, diabetes and mental disorders because biological, psychological and social components of these problems have been found to have significant impact on effective disease management. This biopsychosocial model arrived in answer to the biomedical model, seen as reductionistic in its view of natural systems at their lowest molecular level. In contrast, the Biopsychosocial approach recognizes the importance of viewing a person at several levels and within a natural systems continuum (Borrell-Carrio & Epstein, 2004).

According to Langendoen (2004), patient-centeredness is considered to be the practical application of the Biopsychosocial model and builds one of the three cornerstones of evidence-based practice: practical, patient-centered application. Mead and Bower (2000) in an attempt to clarify patient-centeredness, define it further as an understanding of the illness of the patient from within a broader Biopsychological framework by understanding the patient's experience of the illness.

1.3.2 Psychoneuroimmunology

The recognition of the individual patient as a biopsychosocial being is not a fresh rejection of the medical model. It is, in fact, a theory that has been researched beginning in the 1960s. The name of that theory is Psychoneuroimmunology (PNI), the study of the mind/body

connection and the interactions between consciousness (psycho), central nervous system (neuro) and the body's defense against invaders (immunology) (Bauer, 1994). Interest in developing and understanding the relationship between body and mind began with evaluations of relationships among stressors and disease. In the mid1970s and early 80s when Ader and Cohen (1995) were able to demonstrate a classically conditioned immune response, interest in PNI increased significantly (Zeller, 1996). PNI is now being referenced in the literature as PNIE, incorporating the endocrine system as an integral part of the dynamic relationships between the mind, endocrine and immune systems. The literature focuses on states of mind such as stress and depression and demonstrates the link to physiological conditions, representing the bidirectional nature and crosstalk between these systems that occurs. In 2012, two symposia (The Interface Between Anxiety and Medical Disorders and Integrating Mind-Body Connections) were presented at the Annual Meeting of the Anxiety and Depression Association of America (ADAA). In a review of that symposia several studies describing the relationships between the endocrine, nervous and immune systems were recognized as the major communication systems in mammalian organisms and with input from psychological processes they communicate with each other. Further, the impact of psychological stress on the physical condition of the body is asserted after review of these studies (Nemeroff, 2013).

Type 1 diabetes, an autoimmune disease associated with high levels of stress related to disease management and potential complications, can be examined utilizing the concepts of PNIE. The model provides conceptualization of a physiological basis for effectiveness of psycho-behavioral interventions designed to serve as a buffer promoting stress management and positively influencing health outcomes. As such, PNIE provides the researcher with a comprehensive framework for integrating the Engel biopsychosocial model with a cognitive

behavioral therapy such as Mindfulness Based Stress Reduction (MBSR) to examine the psycho-

behavioral processes that are part of the stress-disease relationship.

Stress/Stimuli

Stress /Stimuli

Mindfulness Training

Neurological
System:
Perceptions ,
Thoughts and Mood

Psychosocial
Components:
Mental and Social
Phenomena

Biological Systems:
Endocrine &
Immune System
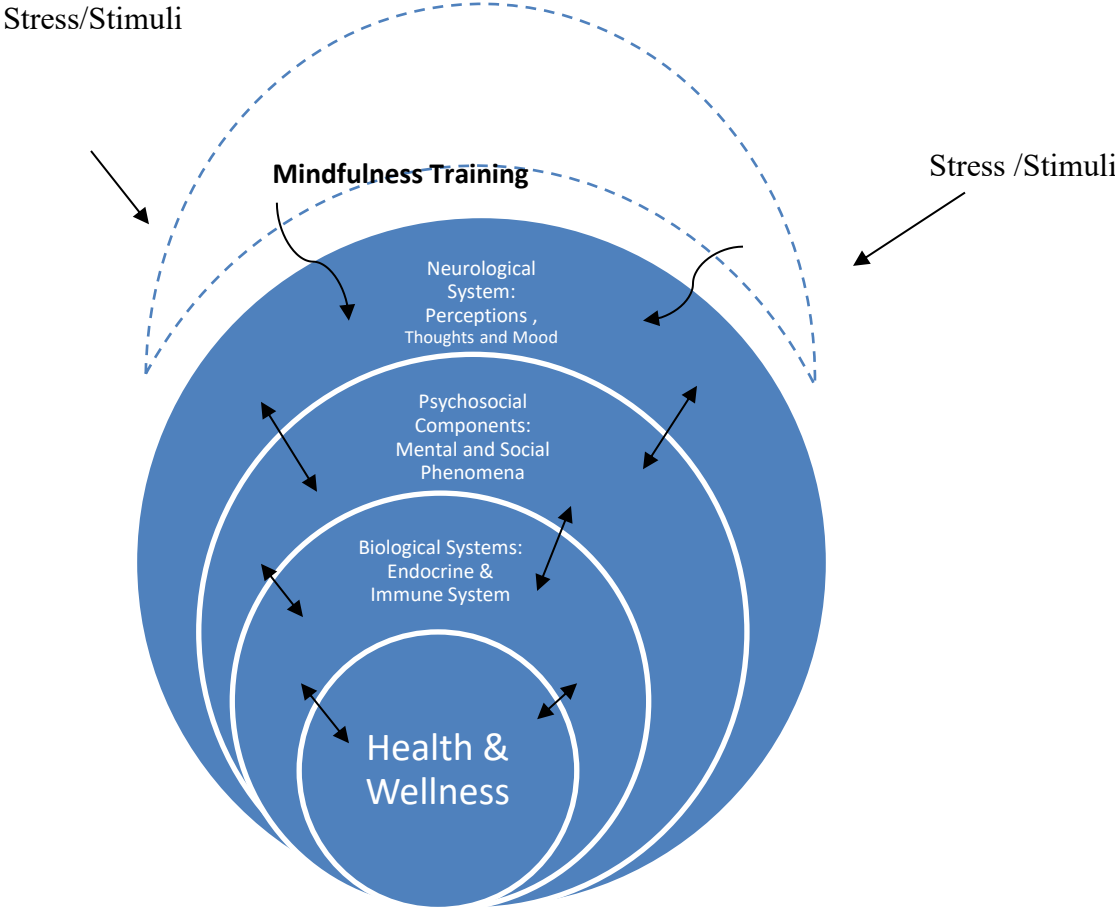
Health &
Wellness

Figure 1. 1 *Physiological and Psychological Effects of Mindfulness training on Health and Wellness of Adolescents with Type 1 Diabetes*

1.4 Critical Analysis of Relevant Literature

A comprehensive analysis of research and scholarly works were sought that discussed the stress/illness connection and the psychological health issues related to diabetes and chronic illnesses. Further research was sought for articles that described coping mechanisms and control of diabetes with various cognitive behavior techniques to improve patient outcomes by enhancing stress management.

The examination of the literature reviews the impact of T1D as a stressor influencing psychological well-being and quality of life. Coping and interventions designed to improve adherence and outcomes specifically for adolescents with diabetes were also reviewed. A specific intervention, Mindfulness Based Stress Reduction Training (MBSR) was further examined demonstrating its effectiveness as a treatment of other chronic physical/psychological conditions.

Clearly, T1D is a known stressor (Wiesli, 2005; Watts, 2010) and adolescents, in particular, have been identified as being at risk for psychological distress and poor management of T1D (Trast, 2014; Tilden, 2005). Prior studies show that MBSR has been used with positive results as an intervention for many chronic illnesses (Prouix, 2003). In addition, several online programs and e-health systems have been utilized to enhance delivery of psychoeducation for this population (Whittemore, 2013; Tercyak, 2009; Cafazzo, 2012).

Several gaps in the literature are identified concerning the development of a comprehensive approach to address both the psychological and physiological well-being of adolescents managing T1D. There were no studies that focused on the use of MBSR for these adolescents and we do not know whether MBSR has psychological and/or physiological benefits associated with effective management of stressors specific to TID in adolescents. This research

was needed to determine if the use of MBSR for this population would have an effect on stress reduction, HbA1c and quality of life in adolescents managing T1D

1.5 Problem Statement

Adolescence is often recognized as a particularly challenging time in the growth and development of youth even without the complication of a chronic disease. The existing research on adolescents with T1D focused on well-known issues of adolescence such as peer pressure and relationships with family (Helgeson et al., 2010; Malik & Koot, 2009; Bernstein et al., 2013). The existing research further showed the need for psychosocial screening of these adolescents by providing statistics of psychopathologies and advocating for mental health screenings of the population (Schwartz et al., 2011; Hilliard et al., 2011). While this literature did cite the need for psychosocial screening and the development of psychopathologies, the primary identification of specific experiences and perceptions leading to these problems revolved around the intensive demands of diabetes management. In addition, much of the literature relied on the assumption that the issues that matter to adolescents with T1D are the same as those for adolescents without diabetes. (Sultan et al., 2008; Berg et al., 2009; Hema et al., 2009). Whether or not this is true remains to be seen.

Few intervention studies have been conducted to date that have examined ways by which adolescents can reduce stress associated with the demands of diabetes management. Those that have, examined the effects of coping skills training (Grey et al., 1998); cognitive behavioral therapies (Perfect & Elkins, 2010); motivational enhancement therapy (Ismail et al., 2008) and multi-systemic therapy (Ellis et al., 2005).

MBSR programs have been used and applied with diverse populations and as an intervention, they are increasing in popularity. While the traditional MBSR course is structured

with specific content and presentation, the intervention has been modified in content and length for adolescents (Kerrigan, et.al., 2011; Brown, et.al., 2011; Smith, et.al.2008) and in delivery format such as online, web-based mindfulness training (Mak, et.al., 2015; Davis & Zautra, 2013). MBSR has been taught and then studied in those with many different chronic illnesses and for those with depression or anxiety disorders. MBSR has also been used and studied with the adolescent population. While it has been seen as an effective intervention for chronic illness and for adolescents, it has not been examined in the adolescent population with the chronic illness of T1D.

1.6 Research Questions and Hypotheses

The purpose of this study was to determine the effectiveness of MBSR, a learned stress reduction method offered online to adolescents with Type 1 diabetes on mindful attention, reported quality of life and blood glucose control. The overall objective was to examine changes in psychosocial and physiological measures following MBSR training at three time points. The specific aims of the research were to:

(a) Test MBSR training for positive influences on Mindfulness, Quality of Life and HbA1c in adolescents with Type 1 Diabetes.

(b) Examine the relationships between Mindfulness and Quality of Life and Mindfulness and HbA1c over time

The following hypotheses were tested:

1. MBSR training will increase mindfulness in adolescents with Type 1 Diabetes at two post intervention time points compared to a control group of adolescents with Type 1 diabetes.

2. MBSR training will improve quality of life in adolescents with Type 1 Diabetes at two post intervention time points compared to a control group of adolescents with Type 1 Diabetes.

3. MBSR training will decrease HbA1c in adolescents with Type 1 Diabetes three months post intervention compared to a control group of adolescents with Type 1 Diabetes.

1.7.1 Assumptions

The assumptions for this study are as follows:

1. Adolescents with T1D have the knowledge, skills and experience to respond to questions related to diabetes management.

2. Adolescents with T1D are willing to provide accurate information related to their stress levels, quality of life and HbA1c.

3. Management of T1D is complex and stressful.

4. Adolescence as a time of physical (puberty) and psychological changes add to the challenge of T1D management.

5. Adolescents will be able to learn mindfulness via an online program and practice this technique when given the proper tools and training.

6. MBSR can be taught and learned in an online, web-based environment.

1.7.2 Limitations

Offering MBSR in an online format will be a challenge. In this study, data concerning the response to the MBSR training will be collected using two main questionnaires also offered online. Specific instructions will be provided for each, however, there will be limited control over the environment in which questionnaires are completed. Conducting an intervention study online may not be the most advantageous method as there will be little control over practice.

Also, socioeconomic status may reduce generalizability as some may not have access to computers and would not be able to participate.

1.8 Definitions

The terms used in this study are defined as follows:

Adolescence: The World Health Organization defines adolescence as the period in human growth and development that occurs after childhood and before adulthood, from ages 10 to 19. Adolescence represents one of the critical transitions in the human life span, it is characterized by a tremendous pace in growth and physical changes that are second only to those seen in infancy. Biological processes drive many aspects and the onset of puberty marks the passage from childhood to adolescence. The biological determinants of adolescence are fairly universal; however, the duration and defining characteristics of this period by individuals varies among culture and socioeconomic situations. The defining time of adolescence has changed several times over the past century with the earlier onset of puberty, later age of marriage, urbanization and changing sexual attitudes and behaviors (WHO, 2014).

Quality of Life: This is a standard measurement of health, comfort, and happiness experienced by an individual or group.

Diabetes Quality of Life: In this study, quality of life will be measured by the Diabetes Quality of Life scale (Jacobson et al., 1988) and provides a measurement and score that predicts self-reported diabetes care behaviors and satisfaction with diabetes control. It is intended to be an assessment of individuals with diabetes and their specific treatment-related concerns.

HbA1c or A1c: This is a lab test of the blood that represents the average level of glucose that is attached to the hemoglobin molecule over the previous 3 months and is a good representation of how well diabetes is controlled. It is also called: Glycated hemoglobin test;

glycosylated hemoglobin test; hemoglobin glycosylated test and glycohemoglobin test. A

normal test (no diabetes) result is 5.7%; pre-diabetes result is 5.7% to 6.4%; and, diabetes is

diagnosed with a result of 6.5% or higher. The HbA1c test is used to diagnose diabetes but it is

most often used with those who have already been diagnosed to monitor how well the blood

glucose is being controlled. A value of 5% corresponds to an average blood glucose of 100

mg/dl; a value of 8% corresponds to an average blood glucose of 183 mg/dl and a value of 13%

corresponds to an average blood sugar of 326 mg/dl. In this study, HbA1c will be measured

upon entry into the study and three months after MBSR training to determine whether MBSR

used over time has physiological effects on long term blood sugar control and thus, ability to

control diabetes better.

Mindfulness: A mental state achieved by focusing one's awareness on the present

moment, while calmly acknowledging and accepting one's feelings, thoughts, and bodily

sensations.   Jon Kabat-Zinn, the founder of the Mindfulness-Based Stress Reduction program at

the University of Massachusetts Medical Center describes the practice of mindfulness as "a sense

that there is a way of being, a way of looking at problems, a way of coming to terms with the full

catastrophe that can make life more joyful and rich than it otherwise might be, and a sense also

of being somehow more in control. We call this way of being the way of awareness or the way of

mindfulness" (Kabat-Zinn, 2009, p. 19). In this study, mindfulness will be measured by the

Mindful Attention Awareness Scale – Adolescent (MAAS-A) (Brown, Ryan, Loverich, Biegel,

& West, 2011).

Mindfulness Based Stress Reduction (MBSR):   A program to learn about mindfulness that

assists a person to calm their mind and body through concentration on breath and the present

moment. Learning this process assists a person in coping with stress, pain and illness. It is

learning to pay attention fully to the present moment and to be aware of emotions, thoughts and sensations of the body in a non-judgmental way. This study will teach MBSR in an online, web-based format designed for adolescents. MBSR is an independent variable in this study.

Psychological Stress: Psychological stress occurs when an individual perceives that environmental demands tax or exceed his or her adaptive capacity (Cohen & Kamarck, 1996).

1.9 Significance to Nursing

The significance of this nursing research study is in the potential for improving the quality of life and management of diabetes in adolescents with T1D. The use of MBSR could provide a stress management technique and buffer for stress for this population thereby improving management of diabetes. This could lead to significant reductions in both the psychological stressors associated with the management and care of diabetes and the potential reduction in physiological complications associated with poor glucose control.

Insight gained from this study will advance the science in nursing and provide nurses and other health care professionals with a better understanding of the challenges faced by adolescents with T1D as well as the importance of a comprehensive approach to health and wellness of patients, especially those with a chronic illness such as diabetes. Results of this study may inspire nurses and other diabetes health care professionals to utilize a more comprehensive and mind-body holistic approach to care for adolescents with TID.

CHAPTER TWO

REVIEW OF THE LITERATURE

The review of the literature provides a theoretical and research background for the issues addressed by the research questions. An extensive search of the literature was conducted including Health and Psychosocial Instruments database, Cinahl, MEDLINE, PubMed, PsycINFO and ProQuest Digital Dissertations to determine the current state of the literature on the described research. The search terms used were *psychoneuroimmunology*, *Type 1 diabetes*, *adolescents, stress* and *mindfulness*. The literature returned was reviewed, study variables were identified and a conceptual framework was selected. Additional searches were then conducted using the terms: *Mindfulness Based Stress Reduction* and *quality of life*.

This chapter will first review the theoretical framework that will guide this study. In addition research studies concerning the physical and psychological effects of stress; adolescents coping with diabetes; interventions to enhance coping skills and MBSR interventions will be discussed. Lastly, gaps in the literature will be addressed.

2.1 Theoretical Framework

A combination of the theoretical concepts of the biopsychosocial model and the PNIE model are used to inform this research. The Biopsychosocial model identifies that health and disease are a result of interactions between social, psychological and biological factors, as such all of these factors must be considered in the care of patients. This model has been used frequently to address treatment of those with cancer, diabetes and mental disorders because biological, psychological and social components of these problems have been found to have significant impact on effective disease management.

Psychoneuroimmunology (PNI) is the study of the mind/body connection and the interactions between consciousness (psycho), central nervous system (neuro) and the body's defense against invaders (immunology) (Bauer, 1994) PNI has been expanded to PNIE, now incorporating the endocrine system as an integral part of the dynamic relationships between the mind, endocrine and immune systems.   The literature focuses on states of mind such as stress and depression and demonstrates the link to physiological conditions, representing the bidirectional nature and crosstalk between these systems that occurs.

2.2 Psychosocial Consequences of Diabetes

Most of the literature speaks to the stressors of T1D with evaluation and description of the existing coping responses. The Diabetes Attitudes, Wishes, and Needs (DAWN) Study, (Funnell, 2006) has been referenced in multiple published articles in 2005 and 2006 and was a cross-sectional international survey initiated in 2001 in collaboration with the International Diabetes Federation.   This study was the result of structured interviews in 13 countries with 2,705 physicians, 1,122 nurses and 5,104 patients with diabetes. The purpose of this study was to identify the attitudes, wishes and needs among people with diabetes and their care providers. The majority of the patient participants (85.2%) reported distress upon diagnosis with feelings of anxiety, depression, and helplessness. Well-being was reported as poor by 41% of the patients with only 10% receiving psychological treatment. Most of the providers (69.8%) reported that they would want a better understanding of the psychosocial consequences of diabetes. According to Funnell (2006), this study confirmed that diabetes causes multiple psychosocial problems which are barriers to achieving glycemic control. The psychosocial consequences also interfere with self-management behaviors and our current health care system is poorly equipped to handle chronic illness care.

The second DAWN study published in May 2013 again reviewed the attitudes, wishes and needs in a cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Nicolucci et al. (2013) reported that despite some progress made from the initial DAWN study, the impact of the psychosocial burden of diabetes is still not fully recognized and addressed by the health care system across many different nations and health care environments. There were 8,596 adults with diabetes across 17 countries in this study, with results showing that 13.8% were likely depressed; 44.6% reported diabetes-related distress and 12.2% rated their quality of life as 'poor' or 'very poor'. Diabetes was reported by the respondents to have a negative impact on all aspects investigated ranging from 20.5% on relationships with family and friends to 62.2% on their physical health. Only 48.8% had participated in diabetes educational programs or activities to help with management of the diabetes. Overall, the study concluded with a call for cross-national benchmarking of psychometrically validated indicators to help identify areas for improving outcomes.

Clinical Application of Psychoneuroimmunology

Zeller, McCain and Swanson (1996) discussed psychoneuroimmunology (PNI) as an emerging framework for nursing research because it identifies the bidirectional communication between the neuroendocrine and immune systems. In 1964, George Solomon proposed this new science called psychoimmunology and at that time, systematic attempts were made to identify the relationship between stress, the immune system and disease. Subsequently, much of the research has focused on the relationship between stress and the immune system with research demonstrating that psychological stress and illness are related through immunomodulation. Many studies have demonstrated the negative relationship between stress and the immune system

– as stress increases, the effectiveness of the immune system decreases – leaving the person more susceptible to illness.

These authors reference the maintenance of the holistic focus of nursing and describe nursing as a discipline that has historically considered both the biology and behavioral processes of patients. They cite nursing research grounded in PNI and the use of biobehavioral strategies such as relaxation, biofeedback, imagery and hypnosis that demonstrate an immunomodulatory effect. Research within the PNI/PNIE framework allows nursing science to move forward in the understanding and utilization of biobehavioral approaches to enhance patient outcomes.

Cohen and Herbert (1996) conducted a review of PNI to discover the role that psychological factors play in physical illness. The psychological factors that might influence immunity and the immune response are explained along with a review of the evidence concerning stress and how negative affect, clinical depression, lack of social support and repression or denial can influence the cellular and humoral indicators of immune status and function. The authors also discussed the link between stress and the onset and progression of disease with further discussion of the role that psychological factors may have in autoimmune disease.

2.3 Physical Effects of Stress and Psychological Effects of Diabetes

Several researchers have explored and measured the relationship between stress and illness, describing the physiological effects of stress on the body. In addition, the effects of stress on adolescents with diabetes and the impact on metabolic control have also been studied.

2.3.1 Physiological Effects of Stress

Sepa, Wahlberg, Vaarala, Frodi, and Ludvigsson (2005) investigated the possibility that psychological stress induces diabetes-related autoimmunity in infancy. Retrospective studies

have proposed several environmental factors as trigger mechanisms for T1D or the autoimmune process behind the disease. In Southeast Sweden all babies were invited to participate in this study, 17,055 families agreed and as a result, parental questionnaire responses from birth and one year as well as blood samples from year one were examined on the first 4,400 consecutive families. The researchers reported that psychological stress as measured by psychosocial strain was involved in the induction or progression of T1D. Factors such as high parenting stress (odds ratio 1.8 [95% CI 1.2-2.9], P <.0.01), experiences of a serious life event (2.3 [1.3-4.0], P<0.01) foreign origin of the mother (2.1 [1.3-3.3], P<0.001 and low paternal education (1.6 [1.1-23], P < 0.01) were associated with T1D in the child. Most importantly, these results were independent of family history of diabetes. The authors also reported that a body under stress shows hyperglycemia and decreased insulin sensitivity related to upregulation of cortisol and catecholamine levels. This increases the demand on the insulin-producing beta cells of the pancreas. The authors indicated that their results imply that psychosocial stress, measured as psychosocial strain on families, is implicated in the induction or progression of beta cell autoimmunity caused by beta cell stress during the first year of life. This study is significant because of the demonstration of the relationship between physiological and psychological conditions with a large number of participants.

Wiesli et al., (2005) demonstrated that acute psychological stress induced a significant delay in the decrease of glucose concentrations in participants with T1D. The authors knew that chronic psychological stress has been associated with higher levels of glycosylated hemoglobin (HbA1c) and they hypothesized that increased cortisol levels associated with stress could cause elevated glucose concentrations in participants with T1D. In their study, 20 patients were exposed to moderate psychosocial stress by means of the Trier Social Stress Test (TSST) in the

fasting state and 20 patients were given a meal and exposed to the same moderate psychosocial stress (TSST) after 75 minutes. In both groups, the blood pressure increased, however, it was noted that those who had eaten experienced a delay of 45 minutes for their glucose concentrations to decrease ($F = 646.65/$ p <0.0010). This research further highlights the impact psychological state has on the physiological condition of blood glucose levels.

Helgeson, Escobar, Siminerio and Becker (2010) evaluated the impact of stressful life events on adolescents with diabetes by interviewing adolescents with T1D annually for five years. The researchers measured stressful life events, psychological distress and self-care behavior. They downloaded information from the glucometers of the participants and their HbA1c measurements from medical records. These researchers again propose the relationship between stress and glucose control to be derived from the activation of the sympathetic nervous system by psychological distress. This leads to the release of stress hormones such as epinephrine and cortisol. These stress hormones increase glucose production in the liver, and/or decrease the insulin response to glucose through insulin resistance. This study demonstrated that stressful life events were predictive of greater psychological distress, poorer self-care behavior and worse metabolic control in cross-sectional and longitudinal (lagged) analysis. In the cross-sectional analyses on mental health, stressful life events predicted more depressive symptoms and metabolic control was associated with poor metabolic control for older but not younger adolescents. In the longitudinal analyses, stressful life events predicted significant changes in depressive symptoms; changes in anxiety, and changes in anger. Stressful life events predicted changes in self-care behavior and meter readings as well as changes in metabolic control over time. The researchers concluded that stressful life events are correlated with poorer metabolic control and this was especially true for older adolescents.

2.3.2 Psychological Stress of Type 1 Diabetes

T1D is a demanding and difficult condition to manage with significant psychological impact. Of those with T1D, 65 to 70% will experience psychological problems of one kind or another, including depression, anxiety, stress, burnout, anger, hostility, resentment and denial (Hilliard et al., 2016; Peyrot et al., 2005). As a result of this awareness, more focus is being placed on the psychological components of the diabetic regimen and understanding the relation that the diabetic has with their illness (Watts, O'Hara, & Trigg, 2010). Four participants with T1D were interviewed in an attempt to review the difficulties of living with diabetes. Results showed that "T1D is not just a physical condition, but also a profoundly social and psychological one, and this leads us to conclude that access to insulin should probably come hand-in-hand with access to personal, emotional and psychological support." (Watts et al., 2010, p. 504). Although limited by the number of participants, insight was gained through in depth interviews of the lived experience of these individuals. In this way, our larger and quantitative studies can be informed by this research.

T1D is associated with a high risk of psychiatric disorders in children and this seems to be a consequence of the disease rather than familial etiology (Butwicka, Frisen, Almqvist, Zethelius & Lichtenstein, 2015). In their large study of children and adolescents with T1D (n = 17,122) and their healthy siblings (n= 18,847) it was found that the risk of psychiatric morbidity in children with T1D compared with the general population was tripled within 6 months of the onset of diabetes and doubled over the total observation period. This was not true of the siblings of those with T1D allowing the researchers to remove familial tendencies as part of the etiology. This has significant implications for the care of this population as it highlights the need for preemptive psychological care of this population.

Adolescents, in particular, are considered to be an important population to study as it relates to the psychological components of management of T1D. Tilden, Charman, Sharples and Fosbury (2005) conducted a single case study with psychotherapy to examine poor adherence to self-care and subsequently poor health and diabetic complications. They describe metabolic control worsening in adolescence and hypothesize that there is a tendency in adolescents with diabetes to be angry and in denial and that these reactions are to the restrictions placed on them by TID, differentiating them from their peers. Results showed that adolescents resented and rejected the attention given to their diabetes and just wanted to be recognized for "self" and this circumscribed self (through rejection of diabetic identity) affected social and personal development. This is an interesting study in that it demonstrated the importance of addressing the psychosocial components of T1D as a chronic illness.

Malik and Koot (2008) sought to explain the adjustment of adolescents with T1D by looking at diabetes-related quality of life, general well-being and psychopathology.   They used questionnaires with 437 adolescents and their family members with the additional assessment in one laboratory of the metabolic control through HbA1c measurement. The results showed that diabetes stress mediated between HbA1c and adjustment with a 15% variance in general well-being and a 19% additional variance in psychopathology was explained by both diabetes-related and general stress. The researchers conclude that both diabetes-related and general stress are critical predictors of adjustment in adolescents with T1D.   Diabetes-related stress mediated between HbA1C and adjustment explained an additional 16% variance in quality of life and 15% variance in general well-being after controlling for protective factors. Also, an additional variance in psychopathology was explained by diabetes-related and general stress. Results of this study suggested that it is important to promote protective factors of adjustment and assess

the burden on adolescents of disease-related stress so as to provide them with a means to cope with it.

Bernstein, Stockwell, Gallagher, Rosenthal and Soren (2013) showed that screening for mental health issues in adolescents and young adults with T1D is an important component of care. More than one third of the participants were positive for: depression (11.3%), anxiety (21.3%) and eating disorders (20.7%). In addition, 14.7% of the participants showed two or more of the screenings conditions. This study supports the need for screening for mental health issues in adolescents and young adults with T1D as an essential component of care.

Kanner, Hamrin and Grey (2003) explored the co-morbidity of youth with diabetes and psychiatric conditions such as depression. A significantly higher rate of depression over the general population in youth with T1D was reported by Kokkonen (1995) in which depression prevalence was reported to be 12% in children between the ages of 8 and 12 and 18% in adolescents. They conclude by saying, "because people with type 1 diabetes undergo extreme rigidity in lifestyle, frequent glucose monitoring, and strict dietary habits, they require extraordinary coping skills to maintain adequate physical and psychological adaptation" (Kanner et al., 2003, p. 23).

Another study by Schwartz, Axelrad, Cline and Anderson (2011) noted the importance of psychosocial factors and the need for screening of children with Type 1 diabetes. The authors proposed a model psychosocial screening program and tool for children newly diagnosed with diabetes. Participants in the study were 121 children with T1D and their caregivers. They were seen within three days of their initial diabetes diagnosis and screenings were completed using questionnaires to create a short battery that still provided enough information for efficient screening. Group differences with these tools were established as Low, Moderate and High-risk.

Diabetes-related emergency room visits occurred for 1% of the low-risk group, 2% of the moderate- risk group and 22% in the high-risk group. These differences were significant F $(2,118) = 5.88$, $p < .005$, even when holding Medicaid status constant. The low and moderate-risk participants missed 0.51 and 0.66 appointments, respectively, while the high-risk group missed 1.67 appointments, significant at $F (2,118) = 4.20$, $p = .017$. The authors concluded by reporting that this psychosocial tool can help identify and reduce the risk faced by these children, better allocate psychology resources and provide for the development of preventative interventions.

Hilliard, Herzer, Dolan and Hood (2011) showed that there was an increased risk for depression and anxiety in this population which adversely affects diabetes management, quality of life and glycemic control. Their study involved 150 adolescents between the ages of 13 and 18 who completed depression and anxiety screenings. These same adolescents were assessed again one year later and found that their HbA1c values were significantly inversely associated with the participants' quality of life rated by caregivers ($b = -0.71$, $p < .01$). Higher depression scores predicted less frequent blood glucose measurement and poorer quality of life. Higher anxiety scores predicted higher HbA1c ($b = 0.07$, $p < .05$). The authors suggested that psychological screening for depression and anxiety can assist in referrals for appropriate interventions to prevent deterioration in diabetes management.

2.4 Adolescents Coping with Diabetes

In recognition of the well-documented physiological and psychological demands of diabetes, Sultan, Epal, Sachon, Vaillant, and Hartemann-Heurtier (2008) examined anxiety, coping and long-term glycemic control measured by HbA1c in 115 patients with TID at baseline and five years later. High trait anxiety was found to exaggerate sympathetic reactivity,

specifically cortisol levels and thus promoted insulin resistance and subsequently higher HbA1c measurements. Active coping skills may have an important long-term prognostic value. Furthermore, intervention programs for those with T1D that promote coping skills training and cognitive behavioral group training may be beneficial for this population (Grey et al., 2000; Snoek, Pouwer, Welch, & Polonsky, 2001).

Berg et al., (2009) examined 252 adolescents with T1D and their ability to cope collaboratively with their mothers was correlated with several beneficial outcomes for the adolescents. In this study, the participants had stress and coping interviews, dyadic stress appraisal (was either parent involved), dyadic coping (was either parent involved), perceived coping effectiveness (PCE), depressive symptoms, self-report of self-care behaviors, self-efficacy and metabolic control. A series of multiple regressions was conducted with PCE, age of adolescent, and the interaction of PCE by age as independent variables. This study demonstrated the value in measuring appraisals in addition to global adjustment of the adolescents because their appraisal of higher PCE was associated with fewer depressive symptoms, higher self-efficacy for diabetes management, better HbA1c, and better adherence.

Hema et al., (2008) cited the higher incidence of psychopathology (depression, anxiety, behavioral problems) found in individuals with diabetes in their study. They propose that understanding the daily stressors and challenges of those with diabetes could better help practitioners to design interventions to help young people cope with the challenges they face managing diabetes. They used a qualitative descriptive study analyzing the daily stressors and coping responses of 19 children and 33 adolescents with T1D. The researchers collected daily dairies and five stressor themes and three coping themes were apparent from that data. The stressors were classified into themes of people, self, context, nothing and ambiguous. The

coping themes were personal responsibility, submission and ambiguous. The authors noted that

there are assumptions made about youth with chronic illness having a more dysfunctional coping

system but they did not find that to be the case, "Clinical interventions designed to support youth

with chronic illness will be more effective when caregivers do not assume that all youth cope

poorly with stress and exhibit maladjustment as a result of negative events" (Hema et al., 2006,

p. 338).

On the topic of resilience and coping of adolescents with T1D, Jaser and White (2010)

conducted research with thirty adolescents with T1D between the ages of 10 and 16 and their

mothers. Their effort was to identify the most adaptive coping strategies and the impact of those

strategies on resilience.   They gave examples of resilience as quality of life, competence and

metabolic control. They were given questionnaires and it was determined that the use of primary

coping strategies such as problem-solving and emotional expression and the use of secondary

control coping strategies such as acceptance and distraction were both associated with higher

competence scores, better quality of life and better metabolic control. The use of disengagement

coping such as withdrawal or denial was associated with poorer metabolic control and lower

competence. The authors concluded that based on the success of primary and secondary coping

strategies, there might be value in educating patients about them. In a study with similar

findings, Yi-Frazier et al. (2015) discussed in their clinical implications section that the prospect

of intervening to bolster personal resilience could have the most impact on improving self-care,

QOL and glycemic outcomes. They define resilience as "a construct describing an individual's

capacity to maintain psychological and/or physical well-being in the face of stress" (p. 1197) and

further suggested that "there may be even more promise for resilience buffering stress and

improving overall outcomes for adolescents" (p. 1197).

The study by Luyckx, Vanhalst, Seiffge-Krenke, and Weets (2010) also identified adaptive and maladaptive strategies in coping with Type 1 diabetes. The study specifically identified the tackling spirit and active coping group as having the most optimum psychological and clinical outcomes. They recruited 109 adolescents into a four-wave, longitudinal study spanning from four years (mean age at Time 1 was 13.77). Patients were visited at home to complete questionnaires and their HbA1c levels were obtained from the treating physician. The study revealed that active coping predicted lower HbA1c levels and that higher HbA1c levels were associated with psychological symptoms and consistently predicted avoidance coping. They concluded that, "accepting and integrating the illness into one's self seems to be a powerful coping mechanism in emerging adulthood. When emerging adults are able to accept their diabetes as part of themselves and integrate it into their personality, they seem to be better equipped to tackle the many daily demands of this illness" (p. 235). Based on these results, the researchers recommend coping strategies and psychological symptoms to be monitored along with HbA1c in the clinical care of adolescents with T1D.

Skocic, Rudan, Brajkovic, and Marcinko (2009) conducted a study looking at the relationship between coping mechanisms and glycemic control in 101 adolescents between the ages 11-18 who had been diagnosed with T1D at least 12 months prior. The authors noted the critical time of adolescence as often corresponding with poor adherence and glycemic control. The participants were divided into three groups based on their HbA1c: those with optimal glycemic control (< 7.5%), suboptimal glycemic control (between 7.5 and 9%) and those at high risk for developing disease complications (> 9%). These values were established by the International Society for Pediatric and Adolescent Diabetes as referenced in the article. They completed two questionnaires: Youth self-report (YSR) assessment of adaptive behavior and

behavior descriptions and Scale of coping with stress (SCS) which is a self-report measuring seven dimensions of coping with stress. They found that internalizing and externalizing psychopathological dimensions, along with emotion-oriented coping were independently associated with poor metabolic control in both girls and boys. The researchers concluded that this creates information about potential psychotherapeutic interventions to improve glycemic control for this population.

In another study by Grey, Davidson, Boland, and Tamborlane (2001), clinical and psychosocial factors associated with treatment goals in 81 adolescent participants after 12 months of intensified treatment of diabetes. They were assessed at baseline and at 12 months using the Diabetes Quality of Life for Youth scale (Ingersoll et al.,1991), the Self-efficacy for Diabetes Scale (Grossman et al., 1987), The Children's Depression Inventory (Kovacs, 1985), and the Diabetes Family Behavior Scale (McKelvey et al., 1993). HbA1c was >9% at baseline and decreased to a mean of 7.8% +/- 0.7% with 30% of the subjects achieving the treatment goal of less than or equal to 7.2%. The participants were randomized to two groups – one with intensive diabetes management with coping skills training (CST) and one with only intensive diabetes management. Logistic regression analysis showed better HbA1c at entry into the study (p = .05); participation in the coping skills training (p = .003); and more parental participation in guidance and control (p = .05). They cite the findings of the Diabetes Control and Complications Trials (DCCT) in 1993 and 1994 demonstrated intensive therapy and better metabolic control reduce the risk of complications by 27-76%. Based on these findings, behavioral interventions such as coping skills training could assist adolescents to better metabolic control.

2.5 Interventions to Enhance Coping Skills

In recognizing that coping skills are an important component of care we can then recognize the potential benefit in examining interventions with this population and how they may or may not improve physical and psychological outcomes.

Sansom-Daly, Wakefield, Peate, and Bryant (2012) conducted a study in which they did a systematic review of psychological interventions for adolescents and young adults living with chronic illness. They reviewed 25 studies with quantitative, two-group methods. Thirteen of the studies were with adolescents and young adults (AYA) with diabetes, 7 AYAs with cancer and 5 AYAs with other chronic illnesses. The results of this meta-analysis revealed that educational interventions did show some significant positive results and several skill-based programs did show some positive results with moderate effect sizes. The interventions that taught communication skills, role-playing and met for at least 6 sessions, spanning 3 months had the most positive outcomes. The authors concluded that the teaching of adaptive coping skills needs to be grounded in theoretical frameworks.

Conn, Hafdahl, LeMaster, Ruppar, Cochran, and Neilsen (2008) conducted a meta-analysis of health behavior change interventions specific to T1D. For this research, they looked at adults but it is interesting for the purpose of this literature review because it addresses interventions specifically for T1D. The researchers evaluated data that had 1435 subjects and their HbA1c outcomes related to interventions to improve health behaviors. The conclusion was that behavior changes did improve metabolic control in T1D. The effect size was 0.26 with a reduction of 0.33 in mean HbA1c levels between the treatment groups and the control groups.

Plante and Lobato (2008) examined psychosocial group interventions for children and adolescents with T1D and found that a review of behavioral interventions had group formats as

their delivery method in over half of the treatments. The thought was that peer sharing may be a more effective method for adolescents. Also, the most common type of group treatment was the psychosocial diabetes group, 16 of the published studies had this format. The psychosocial groups operated with a focus on family functioning, social skills and stress management. The researchers concluded by advocating for the group format acknowledging both the care and cost effectiveness of this method.

Another study described the impact of diabetes camp as an intervention. In this descriptive, comparative pilot study, adolescents 10 to 16 years of age with T1D were given questionnaires to measure self-efficacy and resilience. Information concerning HbA1c was also obtained. Winsett, Stender, Gower, and Burghen (2010) described their findings with 81 campers recruited to explore the concept of self-efficacy and resilience as the mediators that are considered to be influenced by attending diabetes camp. The campers had what could be considered moderately high scores on self-efficacy and resilience. As the authors point out, these results should be compared to those who have not had the experience of attending the camp to ascertain the impact that camp may or may not have. The authors also made several important observations about adolescents and the care that they received in the years after the initial diagnosis. Most of the work of the certified diabetes educator was limited and focused on the needs of newly diagnosed patients. These researchers advocated for the possible use of diabetes camp to assist in programs to meet the needs of this vulnerable population.

Another type of intervention reviewed was motivational enhancement therapy with and without cognitive behavior therapy. In the publication of the randomized trial by Ismail et al., (2008), the authors indicated the importance of measuring the effectiveness of psychological treatments for improving diabetes outcomes. They recruited 344 adults with T1D with HbA1c

levels >8.2% to </= 15% for a two year study to determine if motivational enhancement therapy with or without cognitive behavior therapy would improve glycemic control as measured by HbA1c. They concluded that nurse-delivered motivational enhancement therapy along with cognitive therapy is feasible and resulted in a modest 12-month improvement in HbA1c compared to those who received usual care. Motivational therapy alone did not show significant improvement in HbA1c. The authors noted in their discussion that nurses can be trained to deliver diabetes-specific psychological treatments and that motivational enhancement therapy and cognitive behavior therapy may be an important adjunct to the medical regimen for those with T1D.

Continuing to review cognitive-behavioral therapies (CBT) for adolescents with diabetes, Perfect and Elkins (2010) studied the use of CBT in conjunction with hypnotic relaxation to treat sleep problems. They build the case for this research by citing diabetes as one of the most common disorders in children and adolescents and asserting the strong evidence that stress and sleep impact diabetic health on physiological and psychological levels. These researchers found that integrating CBT with hypnotherapy was even more advantageous and seemed to enhance patient compliance and treatment outcomes. Their research and evaluation of this case example with a 14-year old adolescent girl with T1D and stress-related sleep difficulties revealed some important psychological benefits with these combined interventions. They also found that their subject had improvement in her glucose regulation as well which they hypothesized was related to a reduction in her stress and improvement in her sleep.

Another intervention reviewed in the literature was coping skills training (CST). Grey et al., (1998) conducted a study to examine the short-term effects of CST for 65 youths between the ages of 13 and 20 years with T1D. Using a randomized, prospective two-group experimental

design, half of the participants were randomly assigned to intensive insulin therapy in addition to coping skills training and the other half received intensive insulin therapy alone. The experimental group had lower HbA1c, better diabetes self-efficacy and were less upset about coping with diabetes than the control group that experienced intensive management alone. The CST training focused on enhancing an adolescent's sense of competence for managing diabetes by retraining inappropriate or non-constructive coping styles. The authors concluded that CST not only improved HbA1c but also improved reported quality of life. The authors made some interesting commentary in this study as well with their discussion of education programs for those with newly diagnosed diabetes and suggested combining that education with some support training on self-management to improve self-care and knowledge. The authors concluded that the CST added important coping skills for the subjects and enhanced the abilities of the adolescents to initiate and maintain intensive treatment of diabetes.

Ellis et al., (2005) conducted a study describing multisystemic therapy (MST) to enhance and improve adherence among adolescents with T1D. MST is an intensive family therapy program based in the home and community. It was originally used for youths presenting with serious mental health problems. Their study was conducted with 127 adolescents with chronic poor metabolic control (HbA1c >/= 8% for the past year). Those that were randomly assigned to MST received treatment for approximately six months with data collected at baseline and then at seven months posttest. Those that participated in MST had improvement in frequency of blood glucose testing which was assessed by the blood glucose meter readings (F [1, 125] = 16.75, p = 0.001). They also had a decrease in number of inpatient admissions (F [1, 125] = 6.2, p = 0.0140. Metabolic control for adolescents receiving MST also improved compared with the

control subjects (F [1,114] = 4.03, p = 0.047). The authors concluded that the MST improved all markers tested including blood sugar testing, inpatient admissions and metabolic control.

In another study, a stress management intervention for adolescents with T1D was reviewed. Hains, Davies, Parton, Totka, and Amoroso-Camarata (2000) conducted a stress management intervention study for adolescents with T1D. The 15 youths who participated in the study had HbA1c values greater than 9.0% and were assigned to two groups, the experimental group and the waiting-list control group. The researchers used a stress-management training program with those in the experimental group. This training was cognitive-behavioral training and was conducted in a group format. When within-group comparisons were conducted, there were improvements in the experimental group related to decreases in anxiety, diabetes-related stress and negative coping efforts. Small sample size was clearly a limitation to the study. The authors also suggested that part of screening the participants should include consideration of psychological issues as well as elevated HbA1c. They also suggested that cognitive-restructuring and problem-solving interventions could be helpful tools in stress management with T1D.

The effects of stress management training on glycemic control was reviewed in 60 patients with T1D (Attari, Sartippour, Amini, & Haghighi, 2005). Thirty of the participants attended a three month stress management training class with constant insulin supply, the other 30 did not. The HbA1c from all patients was measured before and after the intervention. All participants were also given a questionnaire to assess coping skills. Patients who had received the stress management training showed significantly improved methods of coping. The differences in the mean HbA1c between the two groups was statistically significant at the end of the study (P < 0.001). The researchers concluded that there were significant beneficial effects of stress management training on glycemic control for patients with T1D.

2.6 Mindfulness

Many research studies have supported the role of chronic stress in both psychological and physiological diseases of the body. Dean Ornish, MD is a cardiologist who has written books and demonstrated the benefits of meditation and other life style changes for those with heart disease. Herbert Benson, MD a cardiologist who published books and articles outlining what he called the "relaxation response", achieved with the use of different types of meditation. In understanding the negative role that stress can play, the systematic reduction in perceived stress through stress management and coping skills has been recognized as an important and attainable goal with mindfulness. An increasing number of physicians and health care professionals have utilized and studied the effects of it. Often, this is accomplished with Mindfulness Based Stress Reduction (MBSR), a systematic program that has mindfulness training as the core.

MBSR involves learning a systematic and patient-centered method of reducing the effects of stress and disease through training in mindfulness meditation. Mindfulness involves the practice of paying attention in a particular way: on purpose, in the present moment and without judgment (Kabat-Zinn, 1994). Mindfulness is not a specific technique, but rather *a way of being* that is meant to be practiced daily regardless of the existence of a problem or upset for an individual. The core of mindfulness revolves around the idea of how we regulate what we pay attention to, this becomes our core of perception. The expectation is that, through this process, we can become less stress reactive by becoming aware of what has our attention. This self-awareness can lead to a foundation of more effective coping which can improve both physical and psychological conditions.

Mindfulness is rooted in Buddhist teachings and is described as a non-evaluative and sustained moment-to-moment awareness of perceptible mental states.   Mindfulness is described

by Kabat-Zinn as "a particular way of paying attention, a way of looking deeply into oneself in the spirit of self-inquiry and self-understanding" (2009, p.12) The practice of mindfulness involves an acceptance of all parts of self and the practice of attention to the present rather than worrying about the past or future. It is through this practice that stress is decreased (Kabat-Zinn, 2012).

MBSR programs have been created and used as interventions with diverse populations. The program usually consists of 8 to 10 weekly group sessions and one of those sessions is typically a full day retreat. It is psychoeducational, with considerable in-session experience and discussion between participants. Participants are educated about the psychophysiological effects of stress. They learn how to practice meditation in various states – sitting, eating and walking. They also learn how to do a body scan and light yoga. They are given homework to practice these skills and they are encouraged to bring mindfulness to their daily activities.

The increasing popularity of mindfulness as an intervention has also brought some variety in the type of intervention employing this concept. Marchand (2012) provided an overview of three main mindfulness variations that are often seen in the literature: Zen meditation; MBSR and mindfulness-based cognitive therapy (MBCT). All three originate from the Buddhist tradition; however, only Zen meditation is an actual Buddhist tradition. Both MBSR and MBCT have clinically based and standardized techniques that are secular. They are also both widely used for antidepressant and antianxiety effects. MBCT is often recommended for unipolar depression. Both MBSR and MBCT are thought to be effective in treating anxiety symptoms and MBSR is considered to be very useful for psychological health and stress management. MBSR and Zen meditation are also used in pain management. For the purposes of this review of the literature, research studies that look at both MBSR and MBCT were

evaluated because of their reliance on systematic and standardized techniques for learning the intervention.

Mindfulness has been studied in many areas and on both healthy and ill participants. The studies cited below discuss the use of mindfulness in research. Much of the literature review demonstrates statistically significant stress reduction for participants who used mindfulness as a core concept. This was, however, dependent upon how mindfulness was taught and used as a practice. It is hypothesized that there is potential for utilization of this concept for adolescents with T1D.

2.7 MBSR Interventions

There has been increased interest in mindfulness and as such, a significant increase in published research. Methods of evaluation of mindfulness are reviewed as well as the research focus. The research of interest for the purposes of this review included general research on mindfulness, research related to the use of mindfulness with adolescents and research related to diabetes.

Prouix (2003) conducted an early integrated review of 21 identified clinical studies involving MBSR. The purpose of the review was to analyze existing knowledge regarding clinical effects of MBSR and to identify gaps in the knowledge base. Twenty peer-reviewed studies were found published between 1982 and 2003 from the fields of medicine, nursing and psychology. Twelve of the studies were on those with chronic illness, four aimed at stress reduction and three were related to mindfulness training for students. There was also one qualitative, peer-reviewed grounded theory study. The author identified insufficient sample size and lack of a randomized control group as design limitations of the studies reviewed. In addition, none of the published studies in this review involved children younger than 18. The

studies reviewed suggested that MBSR is efficacious for individuals experiencing chronic illness. This integrated review suggested the importance of thoroughly exploring the potential of this intervention. The author suggested that further study is needed with underserved and minority populations including younger children. Since the time of this integrated review, MBSR has continued to become increasingly popular with practitioners and the public. As a result, there have been many more studies examining methods of incorporating mindfulness as an effective intervention.

A more recent meta-analytic review of mindfulness-based therapy was done with a focus on the use of this intervention in anxiety and depression. The study was conducted by Hofmann, Sawyer, Witt and, Oh (2010). These authors cite the rising popularity of mindfulness-based therapy and the need to study its efficacy. They reviewed 39 studies totaling 1140 participants who received mindfulness-based therapy for a variety of conditions including cancer, generalized anxiety disorder, depression and other psychiatric or medical conditions. The effect sizes were robust (Hedges's g of 0.97 and 0.97) for improving anxiety and mood symptoms respectively. The results of this metal-analysis suggested that mindfulness based therapy is a promising intervention for treating anxiety and mood problems in clinical populations.

Roberts and Danoff-Burg (2010) conducted a study to examine the relationship between mindfulness and health behaviors of 553 undergraduate college students. These participants completed questionnaires assessing mindfulness, perceived health, health behaviors, health-related activity restriction and stress. This was a robust study with a large amount of collected data from the students. The authors concluded that mindfulness is related to decreased stress which contributes to increased positive health perceptions and behaviors. The utility of mindfulness in promoting physical and psychological health was supported.

In another study evaluating mindfulness with adolescents, Marks, Sobanski, and Hine (2010) examined the moderating effects of dispositional rumination and mindfulness on the relationship between recent life hassles and adolescent mental health. Three hundred and seventeen Australian high school students completed questionnaires on recent life hassles, measures of dispositional rumination, dispositional mindfulness, and symptoms of depression, anxiety and stress. Moderation analyses revealed that dispositional mindfulness attenuated the relationship between life hassles and symptoms of depression, anxiety and stress. The authors proposed interventions to increase dispositional mindfulness during childhood to prepare for adolescence.

2.7.1 MBSR for Urban Youth

A qualitative study by Kerrigan et al., (2011) involved the recruitment of 59 adolescents between 13 and 21 years of age to a non-controlled intervention study to gain insight into the effects of MBSR on participants recruited from a pediatric and adolescent outpatient clinical site at Johns Hopkins Hospital. They received the structured eight-week program with some identified modifications. The authors discovered the benefits of MBSR and also reported that "mindfulness-awareness methods are distinct as potential tools for individual transformation not easily confined to linear models of cognitive-behavioral change" (Kerrigan et al., 2011, p. 101). Open-ended questions were used to gain a better understanding of the participants' perceptions of external stressors; mindfulness and transformational shifts in sense of self and positive changes.

The study by Brown, West, Loverich, and Biegel (2011) also addressed the assessment of adolescent mindfulness utilizing an adapted mindful attention awareness scale (MAAS). These authors noted, "There is a growing body of research investigating the use of mindfulness

interventions in adolescent normative and clinical populations" (p. 1023) and thus, promoted the use of the MAAS scale for adolescents. Increased MAAS-A scores among MBSR participants were significantly related to beneficial changes in numerous mental health indicators.

Black, Sussman, Johnson, and Milam (2012) conducted a psychometric assessment of mindful attention awareness among Chinese Adolescents. They had 5287 students in the study and obtained three waves of longitudinal data using a 15-item MAAS construct. Results suggested that programs aimed at enhancing mindfulness can enhance adolescent health.

2.7.2 A Comparison of MBSR to Cognitive-Behavioral Stress Reduction

In a pilot study by Smith et al., (2008), the effects of mindfulness-based and cognitive-behavioral stress reduction techniques were examined. The participants in this study selected the type of intervention they wanted and each participant went through an eight week course based on their choice. A questionnaire was given before the course and within one week of completion; it assessed demographics, mindfulness and several aspects of psychological and physical health. The mindful awareness and attention piece of the questionnaire were assessed using the MAAS (Brown & Ryan, 2003) – a measurement of receptive awareness of and attention to present events and experience. Analysis was done via a general linear model with repeated measures and showed that the MBSR group of participants improved on all eight outcomes. Significance was shown in all pre and post test questions.

2.7.3 Evaluating a Mindfulness-Based Stress Reduction Program

Carmody and Baer (2008) examined the relationship between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. The participants attended an eight session group program that

was provided to individuals enrolled in the University of Massachusetts Medical School MBSR program in Worcester MA during 2006. The individuals self-identified as dealing with stress-related problems, illness, anxiety, and chronic pain. The participants completed pre and post MBSR measures of mindfulness, perceived stress, symptoms and well-being. They also monitored their use of MBSR at home and formal meditation exercises which were found to be key in the reduction of symptoms. These authors discussed the difficulty in operationalizing mindfulness which is the key piece of MBSR. The facets of mindfulness are listed by the researchers as: observing - nonreactivity to inner experience; describing - nonjudging of inner experience; and acting with awareness. The changes in level of mindfulness were measured by the Five Facet Mindfulness Questionnaire (FFMQ) (Baer et al., 2006). For this study of 174 participants, all scores on all mindfulness facets increased significantly pre to post program. Medical and psychological symptoms of the participants as well as perceived stress levels decreased significantly with moderate to large effect sizes (Carmody & Baer, 2008).

2.7.4 Evaluating an MBSR Program on Physical Measures

Majmudar, Grossman, Dietz-Waschkowski, Kersig, and Walach (2002) examined whether mindfulness meditation contributed to health. The researchers systematically evaluated the effects of an eight week mindfulness meditation program to determine if there would be any impact on their participants. The participants for the study initially reported chronic physical, psychological or psychosomatic illnesses and were examined in a longitudinal pretest and post-treatment design with a three month follow-up. The interventions led to high levels of adherence as well as lasting reductions in symptoms (especially psychological symptoms of distress, well-being and quality of life). There were moderate-to-large effect sizes. This study did not utilize a measurement in mindfulness. Instead, five standardized questionnaires were used to measure the

main quantitative dependent variables: Changes in overall psychological distress with the Hopkins Symptom Checklist 90 (SCL-90-R) (Franke, 1995); Momentary emotional well-being with the Bf-S (Befindlichkeitsskala, von Zerssen, & Koeller, 1976); General physical complaints were measured with the Freiburg Complaint List FBL-R (Freiburger Beschwerdenliste) (Fahrenberg, 1994); Dispositional orientation "Sense of Coherence" (SOC) (Antonovsky, 1987) and, Life satisfaction with Fragen zur Lebenszufriedenheit Questionnaire of Life Satisfaction (FLZ) (Bullinger, 1997). The results of this study showed emotional well-being and general physical well-being increased significantly (Majumdar et al., 2002). The researchers concluded that controlled studies are warranted to study the efficacy and cost effectiveness of MBSR as an intervention for chronic physical and psychosomatic disorders.

2.7.5 Diabetes Studies with MBSR and Cognitive Behavioral Therapies

Studies utilizing MBSR and Cognitive Based therapies were reviewed and the studies found that stress management – as accomplished with MBSR – has been shown to have an impact on both psychosocial and physiological components of diabetes. In some cases in the research cited below, the impact was significant.

In a pilot study by Rosenzweig et al., (2007) psychological distress was linked with impaired glycemic control in diabetics. This study had 14 participants who participated in a standard Mindfulness Based Stress Reduction (MBSR) program. Outcome measures were taken at three time points – before the program, at program completion and one month follow-up. The areas of measurement were compliance with home meditation, selected subscales from the Symptom Checklist 90 Revised (depression, anxiety, somatization general severity index), HbA1c, blood pressure and weight. No changes in diet or exercise regimen were reported during the investigation. The HbA1c was reduced by 0.48% which is a large magnitude effect size (*P=*

.03, *d*= 0.88), blood pressure was reduced and reached statistical significance at 1 month follow-up (*P*=.009, *d*= 0.48) and psychological symptoms of depression, anxiety and general psychological distress were decreased significantly (43%, 37% and 35%, respectively) upon completion of the intervention (depression: *P*= .03, *d*=0.86; anxiety: *P*=.33, *d*=0.43; general severity index: *P*=.07, *d*=0.60). This pilot study showed significant physiological and psychological benefits to MBSR at one month follow-up. Results of the study supported the hypothesis that MBSR training is associated with improvement in glycemic regulation in those with Type 2 diabetes.

A five year study by Selfridge (2012) strongly suggested that mindfulness training in an MBSR program can reduce mood disorder and reduce stress in patients with chronic diseases. According to this study, "Psychological stress is linked to activation of pro-inflammatory factors involved in late diabetes complications. Thus, a stress-reducing strategy for diabetic patients may have long-term beneficial effects on target end organ disease" (p.43). This study involved 110 Type 2 diabetic patients and the standard 8 week modified MBSR program was conducted for the intervention group. The PHQ depression score was obtained at one year and showed significant improvement in the MBSR group.

Young, Cappola, and Baime (2008) assert the high levels of psychological distress that is common for those with diabetes and thus examined the impact of MBSR to improve stress management skills in 25 patients with diabetes. Overall mood as well as subscale mood measurements improved significantly following MBSR training.

Van Son et al. (2013) also studied the effects of MBCT on emotional distress, quality of life and HbA1c in outpatients with diabetes. One hundred and thirty nine outpatients with Type 1 and Type 2 diabetes and low levels of emotional well-being were randomized into MBCT

group or the waiting list. Perceived Stress Scale (PSS) (Cohen et al., 1983), Hospital Anxiety

and Depression Scale (HADS) (Zigmund et al., 1983), Profiles of Mood States (POMS)

(McNair, Lorr, & Droppleman, 1971), and Problem Areas in Diabetes (PAID) (Snoek et. al.,

2000) questionnaires were administered. They also looked at secondary outcomes that were

health-related quality of life and HbA1c. The results showed that the MBCT group was more

effective than the wait list group in reducing reported stress ($P < 0.001$, Cohen $d = 0.70$),

depressive symptoms ($P = 0.006$, d- 0.59), and anxiety ($P = 0.019$, $d = 0.44$). It was also more

effective in improving quality of life (mental: $P = 0.0003$, d- 0.55; physical: $P – 0.032$, d- 0.40).

The researchers did not find any significant effect on HbA1c or diabetes-specific distress but

concluded that MBCT resulted in a reduction of emotional distress and increase in the health-

related quality of life in diabetic patients who had lower levels of emotional well-being.

In a follow-up study to this one, (van Son et al., 2015) proposed that mindfulness could

serve as a buffer against emotional distress in adults with diabetes. In a study of 666 participants

with diabetes they found that the presence of mindfulness facets in those participants was

negatively related to both depression and anxiety symptoms and that because of this, there is

promise for teaching mindfulness as a protective characteristic against stressful life events. They

concluded that "mindfulness based interventions might be valuable to apply in the clinical care

of people with diabetes who experience stressful life events" (p. 259).

In a study utilizing cognitive behavioral therapy (CBT) to improve glycemic control and

psychosocial wellbeing in adolescents with T1D, Serlachius et al. (2016) cited the need for

diabetes care of adolescents to address the elevated levels of psychopathology in this population

to promote resilience and reduce morbidity. This study was particularly interesting because it

had similar design components and target population as our study but utilized CBT instead of

MBSR. They cited the history of effectiveness of CBT in a wide range of psychiatric disorders (Butler et al., 2006). Significant evidence of psychosocial wellbeing improvement in the intervention group but little evidence of differences in glycemic control were found.

In a study by Friis, Johnson, Cutfield, and Consedine (2016) utilizing Mindful Self-Compassion as an intervention found that this training produced statistically significant reductions in depression and diabetes distress in the intervention group in addition to a meaningful decrease in HbA1c compared to the control group.   This training used one of the main concepts of MBSR – self-compassion --which seems to predict better physical and mental health in chronically ill populations.

Finally, a systematic review of 11 studies concerning the effectiveness of mindfulness-based interventions on physiological and psychological complications in adults with diabetes (Noordali, Cumming, & Thompson, 2017) was reviewed. In this review, the authors determined that there were psychological benefits such as the reduction in depression, anxiety and distress symptoms across several studies that looked at the effectiveness of mindfulness-based interventions on reducing diabetes-related psychological and physiological symptoms in adults with Type 1 and Type 2 diabetes. The authors also determined that the short term nature of the studies made it difficult to observe physiological changes and long-term efficacy. Consequently they proposed that more long-term studies be conducted to evaluate the effectiveness of mindfulness based interventions.

2.7.6 eHealth Promotion and Online delivery of MBSR Intervention

Further evaluation of MBSR as an intervention for adolescents with T1D may provide valuable information for future care of this population. Considering advances in technology and the use of technology by adolescents in today's world, an effective method to study the efficacy

of MBSR may be through online methods or what is now referred to as eHealth Promotion. Several reviewed studies evaluated the use and effectiveness of online delivery of an intervention for the purposes of health promotion and results have been promising.

Tercyak, Abraham, Graham, Wilson and Walker (2008) studied the willingness of adolescents to use the internet and other forms of technology for health promotion purposes. In a study of 332 adolescents with self-reported, moderate willingness to engage in eHealth promotion, they concluded that eHealth is an acceptable and promising intervention approach to learning in this population.

Whittemore et al., (2013) published a study concerning the recruitment, participation and satisfaction of youths with T1D in two eHealth Psychoeducation programs. A total of 320 teens participated in the study with high participation and satisfaction with the two programs. Recruitment of African Americans, Hispanic or mixed race/ethnicity was limited as well that of lower-income youth. However, as indicated by the authors, it is important to design eHealth intervention programs to maximize recruitment and retention. It may be that an innovative eHealth approach would improve access to psychoeducational programs for youths.

2.8 Gaps in the Literature

Review of literature revealed a significant gap in research on Mindfulness as an intervention for adolescents with Type 1 diabetes. Numerous studies have been conducted that discuss the relationships between stress and coping for these adolescents. Studies have also been done that demonstrated the benefits of mindfulness as a stress moderator. Several types of interventions have been studied for this population but there were no studies that focused specifically on the use of MBSR for adolescents with T1D.

The literature also suggested that further research is needed to identify stressors of T1D with the need for psychosocial evaluation based on the prevalence of psychological and behavioral issues in this population.

Furthermore, gaps in the existing literature regarding the benefits of various coping methods were also found. Mindfulness has been increasingly studied as an intervention with many age groups, including adolescents. It is increasingly being used for those with chronic illness. As discussed earlier, the Serlachius (2016) research study using MBCT with patients with diabetes was a close match to this proposed research. However, the focus for that study was on adults and while there were a few individuals with T1D, the participants represented a broad range of patients. The van Son et al. (2015) research utilized mindfulness as an intervention to develop a "buffer" for patients with diabetes. This study also looked at adults. The existence of these recent research studies demonstrates the recognition of this gap and need for additional research in this area. In this review, it has been demonstrated that there is extensive research and documentation of the psychosocial issues to be addressed for this population. Attempts are being made to determine effective interventions to manage reactions to stress in this population in order to promote psychological and physiological health benefits.

The amount of research involving the use of mindfulness for adolescents is increasing. From a developmental perspective, adolescence is identified as a time of vulnerability and stress - even without being accompanied by a chronic illness. The effects of MBSR on stress reduction, HbA1c and quality of life in adolescents with T1D is not yet known.

2.9 Summary

Research in PNI has demonstrated the interaction between immunological and psychological processes. The research evaluated examined the use of various interventions

including MBSR which demonstrated beneficial outcomes for patients. Also demonstrated across several of the studies was the negative relationship between immune response and depression.

Many of the studies focusing on PNI seemed to peak in the early 90s with articles lauding the research and its potential at that time. The literature has shown that the use of mind/body techniques and complimentary alternative medicine (CAM) has gained more mainstream popularity just as systematic research of the mind/body relationship has declined in the published literature. The studies and research have moved from proving the existence of the relationship to exploring certain aspects of it.

The results of this literature review seem to be a suggestive glimpse at the rewarding area of intervention and study thereof. Kiecolt-Glaser and Glaser (1992) point out that we know more about the effects of the specific psychological stressors on the physical body than we know about the consequences of psychological interventions, specifically the duration of any effects caused by interventions. These authors also cite the fact that many immunological measures do not have "normal" values making randomization of subject to control and treatment groups especially important. A study with participants with T1D is an especially good candidate for this type of research because T1D is an autoimmune disease and meets criteria for immunity modulation. Also, research has shown the role that stress plays in increasing blood glucose levels. The blood glucose measurement of HbA1c pre and post treatment has a "normal" range and can provide an important benchmark of physiological significance.

In this research study we utilized MBSR with this vulnerable population of adolescents with T1D, a chronic illness, to determine if there were psychological and/or physiological benefits to this intervention for this population.

CHAPTER 3

METHODOLOGY

In this chapter, the design, setting, population under study, recruitment methods, instruments used for data collection, planned analysis and protection of human subjects are discussed. The purpose of the study was to determine if a learned stress reduction method in adolescents with Type 1 diabetes would result in improvement in physiological measurements of blood sugar control and psychological measurements of reported quality of life. The overall objective of the study was to examine changes in psychosocial and physiological measurements following MBSR training offered via an online website and data collection site.

3.1 Design

This study utilized a between group experimental design to measure the effects of a six-week, online/web-based instructional MBSR program at three time points (Time 1 = pre-intervention, Time 2 = immediately post intervention and Time 3 = three months post intervention) on 65 adolescents with T1D randomly assigned to either the Active Group or Control (Wait) Group. MBSR was the independent variable. Dependent variables include diabetic quality of life, mindfulness and HbA1c. The Diabetes Quality of Life for Youth (DQOLY) (Appendix A) and Mindful Attention Awareness Scale - Adolescent (MAAS-A) (Appendix B) questionnaires were administered online at all three time points to examine the effects of MBSR Diabetes Quality of Life and Mindful Attention Awareness. HbA1c was measured at Time 1 and Time 3. Descriptive statistics and perceived stress data were used to describe the population, the demographic data was collected with the Demographic Data Sheet (Appendix C). The physiological measure understudy, HbA1c, reflected glucose control over the previous three month period with percentage value correlating to an average blood glucose

reading in that time period. Appendix D provides a table of the blood glucose level associated with HbA1c readings. This measurement was obtained at Time 1 and Time 3. The purpose of this design was to explore and measure the intervention effects on the study population

MBSR was the independent variable. Dependent variables include diabetic quality of life, mindfulness and HbA1c. The Diabetes Quality of Life for Youth (DQOLY) (Appendix A) and Mindful Attention Awareness Scale - Adolescent (MAAS-A) (Appendix B) questionnaires were administered online at all three time points to examine the effects of MBSR on Diabetes Quality of Life and Mindful Attention Awareness. HbA1c was measured at Time 1 and Time 3. Descriptive statistics and perceived stress data were used to describe the population, the demographic data was collected with the Demographic Data Sheet (Appendix C). The physiological measure understudy, HbA1c, reflected glucose control over the previous three month period with percentage value correlating to an average blood glucose reading in that time period. Appendix D provides a table of the blood glucose level associated with HbA1c readings. The purpose of this design was to explore and measure the intervention effects on the study population.

3.2   Setting

Participants of this study were able to participate in this study in the privacy of their own home via a website for learning MBSR. Study participants accessed the intervention through a developed website, www.MySweetMind.org. In addition, collection of psychosocial data occurred over a secure online data collection site. HbA1c was self-collected at specific time periods and results sent to the researcher for analysis.

3.3 Sample and Recruitment Activities

The criteria for inclusion in this study were: (a) between the ages of 12 and 19; (b) ability to read English at a fourth grade level; (c) diagnosis of Type 1 diabetes; and (d) access to a computer and internet. A power analysis was conducted to determine the appropriate sample size using a medium effect size of 0.35. In consultation with a statistician, it was determined that a sample size of 86 participants would be needed to achieve a power of 0.80 with alpha set at .05 using a two tailed test of significance (W. Sethi, personal communication, November 1, 2014). Every attempt was made to recruit 95 participants for this study to account for attrition. Half of these participants were randomly assigned to a wait list/Control Group receiving no MBSR training intervention. Wait list/Control Group participants were given an opportunity to learn the MBSR via the website after all data was collected. Participants in the Control Group were required to access the data collection site and complete the questionnaires at Time 1, Time 2 and Time 3 and provide the results of the HbA1c at Time 1 and Time 3.

Exclusion criteria included people who fell outside of the age range established at 12 to 19 years old at the beginning of the study, were not able to speak English or did not have access to a computer or the internet.

The primary method of recruitment was through the Diabetes Education and Camping Association (DECA) and several pediatric endocrinology offices in New Jersey (Appendix E). Additional and extensive recruitment was conducted at several diabetes camps, endocrinology offices, networking at JDRF events, walk-a-thons for T1D, seminars and panel discussions at diabetes presentations. In addition, advertising postcards and business cards were sent out to offices and camps that the researcher could not visit personally with a return post card provided to simplify response (Appendix F). Presentations were made to school nurses regarding the

study and postcards were provided. The use of social media – specifically through the creation

of a Facebook page and use of Facebook ads – was helpful along with posts to T1D advocacy

pages and sites. These were all useful methods to recruit participants to the mysweetmind.org

website. These efforts were beneficial and pursued for more than two full years at which point,

recruitment activities were halted. The physicians, nurses, camp administration and counselors

were provided with information about the study prior to the start of recruitment. The parents and

adolescents attending the camp and at the physicians' offices were able to obtain information

about the study via fliers posted, postcards and business cards that were available. In addition,

parents and adolescents attending the camp and also parents from several endocrinology offices

were mailed invitations to participate via a post card sent via U.S. mail.

Recruitment for this study was bi-directional. Primarily participants were recruited

through direct promotion to parents and campers at two summer camps for adolescents with

diabetes, one day camp and several other two-week/overnight camps. Information was provided

at intake and outtake days of the camp to the parents and campers. Campers were given a

postcard with the website address and general information about participating (Appendix G) and

letters were also available for parents to provide information about the study (Appendix H).

Secondly, Pediatric Endocrinology offices in New Jersey were contacted in order to gain access

to adolescent patients diagnosed with Type 1 diabetes. Physicians were sent the letter about the

study and asked to return an included post card if they were interested in having their patients

participate in this study and if they are willing to help with recruitment including posting

recruitment fliers and sending invitations to adolescents and the parents of adolescents with Type

1 diabetes. Several of the endocrinology offices had the primary researcher come to their office

and present details of the study to the endocrinologists and the practice personnel. Permission to

recruit at these sites was obtained. Another effective manner of recruitment was word of mouth.

3.4 Instruments

Two instruments were used to collect data on psychosocial measures at the three time

points including: (a) Diabetes Quality of Life Measure for Youths (YDQOL) (Ingersoll, 1991)

and (b) Mindful Attention and Awareness Scale for Adolescents (MAAS-A) (Brown, 2011). A

demographic form will be administered once to describe the population as well as a Perceived

Stress Scale – 4 (PSS-4). In addition, participants were asked to provide a small drop of blood

for the physiological measurement of blood glucose, HbA1c, at the beginning of the study (Time

1) to measure blood glucose over the previous three month period as reflected in the HbA1c

blood test and at the end of their participation (Time 3).

3.4.1 Diabetes Quality of Life Measure for Youths (DQOLY)

 Originally, Jacobson, Barofsky, Cleary, and Rand (1988) developed the DQOL primarily

to measure young adults and adolescents in four subscales concerning life satisfaction, diabetes

impact, worries about diabetes, and social/vocational concerns. This tool was developed from a

population of 192 subjects between the ages of 13 to 39, adolescents (13 to 17 years old)

comprised 56 of the 192 subjects. The questionnaire consists of 46 items which subjects rank on

a 5-point Likert scale. Reliability of the DQOL, as measured by Cronbach's alpha, was tested

separately for adolescents and adults and both were rated extremely high with an alpha = 0.92.

The test-retest correlations of the DQOL were also excellent for the adolescents and adults,

ranging from 0.80 to 0.92, high statistical significance (Jacobson, 1988). This tool has been used

and validated with Type II diabetics as well (Jacobson, 1994); however, it was designed

specifically for Type 1 diabetics because of the need for intensive insulin treatment and may not

be as effective when questioning non-insulin dependent diabetics (Manucci et al.,1996).

Ingersoll and Marrero (1991) modified the DQOL for specific use with older children and adolescents. They dropped questions more specific to adults and added items relating to school life and peers. The result is the DQOLY (Appendix A), used in this study. This questionnaire was used to measure diabetes quality of life at Time 1, Time 2 and Time 3. This DQOL took approximately 10-15 minutes to complete.

3.4.2 Mindful Attention Awareness Scale - Adolescent

Brown, West, Loverich, and Biegel (2011) developed the Mindful Attention Awareness Scale – Adolescent (MAAS-A). They did this in acknowledgement of the need for validated instruments for assessing mindfulness in youths. The original MAAS scale had been developed and validated for adults. The rapid increase in mindfulness based interventions for children and adolescents, led the developers to determine that The MAAS-A would be an important tool for measuring mindfulness in this age group. Two large samples were obtained to validate a measure of mindfulness. In the first study with an N equal to 595, the internal consistency was high with test-retest reliability, Cronbach's alpha was good, varying from .82 to .84. In the second study with an N of 102, significant increases in MAAS-A scores were found from baseline to 3 month follow-up. The MAAS-A has been found to correlate with psychological well-being and healthy self-regulation and does measure the effects of mindfulness training. In addition, increases in MAAS-A scores among mindfulness-based stress reduction participants were significantly related to beneficial changes in numerous mental health indicators. These findings support both the reliability and validity of the MAAS-A in adolescent populations and also suggest that this tool is useful in assessment of mindfulness intervention research. The MAAS-A (Appendix B) was used to measure mindfulness in participants in both the Active and

Control group at Time 1, Time 2 and Time 3 and was administered via a secure, online data collection site. The MAAS-A took approximately 10 minutes to complete.

3.4.3 Glycated Hemoglobin test (HbA1c)

The HbA1c is a blood test requiring a venipuncture or finger stick. For this study, a finger stick was self-obtained from each participant at Time 1 and Time 3. The instant HbA1c required a drop of blood from the finger stick that provided results in less than 10 minutes. This measurement is useful because it is less affected by the day to day variations in blood glucose levels. The HbA1c returns values which are representative of an average blood glucose over a 90 day period. Appendix D provides a table of the blood glucose level associated with HbA1c readings. The goal for people with diabetes is to have a lower HbA1c in order to prevent the complications associated with elevated blood glucose levels such as retinopathy, kidney disease, neuropathy and other indicators of microvascular disease. The HbA1c test kit was sent to the home of the participant with simple instructions to place one drop of blood on the card provided. Parents or the adolescent participant were asked to put the card into a reader that provided the results in the form of an electronic read out in less than 10 minutes. Those with T1D are familiar with this process as it is a common diagnostic test performed in the Endocrinologist's office at each visit. These kits are also available to buy over the counter. The participants or their parents were asked to e-mail this information to the researcher at Time 1 and Time 3. Reminder texts and e-mails were sent to the participants in both the experimental and waitlist/control group. Reminders were also posted on the website.

3.4.4 Demographic Data Sheet (DDS)

The DDS was investigator generated (Appendix C) and included 11 questions to obtain demographic information about the participants. This information was used to describe the

population under study including information such as age, gender, race, school grade and number of years with diabetes including date of diagnosis. Respondents were also asked to describe their typical level of activity, if they wear an insulin pump or continuous glucose meter (CGM) and if they have sibling(s) and/or parent(s) with diabetes. This questionnaire was administered one time via the secure online data collection site at Time 1 for participants of both the Active and waitlist/control groups. This took less than 5 minutes to complete.

3.4.5   Perceived Stress Scale 4 (PSS-4)

The Perceived Stress Scale is a 4-item scale (Appendix I) used at the beginning of the study to measure perceived stress as reported in the last month by the participant (Cohen, Kamarck & Mermelstein, 1983).   Scores can range from 0 to 16 with higher scores indicating more stress. The PSS has been released as a 14, 10 and 4 item scale with established internal consistency, reliability and validity. Cronbach's alpha for the PSS-4 was .68. Although the 10 item PSS has been found to be the most reliable of the three scales (Lee, 2012), the PSS-4 was used in this study in an attempt to reduce subject burden and thus, minimize any potential frustration yet still obtain important information to describe the population understudy on perceived stress as reported by the participants at Time 1 or at the beginning of participation in the study.

3.5 MBSR eHealth Intervention Online

The principles of MBSR were divided into 6 main modules delivered in the online, web-based format. *MySweetMind.org* is a website that allowed those given a password to access a six week module-based site to learn Mindfulness Based Stress Reduction adapted for adolescents. This adaptation of MBSR was based on the work of Dzung X. Vo, MD, FAAP and Jake Locke, MD as presented in the book written by Dr. Vo, *The Mindful Teen*.

The adolescent participant and their parents were able to access an overview of the website and to access the modules one week at a time. Each new module introduced the participant to a new level of MBSR. Key concepts for each Module are in Appendix J

3.6 Procedures for Data collection

Approval to conduct this study was obtained from the Institutional Review Board of Duquesne University. The research was conducted through recruitment as detailed earlier. Once a potential participant was directed to the www.mysweetmind.org website, the criteria for the study was listed on the Getting Started page of the website and the participant was able to initiate their participation by downloading the consent forms. Participants under 18 needed the consent of their parents (Appendix K) and the participants under 18 signed an assent form (Appendix L). Participants 18 and over only had the consent form to sign (Appendix M). Once complete, the required forms were mailed, e-mailed or faxed back to the researcher. Through the website, participants set up their own password for access to the website, providing an e-mail and contact information to allow for effective communication between the participant and researcher. Once the consents were received, the website was unlocked for the participant to answer the Time 1 set of questionnaires which included the Perceived Stress Scale – 4; Demographic Data Survey; Diabetes Quality of Life for Youth and Mindful Attention Awareness Scale – Adolescent. In addition, a set of (2) A1c test kits were sent via U.S. mail to the home address of the participants. The participants were asked to complete one of the A1c tests and e-mail the results to the researcher immediately at the beginning of the study. Frequent communication was maintained with each participant via phone, text and e-mail. Any changes made to the access of the website or progress through the study was communicated through the website via e-mail with the participant.

Participants were asked on the website to indicate their preference for the Amazon or *iTunes* gift card and once the first set of questionnaires and the A1c test kit result were received by the researcher, the participant was sent the first gift card of $15.00.

The online Modules were then opened sequentially for the participant with one full week for each to learn and practice. The website was designed to count the time and automatically open the next module after seven days. Additionally, the researcher was able to track progress of each participant as an administrator on the website. Additional details concerning the Modules and the intervention is provided in Table 1. Modules for Teaching Mindfulness on the www.mysweetmind.org website. Each module builds upon the last and participants had access to a printable written highlight sheet for practicing the material taught in each week's module. Participants could also review any of the previous modules on the website. While they could return to previous modules and utilize the review sheets, they could not skip ahead. Once all 6 Modules were complete, the participant was asked to complete the DQOL and MAAS questionnaires again which were measurements for Time 2.

Participants were reminded to utilize the concepts they learned and permitted to have access to the modules over the remaining 6 weeks of their study time. At the three month mark from the date of the first HbA1c test and results, the participant was requested to take the second HbA1c test and submit the results via e-mail to the researcher. They were also requested to take the DQOL and MAAS questionnaires measurements for Time 3. Once they sent the HbA1c results and completed the questionnaires, a $25.00 gift card was sent along with a thank you for their valuable participation. The researcher also sent an additional list of resources for participants and their parents who wanted mindfulness materials - both online and hard copy – after completion of their time in the study.

Participants in the Control Group were asked to wait for their online participation with the Mindfulness Modules after Time 1 collection of data and HbA1c results were sent. The first gift card was also sent. At the end of the 6 weeks, they were asked to complete Time 2 questionnaires again and they were told they were still waiting. At the 12 week mark from the initial HbA1c test results, they were asked to complete Time 3 questionnaires and provide results for the second HbA1c test and then the Mindfulness modules would be opened to them should they want to participate in the modules. Once questionnaires were completed and the HbA1c test results were received, participants in the Control Group were sent the second $25.00 gift card and access to the Mindfulness modules. It was communicated to them at this point that they had been in the Control Group. The website Modules were then accessible and they were encouraged to participate in learning the Mindfulness techniques and to take advantage of the website materials. They were also sent the resource list of additional mindfulness materials.

3.7 Planned Analysis

Once data was collected it was entered into an Excel spreadsheet created by the investigator. All data was checked for quality control and then exported to SPSS for data analysis. Data were analyzed using Statistical Package for Social Sciences (IBM, Version 25). Descriptive statistics and independent t-tests were performed on the demographic variables and PSS-4 scores to describe the sample population understudy and determine whether the Active and Control Groups were comparable at Time 1.

Descriptive statistics were used to describe the population under study including means, standard deviations, ranges, and percentages to summarize the information gathered on the demographic data sheet (DDS). Graphs and histograms were generated to view demographic

data and data collected on the major variables under study at Time 1 including mindfulness, diabetes quality of life and HbA1c. Assumptions for parametric testing were tested to determine whether or not parametric testing could be done. The three assumptions for parametric testing included normality, homogeneity of variance and independent errors. In addition, a correlational matrix was created to determine whether any two variables co-varied at ≤ 0.65. Covariates are potentially confounding variables that can produce variation across subjects resulting in group differences not attributable to the independent variable (Polit, 2010).

To test each of the Hypotheses (1, 2 and 3), alpha was set at .05 and beta at .20 with a two-tailed test of significance. The assumption of sphericity for repeated measures analyses was violated, determined by conducting a Mauchly's test. Thus, a mixed between-within subjects analysis of variance (ANOVA) was conducted with one between group factor with two levels (Active and Control Groups) and one within-group factor or repeated measure (time) to examine the group x time interaction for each dependent variable in Hypotheses 1, Hypotheses 2 and Hypotheses 3. Multivariate statistical tests were conducted and Wilks' Lambda was used to report the interaction effect as well as the within-subjects effect (time) (Polit, 2010). The main effect of treatment group was analyzed using ANOVA on 65 adolescents with T1D randomly assigned to either the Active Group or Control (Wait) Group. Pairwise tests were conducted to make comparisons between the groups at each time point and thus, to determine where the differences were over the post-intervention time points (Time 2 and Time 3) on the dependent variables found significant. Hypothesis 3 had only one post-intervention time point (Time 3).

CHAPTERS 4 and 5

RESULTS MANUSCRIPT

The Effects of Learning Mindfulness Based Stress Reduction on Psychosocial Variables and HbA1c in Adolescents with Type 1 Diabetes.

The authors listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any non-financial or financial interest in the subject matter or materials discussed in this manuscript

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Approval to conduct this study was obtained from the Institutional Review Board of Duquesne University

LIST OF MANUSCRIPT FIGURES

LIST OF MANUSCRIPT TABLES

The Effects of Learning Mindfulness Based Stress Reduction on Psychosocial Variables and HbA1c in Adolescents with Type 1 Diabetes.

Background*:* Stress has been shown to increase glucose levels through a sympathetic physiological response resulting in a release of chemicals such as adrenalin and cortisol, a response which results in an even greater need for insulin. Mindfulness has been shown to be clinically effective in managing stress and anxiety and has been used effectively as treatment for medical and mental health conditions.

Objectives*:* To determine if learning Mindfulness Based Stress Reduction (MBSR) has an influence on mindfulness, quality of life and HbA1c in adolescents with T1D.

Methods: This between group experimental design measured the effects of a six-week, online/web-based instructional MBSR program at three time points (Time 1= pre-intervention, Time 2 = immediately post intervention and Time 3 = 3 months post intervention) on 65 adolescents with T1D randomly assigned to either the Active group or Control (Wait) group. The Mindful Attention Awareness (MAAS-A) and Diabetes Quality of Life (DQOL-Y) questionnaires were administered online at three time points to examine the effects of MBSR on mindfulness and QOL respectively and HbA1c was measured at Time 1 and Time 3. Demographic and perceived stress data were collected at Time 1 to describe the population and ascertain any confounding variables.

Results: There were significant interaction effects on time x group assignment (Active or Control Group) on MAAS-A scores, Wilks' Lambda = 0.44, $F(2, 62) = 38.85$, $p = 0.000$; DQOL-Y scores, Wilks' Lambda = 0.793, $F(2, 62) = 8.08$, $p = 0.001$; and, on HbA1c results, Wilks' Lambda = 0.861, $F(1, 63) = 10.13$, $p = 0.001$. Significant main effects on time x group assignment for MAAS-A were also found as well as a significant main effect of time on DQOL-Y score Wilks' Lambda = 0.73, $F(2,62) = 11.18$ $p < 0.001$.

Discussion: Adolescents with T1D may not be able to change or decrease the amount of stress in their lives but they may be able to change the way they respond to the stress they experience by learning the principles of MBSR and applying those principles to their daily lives. These findings suggest that learning MBSR may improve mindfulness, quality of life and lower HbA1c

Key Words: adolescents with Type 1 Diabetes *diabetes quality of life * HbA1c *mindful attention * mindfulness

Introduction

The last 30 years has seen a threefold increase in the number of cases of childhood diabetes, the majority of that increase is in Type 1 diabetes (T1D). According to the most recent report funded by the Centers for Disease Control and Prevention and the National Institutes of Health (2002-2012), the incidences of both Type 1 and Type 2 diabetes among youths increased significantly, especially among youths of minority racial and ethnic groups (Mayer-Davis, et. al., 2017). T1D is an autoimmune disease in which the body attacks and destroys the insulin-producing cells of the pancreas. Individuals are rendered dependent on the exogenous delivery of insulin and as such, are required to perform numerous blood glucose checks to evaluate and treat their blood sugar levels over the course of the day and night. According to government statistics, more than 15,000 children and 15,000 adults are diagnosed with T1D each year and there are three million Americans currently living with it (National Institutes of Health, 2011). It is estimated that the rate of T1D incidence among children under age 14 will increase by three percent annually worldwide. The prevalence of T1D in Americans under age 20 rose by 23 percent between 2001 and 2009 (Juvenile Diabetes Research Foundation, 2011). The dependence of individuals with Type 1 diabetes on the self-administration of insulin and constant monitoring of blood glucose levels related to diet, exercise, health status, growth and sexual maturity make the management of this condition intensely demanding. The fact that T1D strikes most often in childhood also has significant implications for disease management.

Failure to successfully manage blood glucose levels daily results in both short and long term health complications. Subsequently, the demanding management of this disease often creates an environment of immense psychological demands in addition to the obvious physiological demands. Those psychological demands are known to exacerbate the condition

through the physiological stress response of cortisol release resulting in blood glucose increases (Hou, 2015). This known physiological mechanism of stress response is important to understand and manage.

Adolescence is often recognized as a particularly challenging time in the growth and development of youth even without the complication of a chronic disease. The existing research on adolescents with T1D to date focuses on well-known issues of adolescence such as peer pressure and relationships with family (Helgeson et al., 2010; Malik & Koot, 2009; Bernstein, et al., 2013). Clearly, T1D is a known stressor (Wiesl, 2005; Watts, 2010) and adolescents, in particular, have been identified as being at risk for psychological distress and poor management of T1D (Trast, 2014; Tilden, 2005; Bernstein, 2013; Butwicka, 2015).

Few intervention studies have been conducted to date that have examined ways by which adolescents can reduce stress associated with the demands of diabetes management. Those that have, examined the effects of coping skills training (Grey et al., 1998); cognitive behavioral therapies (Serlachius et al., 2016; Perfect & Elkins, 2010); motivational enhancement therapy (Ismail et al., 2008) and multi-systemic therapy (Ellis et al., 2005). In addition, several online programs and ehealth systems have been utilized to enhance delivery of psychoeducation for this population (Wittemore, 2012; Tercyak, 2009; Cafazzo, 2012). Studies have shown that MBSR reduces reaction to stress in other populations and improves the quality of life in those with psychological and physical conditions. Learning MBSR may be an effective intervention for adolescents with T1D.

Mindfulness Based Stress Reduction

Mindfulness based stress reduction (MBSR) involves learning a systematic and patient-centered method of reducing the effects of stress and disease through training in mindfulness meditation.

Mindfulness involves the practice of paying attention in a particular way; on purpose, in the present moment and without judgment (Kabat-Zinn, 1994). Mindfulness is not a specific technique, but rather *a way of being* that is meant to be practiced daily regardless of the existence of a problem or upset for an individual. The core of mindfulness revolves around the idea of how we regulate what we pay attention to and thus, becomes our core of perception. The expectation is that, through this process, we can become less stress reactive by becoming aware of where our attention is. This self-awareness can lead to a foundation of more effective coping which may improve both physical and psychological conditions.

Mindfulness is rooted in Buddhist teachings and is described as a nonevaluative and sustained moment-to-moment awareness of perceptible mental states. Mindfulness is described by Kabat-Zinn (2009) as "a particular way of paying attention, a way of looking deeply into oneself in the spirit of self-inquiry and self-understanding" (p. 12). The practice of mindfulness involves an acceptance of all parts of self and the practice of attention on the present moment rather than worrying about the past or future. It is through this practice that stress is decreased (Kabat-Zinn, 2012).

Prouix (2003) conducted an early integrated review of 21 identified clinical studies involving MBSR. The purpose of the review was to analyze existing knowledge regarding clinical effects of MBSR and to identify gaps in the knowledge base. Twenty peer-reviewed studies were found published between 1982 and 2003 from the fields of medicine, nursing and psychology. Twelve of the studies were on those with chronic illness, four aimed at stress reduction and three were related to mindfulness training for students. There was also one qualitative, peer-reviewed grounded theory study. The studies reviewed suggest that MBSR is

efficacious for individuals experiencing chronic illness and asserted the importance of thoroughly exploring the potential of this intervention.

A more recent meta-analytic review of mindfulness-based therapy was done with a focus on the use of this intervention in anxiety and depression. Hofmann, Sawyer, Witt, and Oh (2010) cited the rising popularity of mindfulness-based therapy and the need to study its efficacy. They reviewed 39 studies totaling 1140 participants who received mindfulness-based therapy for a variety of conditions including cancer, generalized anxiety disorder, depression and other psychiatric or medical conditions. The effect sizes were robust (Hedges's *g* of 0.97 and 0.97) for improving anxiety and mood symptoms respectively. The results of this meta-analysis suggested that mindfulness based therapy is a promising intervention for treating anxiety and mood problems in clinical populations.

In a pilot study by Rosenzweig, Reibel, Greeson, and Edman (2007), psychological distress was linked with impaired glycemic control in diabetics. This study had 14 adult participants with Type 2 diabetes who participated in a standard MBSR program. Outcome measures were taken at three time points – before the program, at program completion and one month follow-up. The areas of measurement were compliance with home meditation, selected subscales from the Symptom Checklist 90 Revised (depression, anxiety, somatization general severity index), HbA1c, blood pressure and weight. No changes in diet or exercise regimen were reported during the investigation. The HbA1c was reduced by 0.48% which is a large magnitude effect size (*p*= 0.03, *d*= 0.88), blood pressure was reduced and reached statistical significance (*p*=0.009, *d*= 0.48) and psychological symptoms of depression, anxiety and general psychological distress were decreased significantly (43%, 37% and 35%, respectively) upon completion of the intervention (depression: p= 0.03, *d*=0.86; anxiety: p=0.33, *d*=0.43; general

severity index: $p=0.07$, $d=0.60$). This pilot study showed significant physiological and psychological benefits to MBSR at one month follow-up. Results of the study support the hypothesis that MBSR training is associated with improvement in glycemic regulation in those with Type 2 diabetes.

MBSR training programs have been used in diverse populations and are increasing in popularity. While the traditional MBSR training course is structured with specific content and presentation, the intervention has been modified in content and length for adolescents (Kerrigan et al., 2011; Brown et al., 2011; Smith et al., 2008) and in delivery format such as online, web-based mindfulness training programs (Mak et al., 2015; Davis & Zautra, 2013). The effect of MBSR has been examined in those with many different chronic illnesses, depression and anxiety disorders. It has also been studied in adults with diabetes as a potential buffer to the emotional distress of disease management (van Son et al., 2014).

Gaps in the Literature

The increased prevalence of T1D in adolescents and the intense demands of disease management, brought to the forefront the need for a comprehensive approach, one that encompasses both the psychological and physiological aspects for better management of this chronic condition in this population. The analysis of available research and scholarly works helped the researchers determine important areas in T1D management that needed further research to improve care. Several gaps in the literature were identified concerning the development of a comprehensive approach to address both the psychological and physiological well-being of adolescents managing T1D. While MBSR has been shown to be an effective intervention to improve both psychological and physiological health outcomes in those with

chronic illness and in the general adolescent population, it has not yet been examined in

adolescents with the chronic illness of T1D or delivered in an online format.

Conceptual Framework

The conceptual framework used to guide this study is a combination of two theoretical models,

Engel's biopsychosocial model (Engel, 1977) and Ader's psychoneuroimmunology framework

(Ader & Cohen, 1975). The conceptual frameworks represented by these models provide a basis

for assessing and reviewing the existing literature. The concepts represented by the models were

also essential in the development of the intervention for this research.

Biopsychosocial Model

Dr. George Engel's Biopsychosocial model was developed as a response to the biomedical

model which had failed to answer many of the psychological components that can be part of

physical illness, especially chronic illness. The Biopsychosocial model acknowledges that health

and disease are a result of interactions between social, psychological and biological factors and it

asks that practitioners recognize the complex interactions between these factors in their care of

patients (Engel, 1977). It has frequently been used to address treatment of those with cancer,

diabetes and mental disorders because biological, psychological and social components of these

problems have been found to have significant impact on effective disease management.

Psychoneuroimmunology

Psychoneuroimmunology is the study of the mind/body connection and the interactions between

consciousness (psycho), central nervous system (neuro) and the body's defense against invaders

(immunology) (Bauer, 1994). Interest in developing and understanding the relationship between

body and mind began with evaluations of relationships among stressors and disease. In the mid

1970s and early 80s Ader and Cohen (1981) were able to demonstrate a classical conditioned

immune response and interest in PNI increased significantly (Zeller, 1996). PNI is now being referenced in the literature as PNIE, incorporating the endocrine system as an integral part of the dynamic relationships between the mind, immune and endocrine systems. The literature focuses on states of mind such as stress and depression and demonstrates the link to physiological conditions, representing the bidirectional nature and crosstalk that occurs between these systems.

The purpose of this study was to determine the effectiveness of MBSR, a learned stress reduction method offered online to adolescents with T1D on mindful attention, reported quality of life and blood glucose control. The overall objective was to examine changes in psychosocial and physiological measures following MBSR training at three time points.

The specific aim of this research study was to test MBSR training for positive influences on mindfulness, quality of life and HbA1c in adolescents with T1D.

The following hypotheses were tested:

1   MBSR training will increase mindfulness in adolescents with T1D at two post intervention time points compared to a control group of adolescents with T1D.

2. MBSR training will improve quality of life in adolescents with T1D at two post intervention time points compared to a control group of adolescents with T1D.

3. MBSR training will decrease HbA1c in adolescents with T1D three months post intervention compared to a control group of adolescents with T1D.

Methodology Design

A within and between group experimental design utilized two groups (Active, Control) x three time points (Time 1, Pre-intervention; Time 2, Post Intervention; Time 3, three months Post Intervention) to examine the effects of MSBR on adolescents with T1D. Quality of life and

mindfulness were measured at each time point and HbA1c at Time 1 and Time 3. Participants were randomized to either the Active Group who had immediate online access to the 6 MSBR Training modules or the Control Group who were offered MSBR training after all data were collected. These individuals were given access to the modules once that occurred.

Sample Size

A power analysis determined that a total sample size (N) of 86 or 43 participants per group (n) was necessary to yield an alpha of .05 with a two tailed test of significance, a medium effect size of .35, and a power of .80 with 2 degrees of freedom.

Measures to Determine Eligibility

The website through which participants gained access to the study, prompted potential participants and their parents to review the requirements to participate prior to consent and data collection. Eligibility criteria for participation were adolescents between 12 and 19 years with T1D, fluent in English, no cognitive impairments, and at least a sixth grade education to assure participants could read, understand and accurately complete the questionnaires. In addition, participants were required to have access to a computer and the Internet. Adolescents, regardless of the length of time since diagnosis of T1D, were included in this study.

Recruitment Activities

Extensive recruitment activities were conducted at several camps for kids with diabetes, through endocrinology offices, and by networking at juvenile diabetes events such as walk-a-thons, seminars and panel discussions. Postcards and letters describing the study were sent to endocrinology offices and to camps for kids with diabetes that the principle investigator (PI) could not visit. Presentations were made to school nurses at their schools as an invited guest during their education day. In addition, the use of social media, specifically the creation of a

Facebook page and use of Facebook advertisements were utilized along with posts to T1D advocacy pages and web sites.

Measures

Demographic Data Sheet (DDS): The DDS, generated by the investigators, included 11 questions used to describe the population including age, gender, race, school grade and number of years with diabetes including date of diagnosis. In addition, information in regard to participants' activity level, whether or not they used an insulin pump or continuous glucose meter (CGM) and if they had a sibling(s) and/or parent(s) with diabetes were ascertained. These data were collected once at Time 1 and at the beginning of participation in the study and took approximately 5 minutes to complete.

Perceived Stress Scale 4 (PSS-4) is a 4-item scale used at the beginning of the study to measure perceived stress as reported in the last month by the participant (Cohen, 1983).   Scores can range from 0 to 16 with higher scores indicating more stress. The PSS has been released as a 14, 10 and 4 item scale with established internal consistency, reliability and validity. Cronbach's alpha for the PSS-4 was 0.68. Although the 10 item PSS has been found to be most reliable of the three scales (Lee, 2012), the PSS-4 was used in this study in an attempt to reduce subject burden and thus, minimize any potential frustration for the participant. The PSS-4 was administered at Time 1 to describe the population and to ascertain any group differences at the beginning of the study. This took the participant less than 5 minutes to complete.

Physiological Measure

Glycated Hemoglobin test (HbA1c): HbA1c was used in this study to reflect the average blood glucose of the participant over a 90 day period and was obtained via a finger stick from each participant at Time 1 and Time 3. The "instant" HbA1c requires a drop of blood that

provides results in 5 minutes. This measurement provides useful information about diabetes management because it is less affected by the day to day variations in blood glucose levels. The result is represented as a percentage and correlates to an average blood glucose reading over the previous three months. HbA1c values range from about 4% which corresponds to an average blood glucose of 68 and 14%, which corresponds to an average glucose of 355. Normal blood glucose levels are 70 to 110. The goal for people with diabetes is to have a lower HbA1c. Lower HbA1c levels correlate to lower average blood glucose levels thereby reducing the complications associated with uncontrolled diabetes such as retinopathy, kidney disease, neuropathy and other indicators of microvascular disease. This test took approximately 10 minutes to complete.

Psychosocial Measures

 Mindful Attention Awareness Scale – Adolescent (MAAS-A): The MAAS-A was developed by Brown, et al. (2011) to assess mindfulness in adolescents. The Mindful Attention Awareness Scale (MAAS) was originally developed and validated for adults. The rapid increase in mindfulness based interventions for children and adolescents led the developers to modify the MAAS to measure mindfulness in this age group. It consists of 14 items that measure the level of mindfulness measured on a six-point scale with 1 (almost always) to 6 (almost never). Higher scores are an indication of more mindfulness in which there is a receptive state of mind to the present. The MAAS-A was validated recently with Cronbach's alpha ranging from .82 to .84 and reported test-retest reliability at .79. The MAAS-A, like the original MAAS adult counterpart, demonstrated strong correlation with healthy self-regulation and well-being. In this study, Cronbach's Alpha was greater than .70 when measured at each time point. The authors

also concluded that the MAAS-A is sensitive to mindfulness training (Brown et al., 2011). This questionnaire was administered at Time 1, Time 2 and Time 3 and took approximately 10 minutes to complete.

Diabetes Quality of Life Questionnaire for Youth (DQOL-Y): Jacobson, Barofsky, Cleary, and Rand (1988) originally developed the Diabetes Quality of Life (DQOL) tool to measure young adults and adolescents with T1D on four subscales concerning life satisfaction, diabetes impact, worries about diabetes, and social/vocational concerns. Ingersoll and Marrero (1991) developed a modified version of the DQOL called the Diabetes Quality of Life for Youth (DQOL-Y). This questionnaire consists of 52 items with three subscales: Diabetes Life Satisfaction scale (17 items) with scores from 1 (very satisfied) to 5 (very dissatisfied), Disease Impact scale (23 items) with scores from 1 (never) to 5 (all the time), and Disease-Related Worries scale (11 items) with scores from 0 (does not apply) to 5 (all the time). Lower scores are indicative of higher quality of life. Also, included at the end is a general self-rating of overall health. To construct this scale, items of the DQOL were analyzed by pediatric specialists and items were dropped that had limited value for adolescents and children and items related to school life and peers were added. Following the three subscales, overall health was measured on a 4-point rating scale from 1 (poor) to 4 (excellent). In this study, quality of life was analyzed using the summation of each of these sub categories (impact, worry, and satisfaction to obtain a total DQOL score. Reliability of the DQOL-Y was tested for both adolescents and adults and Cronbach's alpha for the subscales ranged from 0.82 to 0.85, respectively. The DQOL-Y was used in this study to measure diabetes quality of life at Time 1, Time 2 and Time 3. Cronbach's Alpha was greater than .80 at each time point. This questionnaire took approximately 10 minutes to complete.

Procedures

Once approval was obtained from the Institutional Review Board at Duquesne
University, recruitment activities began. Potential participants who indicated interest in the
study were directed to the www.mysweetmind.org website which provided information about the
study as well as eligibility criteria on the Getting Started page of the website. Participants were
then able to initiate their participation by downloading the voluntary assent or consent form and
parental permission form. Participants 18 and over signed the consent form to participate while
participants under 18 signed the assent form and one parent was required to sign a parental
permission form. All forms were then mailed, e-mailed or faxed to the PI. Through the website,
participants set up their own password for access to the website, providing an e-mail and contact
information to allow for effective communication between the participant, website and PI. In
addition, a kit was sent with two HbA1c tests via mail to the home address of the participant.
Once consent to participate was established, the website was unlocked for the participant to
answer the Time1 set of questionnaires including the DDS; PSS-4; DQOL-Y and the MAAS-A.
Participants were also required to submit the results of their HbA1c to the PI via email. Frequent
communication was maintained with each participant via phone, text and e-mail. Once the first
set of questionnaires and the HbA1c results were received by the PI, the participant was sent the
first gift card of $15.00 as per their preference for Amazon or *iTunes*.

Participants were randomized to either the Active in the Study (Active) Group or the
Control Group. The six online Modules for mindfulness training were then opened sequentially
for those assigned to the Active Group with one full week for each participant to learn and
practice each MBSR module. Each of the six modules addresses an important theme or practice
of mindfulness such as how to do a sitting meditation, body scan and mindfulness movement.

The first module is an introduction and description of mindfulness and the last module gives a review and some tips for maintaining mindfulness practice. The website was designed to count the time and automatically open the next module after 7 days. Additionally, the PI was able to track progress of each participant as an administrator on the website. Additional details concerning the Modules and the intervention is provided in Table 1. Modules for Teaching Mindfulness on the www.mysweetmind.org website. Each module built upon the last and participants had access to a review sheet to print out for each of the modules. This review sheet provided an outline with the most important content highlighted for practicing the material taught in each week's module. Participants were also able to review any of the previous modules on the website. While they could return to previous modules and utilize the review sheets, they could not skip ahead.   Once all six Modules were completed, the participant was asked to complete the Time 2 questionnaires: DQOL-Y and MAAS-A.

Participants had continual access to the modules between Time 2 and Time 3. At the three month mark from the date of the first HbA1c test results, participants were asked to perform the second HbA1c test and submit the results of their HbA1c via e-mail to the PI.   They were also asked to take the DQOL-Y and MAAS-A questionnaires for the third and final time. Once participants submitted their HbA1c results and completed the questionnaires, a $25.00 gift card was sent per their preference for Amazon or *iTunes* along with a thank you for their valuable participation. The participants and/or their parents were sent a resource list of books and websites for continuing mindfulness practice because several had expressed an interest in continuing practice and the website was no longer available to them once they completed the study.

Participants in the Control Group were asked to complete the questionnaires online and send their HbA1c to the PI at the same three time points as did those in the Active Group but were not given access to the Mindfulness Modules until after all of their data had been collected. They were also sent the first gift card after Time 1 collection of data and HbA1c results were received. After all data over the three time points had been received, participants in the Control Group were sent the second $25.00 gift card, were told that they had been in the Control Group and were then given access to the Mindfulness modules. These participants were encouraged to participate in learning the Mindfulness techniques and to take advantage of the website materials. They were also sent the resource list of additional mindfulness materials.

Data Analysis

Data were analyzed using Statistical Package for Social Sciences (IBM, Version 25). Descriptive statistics and independent t-tests were performed on the demographic variables and PSS-4 scores to describe the sample population understudy and determine whether the Active and Control Groups were comparable at Time 1.

To test each of the Hypotheses (1, 2 and 3), alpha was set at .05 and beta at .20 with a two-tailed test of significance. A mixed between-within subjects analysis of variance (ANOVA) was conducted with one between group factor with two levels (Active and Control Groups) and one within-group factor or repeated measure (time) to examine the group x time interaction for each dependent variable in Hypotheses 1, Hypotheses 2 and Hypotheses 3. The assumption of sphericity for repeated measures analyses was violated with the Mauchly's test. Therefore, multivariate statistical tests were conducted and Wilks' Lambda used to report the interaction effect as well as the within-subjects effect (time) (Polit, 2010). The main effect of treatment group was analyzed using ANOVA. Pairwise tests were conducted to make

comparisons between the groups at each time point and thus, to determine where the differences were over the post-intervention time points (Time 2 and Time 3) on the dependent variables found significant. Hypothesis 3 had only one post-intervention time point (Time 3).

Results

Demographic Data of the Sample population

Over a 28 month period, 117 participants were recruited and assessed for eligibility and 29 were excluded for the following reasons including: did not meet inclusion criteria (n=4); declined to participate (n=16); other reasons (n=9). A total of 88 participants were randomized into the study, 48 were originally assigned to the intervention (Active group) and 40 were assigned to the Control group. In the Active group (n=48), 15 participants did not receive the allocated intervention because they did not return the HbA1c results at Time 1 (n=5); were lost to follow up (n=6); or quit the study citing lack of time/interest (n=4). In the Control group (n=40) eight participants did not complete the protocol, did not return the HbA1c results at Time 1 (n=4) or were lost to follow up (n=4). See Consort Table. Figure 4.

A total of 65 adolescents with T1D completed the study with 33 in the Active Group and 32 in the Control Group. As noted in Table 2, there were no statistically significant differences between participants in the Active and Control Groups on the following characteristics including age, race, grade in school, wearing an insulin pump or continuous glucose monitor, and level of activity. However, participants in the Active Group had significantly more years with diabetes (*p* = .02) and were more likely to have a parent with diabetes (*p* = .04) or a sibling with diabetes

(p = .00) compared to those in the Control Group. Equal variances were assumed with the results of the Levene's test for equality of variances at p = .952 and the equality of means showed that there was no significant difference between the Active and Control Groups (p = .471). In addition, demographic variables did not co-vary with the dependent variables on Time 1 including HbA1c, mindfulness, and quality of life.

Pearson's correlation coefficient (r) was used to determine if there were any significant relationships between HbA1c, DQOL-Y scores and MAAS-A scores at Time 1. Significant positive correlations were found at Time 1 between HbA1c and DQOL-Y scores for both the Active $r(31)$ = 0.386, p = 0.027) and Control group $r(30)$ = 0.467, p = 0.007. There were no significant relationships found between HbA1c and MAAS-A scores at Time 1 or DQOL-Y scores and MAAS-A scores at Time 1.

The 4 item PSS was used to further describe the population on perceived stress at Time 1. Raw scores approximated normal distribution of data with most scores occurring in the center and tapering at the extremes. The majority of the responses were between "almost never" and "fairly often". Question 1: "unable to control the important things in life" tended to occur more frequently (80%) for the respondents with ratings between "sometimes" (56.9%) and "fairly often" (23.1%). Questions 2 and 3 tended to occur less frequently for the respondents with ratings between "almost never" and "sometimes": question 2 "confident in ability to handle personal problems" was 90.8%; question 3 "felt things were going your way" was 84.6%. Question 4 "difficulties piling up so high" was less likely to occur for respondents (80%) with ratings ranging from almost never (26.2%) and sometimes (53.8%). After questions 2 and 3 were coded to follow the reverse scale (4 = never, 3 = almost never, 2 = sometimes, 1 = fairly often, 0 = very often). The total PSS score obtained was calculated as the sum of the four questions. The

PSS scores had an average of 7.51, median of 7 and ranged from 4 to 11 indicting that participants had low to moderate stress at the beginning of the study. There were no significant group differences on perceived stress as measured at Time 1.

Hypothesis Testing

Hypothesis 1

A mixed between-within subjects ANOVA was conducted and supported the hypothesis that teaching MBSR would increase mindfulness measures in adolescents with T1D by demonstrating an increase in MAAS-A measurements at two post intervention time points compared to a Control Group of adolescents with T1D who did not receive the mindfulness training until after all data were collected. Figure 1 shows a significant interaction effect of time with group assignment (Active or Control Group) on MAAS-A scores, Wilks' Lambda = .44, F $(2, 62) = 38.85$, p = 0.000. Pairwise tests were conducted to make comparisons between the group assignments at each time point as shown in Table 3. The Active Group had significantly (p=.000) higher MAAS-A scores than the Control Group when comparing Time 1 MAAS-A scores to Time 2 and Time 3 MAAS-A scores. There was no significant differences between Time 2 and Time 3 MAAS-A scores for the two groups. There was a significant main effect of time on MAAS-A score Wilks' Lambda = .55, F $(2, 62) = 24.84$, p = 0.000. Eta square was η = 0.44, where time explained 44% of the variance in MAAS-A scores. There was also a significant main effect of group assignment, F $(1, 63) = 141.15$, p = 0.000. Eta square was η = .691 where group assignment explained 69% of MAAS-A scores.

Hypothesis 2

A mixed between-within subjects ANOVA was conducted and supported the hypothesis that mindfulness training would increase DQOL-Y measures in adolescents with T1D by demonstrating an decrease in DQOL-Y measurements at two post intervention time points compared to a Control Group of adolescents with T1D who did not receive the mindfulness training. Figure 2 shows there was a significant interaction effect of time with group assignment (Active or Control Group) on DQOL-Y scores, Wilks' Lambda = 0.79, $F(2, 62) = 8.08$, $p = 0.001$. Pairwise tests were run to make comparisons between the groups at each time point and shown on Table 3. Pairwise tests indicated that those participants in the Active Group had significantly ($p=0.000$) lower DQOL-Y scores than the Control Group when comparing Time 1 DQOL-Y scores to Time 2 and Time 3 DQOL-Y scores. There was no significant difference in the Control Group between Time 1 and Time 3 or Time 2 and Time 3 scores, only between Time 1 and Time 2. A significant main effect on time on DQOL-Y scores, Wilks' Lambda = .73, $F(2, 62) = 11.18$, $p = 0.000$, was also found. The eta square was $\eta = 0.26$, where time explained 26% of the variance in DQOL-Y scores. There was no significant main effect of group assignment, $F(1, 63) = .75$, $p = 0.389$. Eta square was $\eta = 0.12$.

Hypothesis 3

A mixed between-within subjects ANOVA was conducted and supported the hypothesis that mindfulness training would decrease HbA1c measures in adolescents with T1D by demonstrating a decrease in HbA1c measurements at one post intervention time point compared to a control group of adolescents with T1D who did not receive the mindfulness training. Figure 3 shows that there was a significant interaction effect of time with group assignment (Active or Control Group) on HbA1c scores, Wilks' Lambda = 0.86, $F(1, 63) = 10.13$, $p = 0.002$. Pairwise

tests were run to make comparisons between the groups at each time point but did not demonstrate significantly lower HbA1c scores in the Active Group compared to the Control Group on Time 1 to Time 3 HbA1c scores shown on Table 3. There was no significant main effect of time on HbA1c, Wilks' Lambda = .99, $F (1, 63)$ = .52, p = .471 with eta square of η= 0.008 or significant main effect of group assignment, $F (1, 63)$ = .16, p = .685 with eta square of η= 0.003.

Discussion

This research study examined the effects of an online MBSR program on mindfulness, quality of life and HbA1c in adolescents with T1D at three time points including pre-intervention, immediately post intervention, and three months post intervention. The majority of adolescents who participated in this study were white, about 15 years old and in the 10th grade. Participants' gender was evenly distributed by group. However, only 25% of the sample population were minorities. It would behoove future researchers to increase recruitment of Black and Hispanic adolescents with T1D in order to gain a better understanding of their physiologic and behavioral responses to MBSR.

The majority of the adolescents in this study reported moderate perceived stress on the Perceived Stress Scale at the beginning of the study. The DQOL-Y questionnaire administered at all three times points of the study, allowed us to get a detailed analysis on the perceptions of the participants regarding the stress that diabetes causes in their lives. There was a significant positive correlation between HbA1c and DQOL-Y for these study participants in both the Control and Active Groups. Higher scores in this measure are reflective of less quality of life and were correlated significantly to higher HbA1c values, reflective of poor blood glucose control.

Stress is a known barrier to diabetes-related health outcomes and chronic stress has been strongly associated with poor HbA1c levels, especially in minority groups or adolescents/young adults (Hilliard et al., 2016). The mysweetmind online MBSR program was developed to teach adolescents with T1D to manage their stress by learning the technique of mindfulness based stress reduction to serve as a buffer to the stress they experience. Adolescents with T1D may not be able to change or decrease the amount of stress in their lives but they may be able to learn how to change the way they respond to that stress. Many studies have shown that MBSR has been useful in reducing the psychosocial and physiological effects of stress. The results of this study suggest that learning MBSR may improve mindfulness, quality of life and may help to lower HbA1c in adolescents with T1D.

It is possible that T1D adolescents with even greater perceived stress initially would have increased benefits from the intervention with more positive changes in HbA1c, mindfulness and quality of life. This is something to consider for future studies.

Our overall approach was to utilize a website to deliver the MBSR program due to the success and popularity of e-health programs with this age group. It was also believed that participants would be more interested in participating in an intervention that they could do on their own time. Historically, expansion of MBSR to a greater segment of the population was done with books and audio tapes. The evolution of mindfulness-based interventions has been moving to online programs because of the greater reach and cost effectiveness that this medium provides. In addition, a number of studies have demonstrated that online data collection and completion of questionnaires are generally equivalent to those collected via paper and pencil (Cavanaugh et al., 2013). In our study, the mindfulness intervention was delivered in a six module format on the www.mysweetmind.org website that was designed for this population. The

questionnaires were administered online as well. Each week, a new module would open up to the participant active in the study who also had a weekly worksheet to print out as a quick review and reference for mindfulness practice content that week. The intention with this intervention delivery was to teach the key components of mindfulness in individual sessions with opportunities provided to practice what was learned and build each week on the previously learned content. The main benefits of this online format for learning mindfulness included the expectation that adolescents would readily accept the internet as a medium for engaging in this study, geographic areas for participant recruitment would increase and thus, increase generalizability of findings and reduce obstacles related to traveling and attending MBSR training sessions at prescribed times. Similar to our study, Urech et al. (2017) demonstrated the effectiveness of web-based therapy to manage stress, quality of life, psychological distress, anxiety and depression.

Recruitment was a significant challenge and the original determined sample size of 86 was not achieved despite varied and extended recruitment efforts. The study was advertised with postcards and information sessions at endocrinology offices, diabetes camps, school nurse education seminars and advocacy group social events. The advertising postcards provided to the campers and their parents were most effective during the summer months immediately after camp sessions. The use of social media, a Facebook page and Facebook advertising became the most useful modality for recruiting this population and increased the participant base by almost 50%, adding 21 participants to enrollment in a relatively shorter time frame. This may have been particularly effective because the study was conducted online and the audience may have been more receptive to the format and online nature of the study.

In the preliminary analysis, demographics revealed that the Active Group had significantly more years with diabetes ($p = 0.02$), a greater chance that one of their parents had diabetes ($p = 0.04$), and were more likely to have a sibling with diabetes ($p = 0.00$) than those in the Control Group; however, results of a generated correlational matrix showed that these variables did not influence the major dependent variables studied including mindfulness, quality of life and HbA1c. This is contrary to the results of a study conducted by Berg et al. (2009) whereby parental and sibling T1D diagnosis in the same household may have had an impact on the management of diabetes for the participant because of the intimate familiarity with disease management. In addition, adolescents collaborating with parents to pool resources and problem solve together has been associated with fewer depressive symptoms, better glucose control and better adherence (Berg et al., 2009). In this study, diabetes stressors and other life stressors were measured with the DQOL-Y questionnaire as well.

The results of our study, although statistically significant interaction effects were found, should be interpreted with caution. For example, HbA1c only decreased by 0.124% in the Active group compared to the Control group and thus, it is unlikely that this decrease represents clinical significance. Clinical significance was also questionable in Friis, Johnson, Cutfield and Consedine's study (2016) that showed statistically significant benefits for HbA1c reductions among patients with diabetes using mindful self-compassion rather than MBSR as the intervention. In addition, our results were similar to a study conducted by Serlachius et al. (2016) whereby good psychosocial wellbeing improvements were demonstrated with cognitive behavioral therapy interventions but with no significant positive change in HbA1c. We measured HbA1c over three months in our study; however, it may be that in order to see positive change in HbA1c, the MBSR intervention should be administered for a longer period of time and

HbA1c measured over six or more months. This might provide us with more insight into the potential physiological benefits of this intervention as measured by HbA1c. Similar results as they pertain to the psychological benefits of learning mindfulness have been shown in a systematic review conducted on the effectiveness of mindfulness based interventions for adults with diabetes. As in our study, results on physical benefits were mixed but psychological benefits, specifically a reduction in anxiety and distress were evident (Noordall, Cumming, & Thompson, 2017).

Overall, this research suggests that MBSR taught in an online format may provide adolescents the opportunity to learn techniques that could buffer them from the negative impact of managing T1D. In addition, MBSR may help adolescents with T1D learn techniques for managing their stress and emotions while managing a demanding condition. The parents and caregivers of adolescents and children with T1D may be an important adjunct to this potential modality of care. Much of the burden of T1D management is placed on those parents and caregivers, research in providing MBSR training to the primary caregivers could provide important insights as well. Lastly, nurses, physicians and other diabetes health care providers may find these results interesting and applicable to their practice with this demographic.

Strengths and Limitations

An important strength of the study was the opportunity to deliver the intervention using a website and allowing the participants the ability to participate when it was most convenient for them without the need to travel and attend training sessions. Several of the participants had to be contacted frequently to encourage them to complete the modules. While it was convenient for

them to do the training at home – it was also easily forgotten or put to the side. Participants were

also given the opportunity to print out materials from the website that they could use to reinforce

what they learned and they could also review the material they had learned in previous modules

while logged on to their account. For future studies, it would be interesting to track the frequency

by which adolescents access the MBSR website to review the modules and to practice MBSR.

The delivery of the mindfulness training was asynchronous and self-directed for the

participants. Many had the assistance of their parents to facilitate using the website and the

training modules however, parental assistance could not be measured or relied upon. Although

detailed instructions were provided via e-mail to the participants and their parents for utilizing

the home test kit more effectively, performance on the HbA1c home test kit proved challenging

for some. Several of the participants had difficulty following the directions provided with the

kit. Ultimately, they were sent an additional kit to obtain HbA1c data. These data were reported

via e-mail and thus, there was a possibility that the output was misread or typed incorrectly by

the participant or parents.

A total of 65 adolescents with T1D participated in the study, which was below the

anticipated 86 participants. Consequently, generalizability was limited due to the smaller sample

size. Access to a large cohort of adolescents with T1D within an endocrinology practice would

be an important opportunity to further test this program of training MBSR and the overall effects.

Many endocrinology practices were receptive to learning about MBSR and providing

information to their patients about the study; however, there has been no widely publicized

literature demonstrating the effectiveness of this modality with this population. As a result, they

may not be ready to incorporate this treatment modality or have the personnel who could

introduce this it into their practice. Many of the pediatric endocrinology practices recognize the

essential component of psychological care of their patients, social workers or referrals to psychological care are made but often only after problems have developed. One of the best applications and strengths of MBSR is that when learned, it could serve as a buffer and preventative measure to reduce the impact of perceived stress.

Summary

These findings draw further attention to the fact that adolescents with T1D require psychosocial treatment as well as medical treatment and that we must provide more comprehensive, holistic and preventative care. Our results have important clinical implications and the recognition that there is an opportunity to provide training that may help facilitate not only successful diabetes management but also better quality of life through buffering of the stress response. The creation and utilization of this system for delivering MBSR training in an online format could be an innovative and effective adjunct to care – one which has the potential to improve both psychological and physiological components of care for this at-risk population.

Figure 1.

Physiological and Psychological Effects of Mindfulness training on Health and Wellness of Adolescents with Type 1 Diabetes

stress/stimuli

stress /stimuli

Mindfulness Training

filter/buffer of stress/stimuli

Neurological System: Perceptions , Thoughts and Mood

Psychosocial Components: mental and social phenomena

Biological Systems: Endocrine & Immune System

Health & Wellness
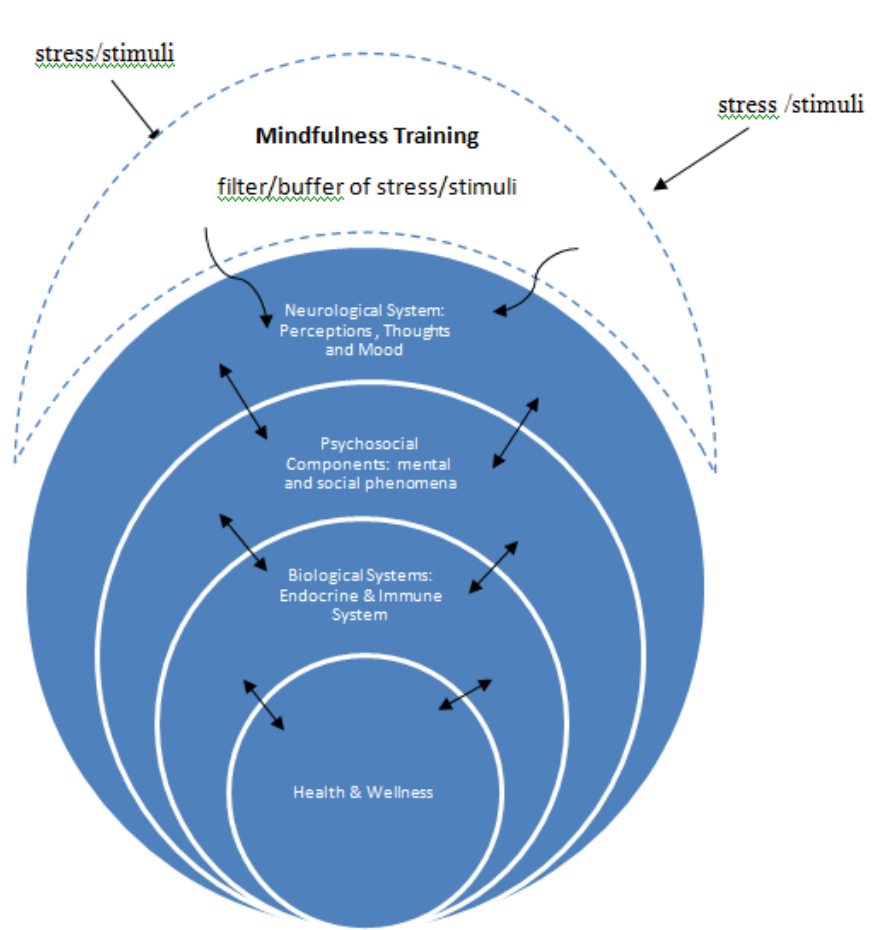
Table 1
Module content MySweetMind.org website

Title	Content
Module 1 – Introduction to Mindfulness and Mindful Eating *Breathing is the Heart of Mindfulness – recorded track* *Eating a Raisin Mindfully - recorded track*	Mindfulness is defined by Dr. Jon Kabat-Zinn as "Paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (1994, 4). Mindfulness is about learning to handle stressful situations with kindness and compassion toward yourself. Learning how to be mindful will help you to be more resilient –Explain the lizard brain, explain Paper Tigers – knowing the difference Bringing attention to the natural breath.
Module 2 – Sitting Meditation *Sitting like a Mountain. – recorded track*	Mindfulness is sometimes described as a bird with two wings: compassion and awareness. In order to practice Mindfulness – like flight – you need both wings. Awareness will help you recognize that you are feeling stressed. Compassion will allow you to look at your situation with kindness – smiling will help you to cultivate this self-compassion and compassion toward others. Be aware if you are being negative or self-critical and if this is happening to you simply be aware of it and then meet those thought with kindness so they will let go of you. Mindfulness of the breath is the foundation of every one of the mindfulness practices – simply being aware of the breath is a powerful antidote to stress. Breath and smile. Just Sit and do nothing. Shift out of autopilot and switch from "doing" to "being" Just sit and be aware of the breath.
Module 3 – Body Scan	Don't allow yourself to be pulled away from the present moment, recognize the healing power of a simple present-moment experience. Using the breath as an anchor. Mindfulness will help you to notice the good things that happen in life more because you will be more aware of and grateful for the positive things in your life by spending some time in the present moment considering those things you are grateful for….

Body Scan – recorded track	Since the mind and the body are deeply connected, releasing stress in your body will help you to release stress in your mind. This is what the body scan allows you to do. It is a gift to your body because it is an invitation of energy into the body from your mindfulness practice. The body scan is good to practice at night before you go to sleep also. Handling Pain and Discomfort with the Body Scan
Module 4 – Mindfulness of Thinking and Everyday Mindfulness *Mindfulness of thinking – recorded track*	Stories of including mindfulness in everyday living Informal Mindfulness – bringing mindful awareness into routine activities you already have Mindful Eating The link between formal and informal mindfulness practice – SOBER: 1. Stop 2. Observe 3. Breathe 4. Expand 5. Respond
Module 5 – Loving Kindness Meditation & Mindfulness Movement *Mindful movement – recorded track*	Loving Kindness Meditation Your thoughts are powerful and can become your reality Mindful movement is the practice of moving your body intentionally with care and attention to what is happening with each movement.
Module 6 – Review & Tips for Maintaining Mindfulness Practice	Breath Awareness and Compassion Listen to recordings Mindfulness in a Moment and in Everyday Living

Note. Summarized content of modules by week. Content for participants included a narrated PowerPoint and recorded track. These key components were also provided for practice weekly in a printable format.

Figure 2. Screening, Enrollment, Allocation, and Completion

Enrollment

Assessed for eligibility (n=117)

Excluded (n=29)
- Did not meet inclusion criteria (n=4)
- Declined to participate (n= 16)
- Other reasons (n= 9)

Randomized (n=88)

Allocation

Allocated to intervention (n=48)
- Received allocated intervention (n=43)
- Did not receive allocated intervention (n= 5) Did not send in the 1st HbA1c

Allocated to control (n= 40)
- Included in the Control Group (n=36)
- Did not receive allocated intervention (n=4) Participant did not send in 1st HbA1c

Follow-Up

Lost to follow-up (n= 6)
- Participant did not return correspondence via phone text or e-mail (n=2)
- Discontinued intervention (n=4)

Lost to follow-up (n=4)
- Participant did not return correspondence via phone text or e-mail (n=4)

Analysis

Analyzed (n=33))

Analyzed (n=32)

Table 2
Demographics

	Active in Study	Control Group	
	Mean (SD)	Mean(SD)	p-value
Age	15.64 (1.901)	14.81 (1.991)	0.093
Number of Years with Diabetes	6.39 (2.957)	4.88 (2.297)	0.024
School Grade	10.27 (1.567)	10.03 (1.750)	0.560
	Active in Study	Control Group	
	Number (%)	Number (%)	p-value
Gender			0.708
Female	16 (48.5%)	17 (53.1%)	
Male	17 (51.5%)	15 (46.9%)	
Has a Parent with Diabetes			0.042
Yes	4 (12.1%)	0 (0%)	
No	29 (87.9%)	32 (100%)	
Has a Sibling with Diabetes			0.003
Yes	10 (30.3%)	1 (3.1%)	
No	23 (69.7%)	31 (96.9%)	
Wears an insulin pump			0.050
Yes	27 (81.8%)	31 (96.9%)	
No	6 (18.2%)	1 (3.1%)	
Wears a continuous glucose monitor			0.267
Yes	13 (39.4%)	17 (53.1%)	
No	20 (60.6%)	15 (46.9%)	
Race Ethnic Origin			0.994
White	26 (78.8%)	26(81.3%)	
Black	3 (9.1%)	2(6.3%)	
Hispanic	3 (9.1%)	3(9.4%)	
Other	1 (3%)	1(3.1%)	
Level of Activity			0.422
Sedentary	5 (15.2%)	2 (6.3%)	
Moderately Active	19 (57.6%)	18 (56.3%)	
Very Active	9 (27.3%)	12 (37.5%)	

Note. * = $p < .05$; There were no significant group differences between Active or Control Groups with the exception of participants in the Active Group who had more years with diabetes and were more likely to have a parent and sibling with diabetes.

Figure 3

MAAS-A Interaction Between Group Level and Time (N=65)
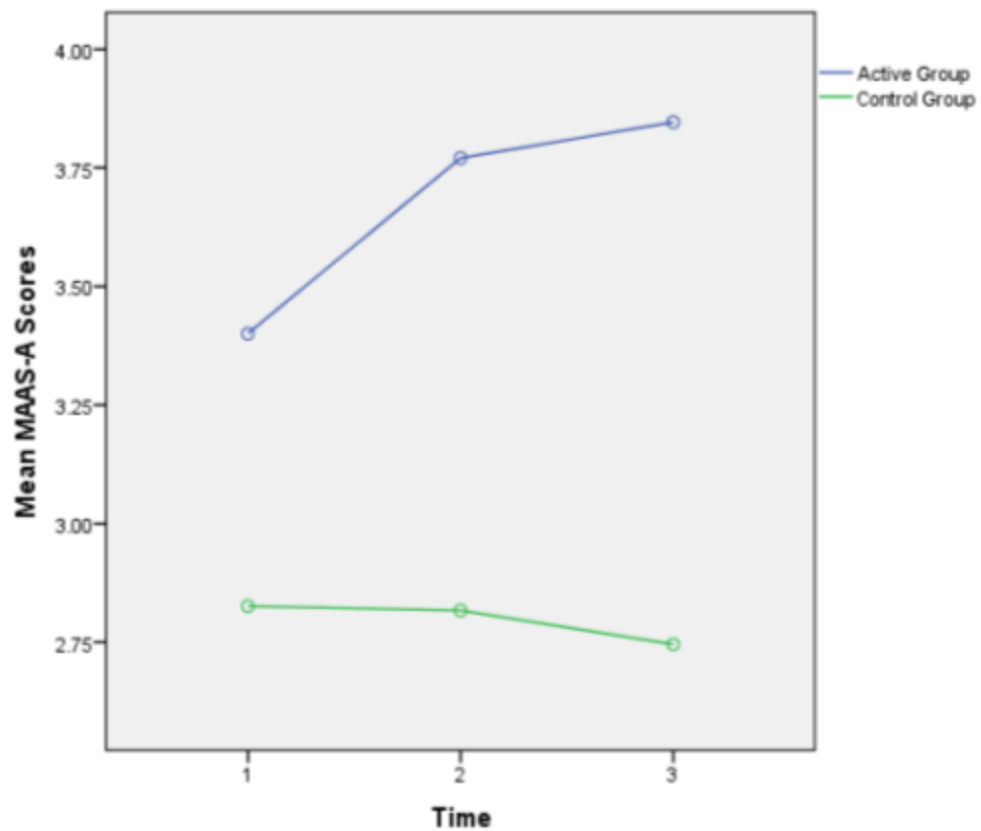
Note. The effect of MBSR training over Time 1, Time 2 and Time 3 for the Active versus the Control Group in Mindful Attention Awareness Scale (MAAS-A) scores. Higher scores indicate increased mindfulness. There was a a significant interaction effect of time with group assignment (Active or Control Group) on MAAS-A scores, Wilks' Lambda = .44, F (2,62) = 38.85, p = 0.000.

Figure 4

DQOL-Y Interaction Between Group Level and Time (N=65)
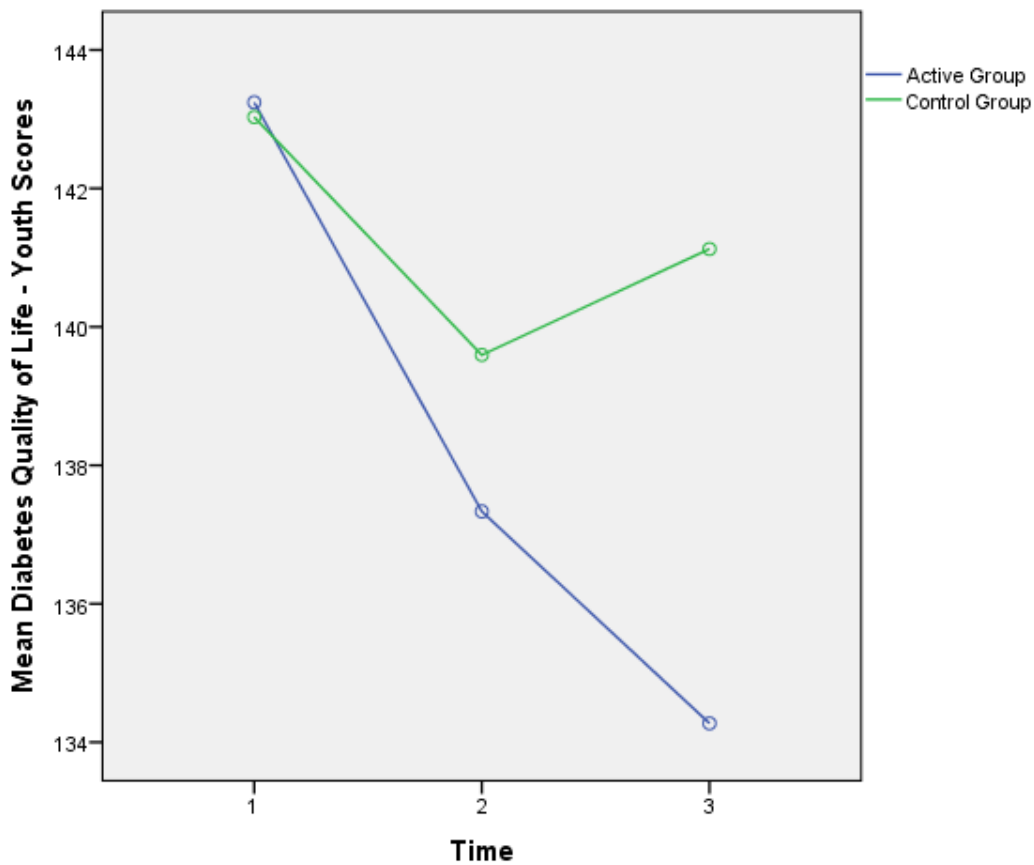
Note. The effect of MBSR training over Time 1, Time 2 and Time 3 for the Active versus the Control Group in Diabetes Quality of Life (DQOLY) scores. Lower scores correspond to a better quality of life. There was a significant interaction effect of time with group assignment (Active or Control Group) on DQOL-Y scores, Wilks' Lambda = 0.79, F (2, 62) = 8.08, p = 0.001.

Figure 5

HbA1c Interaction Between Group Level and Time
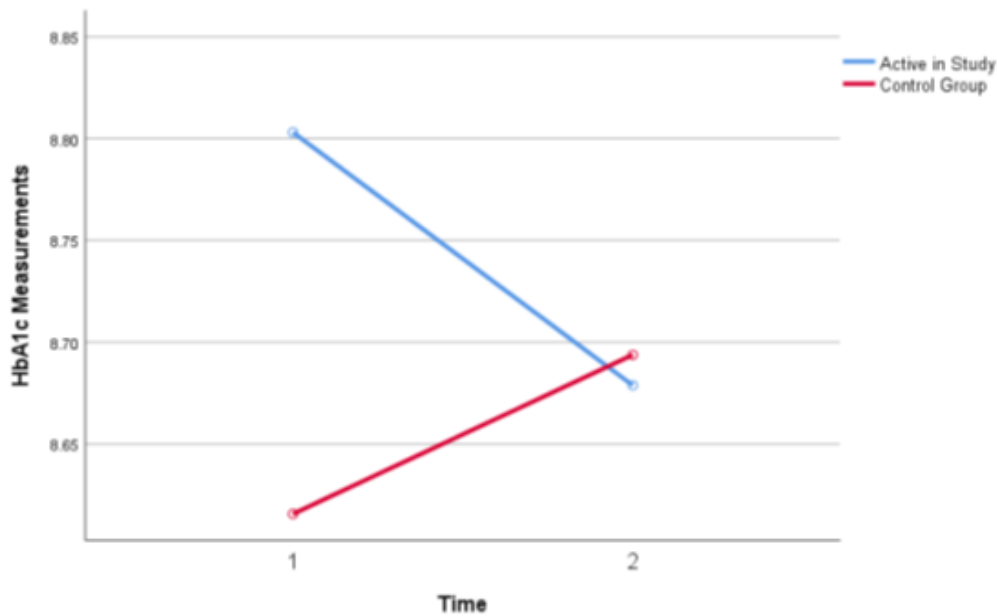
Figure 1. The effect of MBSR training over Time 1 and Time 3 for the Active versus the Control Group in HbA1c results. Lower HbA1c corresponds to lower average blood glucose readings and better diabetes management with less complications associated with elevated glucose levels. There was a significant interaction effect of time with group assignment (Active or Control Group) on HbA1c scores, Wilks' Lambda = 0.86, $F(1, 63) = 10.13$, $p = 0.002$.

Table 3
Pairwise Comparisons of Group MAAS-A and DQOLY Scores by Time

Pairwise Comparisons of Group MAAS-A Score by Time.
Measure: MAAS-A Score

Active in Study	(I) Time	(J) Time	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	95% Confidence Interval for Difference[b] Upper Bound
Active in Study	1	2	-.370*	.037	*.000	-.464	-.277
		3	-.446*	.052	*.000	-.576	-.315
	2	1	.370*	.037	*.000	.277	.464
		3	-.076	.038	.172	-.173	.021
Control Group	1	2	.009	.039	1.000	-.091	.109
		3	.080	.032	.053	-.001	.161
	2	1	-.009	.039	1.000	-.109	.091
		3	.071	.034	.128	-.014	.157

Pairwise Comparisons of Group DQOL-Y Scores by Time
Measure: DQOLY

Active in Study	(I) Time	(J) Time	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	95% Confidence Interval for Difference[b] Upper Bound
Active in Study	1	2	5.909*	1.670	*.004	1.689	10.129
		3	8.970*	1.839	*.000	4.323	13.617
	2	1	-5.909*	1.670	*.004	-10.129	-1.689
		3	3.061*	.736	*.001	1.201	4.920
Control Group	1	2	3.438*	1.296	*.037	.158	6.717
		3	1.906	1.386	.537	-1.603	5.415
	2	1	-3.438*	1.296	*.037	-6.717	-.158
		3	-1.531	1.009	.418	-4.085	1.022

Note. Based on estimated marginal means
*. The mean difference is significant at the .05 level.
b. Adjustment for multiple comparisons: Bonferroni.

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Appendix A

DIABETES QUALITY OF LIFE QUESTIONNAIRE: YOUTHS

A: DIRECTIONS: Read each statement carefully. Please indicate how satisfied or dissatisfied you currently are with the aspect of your life described in the question. Mark [X] the box that matches how satisfied or dissatisfied you feel: 1 = Very Satisfied, 2 = Moderately Satisfied, 3 = Neither Satisfied nor Dissatisfied, 4 = Moderately Dissatisfied, 5 = Very Dissatisfied. There are no right or wrong answers to these questions. We want your opinion.

		Very Satisfied	Mod. Satisfied	Neither	Mod. Dissatisfied	Very Disatisfied
A1:	How satisfied are you with the amount of time it takes to manage your diabetes?	[1]	[2]	[3]	[4]	[5]
A2:	How satisfied are you with the amount of time you spend getting checkups?	[1]	[2]	[3]	[4]	[5]
A3:	How satisfied are you with the time it takes to determine your blood sugar?	[1]	[2]	[3]	[4]	[5]
A4:	How satisfied are you with your current medical treatment?	[1]	[2]	[3]	[4]	[5]
A5:	How satisfied are you with the flexibility you have with your diet?	[1]	[2]	[3]	[4]	[5]
A6:	How satisfied are you with the burden your diabetes is placing on your family?	[1]	[2]	[3]	[4]	[5]
A7:	How satisfied are you with your knowledge about your diabetes?	[1]	[2]	[3]	[4]	[5]

SPEAKING GENERALLY:

		Very Satisfied	Mod. Satisfied	Neither	Mod. Dissatisfied	Very Disatisfied
A8:	How satisfied are you with your sleep?	[1]	[2]	[3]	[4]	[5]
A9:	How satisfied are you with your friendships?	[1]	[2]	[3]	[4]	[5]
A10:	How satisfied are you with your work, school, and household activities?	[1]	[2]	[3]	[4]	[5]
A11:	How satisfied are you with the appearance of your body?	[1]	[2]	[3]	[4]	[5]
A12:	How satisfied are you with the time you spend exercising?	[1]	[2]	[3]	[4]	[5]
A13:	How satisfied are you with your leisure time?	[1]	[2]	[3]	[4]	[5]
A14:	How satisfied are you with life in general?	[1]	[2]	[3]	[4]	[5]
A15:	How satisfied are you with performance in school?	[1]	[2]	[3]	[4]	[5]
A16:	How satisfied are you with how your classmates treat you?	[1]	[2]	[3]	[4]	[5]
A17:	How satisfied are you with your attendance at school?	[1]	[2]	[3]	[4]	[5]

Compared with others your age, would you say your health is:
- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

DIRECTIONS: Read each statement carefully. Please indicate <u>How Often</u> the following events happen to you. Mark [X] the box that matches how satisfied or dissatisfied you feel: 1 = Never, 2 = Very Seldom, 3 = Sometimes, 4 = Very Often, 5 = All the time. There are no right or wrong answers to these questions. We are interested in your honest opinion.

		Never	Very Seldom	Sometimes	Often	All the time
B1:	How often do you feel pain associated with the treatment of your diabetes?	[1]	[2]	[3]	[4]	[5]
B2:	How often are you embarrassed by having to deal with your diabetes in public?	[1]	[2]	[3]	[4]	[5]
B3:	How often do you feel physically ill?	[1]	[2]	[3]	[4]	[5]
B4:	How often does your diabetes interfere with your family life?	[1]	[2]	[3]	[4]	[5]
B5:	How often do you have a bad night's sleep?	[1]	[2]	[3]	[4]	[5]
B6:	How often do you find your diabetes limiting your social relationships and friendships?	[1]	[2]	[3]	[4]	[5]
B7:	How often do you feel good about yourself?	[1]	[2]	[3]	[4]	[5]

		Never	Very Seldom	Sometimes	Often	All the time
B8:	How often do you feel restricted by your diet?	[1]	[2]	[3]	[4]	[5]
B9:	How often does your diabetes keep you from driving a car?	[1]	[2]	[3]	[4]	[5]
B10:	How often does your diabetes interfere with your exercising?	[1]	[2]	[3]	[4]	[5]

B11: How often do you miss work,   [1]   [2] [3] [4] [5]

school or household duties

because of your diabetes?

B12: How often do you find yourself   [1]   [2] [3] [4] [5]

explaining what it means to

have diabetes?

B13: How often do you find that your diabetes [1]   [2] [3] [4] [5]

interrupts your leisure time activities?

B14: How often are you teased   [1]   [2] [3] [4] [5]

because you have diabetes?

B15: How often do you feel that   [1]   [2] [3] [4] [5]

because of your diabetes you go

to the bathroom more than others?

B16: How often do you find you eat   [1]   [2] [3] [4] [5]

something you shouldn't rather

than tell someone that you have diabetes?

B17: How often do you hide from   [1]   [2]   [3] [4] [5]

others the fact that you are

having an insulin reaction?

		Never	Very Seldom	Sometimes	Often	All the time
B18:	How often do you find that your diabetes prevents you from participating in school activities (for example, a school play, playing a sport).	[1]	[2]	[3]	[4]	[5]
B19:	How often do you find that your diabetes prevents you from going out to eat with your friends?	[1]	[2]	[3]	[4]	[5]
B20:	How often do you feel that your diabetes will limit what job you will have in the future?	[1]	[2]	[3]	[4]	[5]
B21:	How often do you find that your parents are too protective of you?	[1]	[2]	[3]	[4]	[5]
B22:	How often do you find that your parents worry too much about your diabetes	[1]	[2]	[3]	[4]	[5]
B23:	How often do you find that your parents act like diabetes is their disease, not yours?	[1]	[2]	[3]	[4]	[5]

DIRECTIONS: Read each statement carefully. Please indicate how often the following events happen to you. Check [X] the appropriate box. There are no right or wrong answers to these questions. If the question is not relevant to you, check "Does not apply".

		Does Not Apply	Never	Seldom	Sometimes	Often	All the Time
		[0]	[1]	[2]	[3]	[4]	[5]
C1:	How often do you worry about whether you will get married?	[0]	[1]	[2]	[3]	[4]	[5]
C2:	How often do you worry about whether you will have children?	[0]	[1]	[2]	[3]	[4]	[5]
C3:	How often do you worry about whether you will not get a job you want?	[0]	[1]	[2]	[3]	[4]	[5]
C4:	How often do you worry about whether you will pass out?	[0]	[1]	[2]	[3]	[4]	[5]
C5:	How often do you worry about whether you will be able to complete your education?	[0]	[1]	[2]	[3]	[4]	[5]
C6:	How often do you worry that your body looks different because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C7:	How often do you worry that you will get complications from your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C8:	How often do you worry whether someone will not go out with you because you have diabetes?	[0]	[1]	[2]	[3]	[4]	[5]

		Does Not Apply [0]	Never [1]	Seldom [2]	Sometimes [3]	Often [4]	All the Time [5]
C9:	How often do you worry that teachers treat you differently because of your diabetes?	[0]	[1]	[2]	[3]	[4]	[5]
C10:	How often do you worry that your diabetes will interfere with things that you do in school (sports, music, drama)?	[0]	[1]	[2]	[3]	[4]	[5]
C11:	How often do you worry that your diabetes causes you to do things with friends like going on dates or going to parties?	[0]	[1]	[2]	[3]	[4]	[5]

Appendix B

Mindful Attention Awareness Scale - Adolescent (MAAS-A)

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1 2 3 4 5 6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1 2 3 4 5 6
I find it difficult to stay focused on what's happening in the present.	1 2 3 4 5 6
I tend to walk quickly to get where Im going without paying attention to what I experience along the way.	1 2 3 4 5 6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1 2 3 4 5 6
I forget a person's name almost as soon as I've been told it for the first time.	1 2 3 4 5 6
It seems I am "running on automatic," without much awareness of what I'm doing.	1 2 3 4 5 6
I rush through activities without being really attentive to them.	1 2 3 4 5 6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing.	1 2 3 4 5 6
I find myself listening to someone with one ear, doing something else at the same time.	1 2 3 4 5 6
I drive places on "automatic pilot" and then wonder why I went there.	1 2 3 4 5 6
I find myself preoccupied with the future or the past.	1 2 3 4 5 6
I find myself doing things without paying attention.	1 2 3 4 5 6
I snack without being aware that I'm eating	1 2 3 4 5 6

Appendix C
Demographic Data Sheet (DDS)

DIRECTIONS: Please complete the following information.

1. Age:____

2. Date of Birth: ____/_____/_____

3. Gender
____Male
____Female

4. Race and/or Ethnic Origin, may check more than one:
____Caucasian
____African American
____Hispanic
____Asian
____Native American/Eskimo
____Other, Please specify

5. School Grade:_____

6. Level of Activity:
____Sedentary (very little physical activity)
____Moderately Active
____Very Active

7. How many year with diabetes?_____

8. Do you have a parent(s) with diabetes?
____Yes
____No

9. Do you have a sibling(s) with diabetes?
____Yes
____No

10. Do you wear an insulin pump?
____Yes
____No

11. Do you wear a continuous glucose meter?
____Yes
____No

Appendix D
HbA1c Values Associated with Average Blood Glucose Values

	HbA$_{1c}$	eAG (estimated average glucose)	
(%)	(mmol/mol)[25]	(mmol/L)	(mg/dL)
5	31	5.4 (4.2–6.7)	97 (76–120)
6	42	7.0 (5.5–8.5)	126 (100–152)
7	53	8.6 (6.8–10.3)	154 (123–185)
8	64	10.2 (8.1–12.1)	183 (147–217)
9	75	11.8 (9.4–13.9)	212 (170–249)
10	86	13.4 (10.7–15.7)	240 (193–282)
11	97	14.9 (12.0–17.5)	269 (217–314)
12	108	16.5 (13.3–19.3)	298 (240–347)
13	119	18.1 (15–21)	326 (260–380)
14	130	19.7 (16–23)	355 (290–410)
15	140	21.3 (17–25)	384 (310–440)
16	151	22.9 (19–26)	413 (330–480)
17	162	24.5 (20–28)	441 (460–510)
18	173	26.1 (21–30)	470 (380–540)
19	184	27.7 (23–32)	499 (410–570)

Appendix E

Sample Pediatric Endocrinologist Recruitment Letter

April 1, 2015

Dr. XXXX

Pediatric Endocrinology

Dear Dr. XXXX,
This letter is to request the participation of your office in research concerning the use of Mindfulness as a stress management technique for adolescents with Type 1 diabetes.

I am conducting this study as partial fulfillment of the requirements for the PhD degree in Nursing at Duquesne University. IRB approval to conduct this study has been obtained through Duquesne University.

I am asking for your help to recruit adolescents between the ages of 12 to 17 with Type 1 diabetes to participate in this study. Participants will be randomized to the experimental group or the waitlist/control group. If interested, the participants will be invited to learn the practice of mindfulness via modules on a website, asked to practice the MBSR techniques, and asked to respond to questionnaires via a secure online data collection site. The home page of the website where your patient will access the course material is www.mysweetmind.com

If you agree to help me recruit, business cards and postcards will be provided to you to give to your patients and their parents that will contain information about the study. If your patients are interested, they will be asked to contact me directly. Participants would be under no obligation to join the study or continue in the study once they join.

Please complete and send via U.S. Mail the enclosed pre-stamped postcard if you permit this study to be advertised in your office. I am available to meet with you and/or your staff directly to describe the study further or answer any questions you may have.

I encourage you to consider this opportunity for your patients. Mindfulness has become quite popular in the last few years and has shown significant benefits for many different individuals with varying conditions/illnesses. The skills that your patient could gain have the potential for helping them for a lifetime.

Please do not hesitate to contact me with any questions.

Sincerely,
Denise Van Sant – Smith, MSN, RN, CNE
PhD Candidate
Duquesne University
 School of Nursing

Appendix F

Return Post Card

___**Yes, I am interested in advertising this study in our Pediatric Endocrinology office**

Please send a packet of information with post card/business cards to my office.

Name:_____

Group Name:_____

Address:_____

_____

Please check here if you would like an office visit by the investigator _____

Please check here if you would like to discuss the study via telephone with the researcher_____

Please check here if you would like additional information sent via e-mail_____

Best time/method to contact you_____

_____

Flier to be posted in the Pediatric Endocrinology offices and at Diabetes Camps

Invitation to Participate in a Research Study
for Adolescents ages 12-17
with Type 1 Diabetes.

Research is being conducted to examine the effects of Mindfulness Based Stress Reduction (MBSR) on adolescents who are taught how to use this method to manage stress.

The research is done via an online, age-appropriate website.

For additional information please contact:
Denise Van Sant – Smith, MSN, RN
PhD candidate
Duquesne University School of Nursing
vansantsmithd@duq.edu

Sample letter to Parents of Adolescents invited by mail to participate

April 1, 2015

Dr. XXXX

Dear Dr. XXXX,
This letter is to request the participation of your child in research concerning the use of Mindfulness as a stress management technique for adolescents with Type 1 diabetes.

I am conducting this study as partial fulfillment of the requirements for the PhD degree in Nursing at Duquesne University. IRB approval to conduct this study has been obtained through Duquesne University.

 If interested, your child could be invited to learn the practice of mindfulness via modules on a website, asked to practice the MBSR techniques, and asked to respond to questionnaires via a secure online data collection site. The home page of the website where your child will access the course material is www.mysweetmind.com

Please contact via phone, text or e-mail with any questions or if you would like to look into having your child participate. Mindfulness has become quite popular in the last few years and has shown significant benefits for many different individuals with varying conditions/illnesses. The skills that your child could gain have the potential for helping them for a lifetime.

Please do not hesitate to contact me with any questions. My cell phone number is 732-xxx-xxxx

Sincerely,
Denise Van Sant – Smith, MSN, RN, CNE
PhD Candidate
Duquesne University
 School of Nursing

Perceived Stress Scale- 4 Item

Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the last month, how often have you felt that you were unable to control the important things in your life?
___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

2. In the last month, how often have you felt confident about your ability to handle your personal problems?
___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

3. In the last month, how often have you felt that things were going your way?
___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?
___0=never ___1=almost never ___2=sometimes ___3=fairly often ___4=very often

Perceived Stress Scale Scoring

PSS-4 scores are obtained by reverse coding the positive items, e.g., 0=4, 1=3, 2=2, etc. and then summing across all 4 items. Items 2 and 3 are the positively stated items.

Conditions of Scale Use
Permission for use of the scale is not necessary when use is for academic research or educational purposes.

Appendix J

Key Concepts for www.mysweetmind.com Module Content

Module 1 – Introduction to Mindfulness and Mindful Eating

Key Concepts

Sometimes when you experience a lot of stress, you get stuck in your thoughts and spend a lot of time feeling bad about the past or worrying about the future. This can cause you to feel bad and maybe act badly toward yourself or toward others.

This is why learning how to handle stress is so important

Mindfulness is defined by Dr. Jon Kabat-Zinn as "Paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (1994, 4).

Mindfulness is about learning to handle stressful situations with kindness and compassion toward yourself. Learning how to be mindful will help you to be more resilient – which means you are able to thrive and do well despite stressful situations. These modules, starting with this one, will give you information about specific mindfulness practices and access to audio recordings to listen to.

Your body and your brain are constantly sending signals back and forth, they are in communication constantly.

Explain the Hand Model of the Brain – the lizard brain

Explain Paper Tigers – knowing the difference

Breathing is the Heart of Mindfulness – recorded track

Pay careful attention to your breath, you don't need to change your pattern of breathing – just bring your attention to your natural breath. You may want to focus in on that part of your body where you notice the breath the most – your nose, your belly, your lungs.

Eating a Raisin Mindfully - recorded track

Module 2 – Sitting Meditation

Key Concepts

Mindfulness is sometimes described as a bird with two wings: compassion and awareness. In order to practice Mindfulness – like flight – you need both wings.

Awareness will help you recognize that you are feeling stressed.

Compassion will allow you to look at your situation with kindness – smiling will help you to cultivate this self-compassion and compassion toward others. Be aware if you are being negative or self-critical and if this is happening to you simply be aware of it and then meet those thought with kindness so they will let go of you.

Mindfulness of the breath is the foundation of every one of the mindfulness practices – simply being aware of the breath is a powerful antidote to stress. Breath and smile.

Just Sit and do nothing. Shift out of autopilot and switch from "doing" to "being" Just sit and be aware of the breath.

Sitting like a Mountain. – recorded track

Daily practice is important

Module 3 – Body Scan

Key Concepts

Don't allow yourself to be pulled away from the present moment, recognize the healing power of a simple present-moment experience.

If you notice yourself thinking about the past or the future or realize your mind has wondered, simply return to the present by using your breathing as an anchor.

Mindfulness will help you to notice the good things that happen in life more because you will be more aware of and grateful for the positive things in your life by spending some time in the present moment considering those things you are grateful for….

Since the mind and the body are deeply connected, releasing stress in your body will help you to release stress in your mind. This is what the body scan allows you to do. It is a gift to your body because it is an invitation of energy into the body from your mindfulness practice.

The body scan is good to practice at night before you go to sleep also.

Body Scan – recorded track

Handling Pain and Discomfort with the Body Scan

Module 4 – Mindfulness of Thinking and Everyday Mindfulness
Key Concepts

Too busy for mindfulness? Stories of including mindfulness in everyday living

Informal Mindfulness – bringing mindful awareness into routine activities you already have

Mindful Eating

The link between formal and informal mindfulness practice – SOBER
    1. Stop 2. Observe 3. Breathe 4. Expand 5. Respond

       Practice mindfulness in small ways everyday

Module 5 – Loving Kindness Meditation & Mindfulness Movement
Key Concepts

Loving Kindness Meditation
Your thoughts are powerful and can become your reality

Automatic thoughts exercise.

Mindfulness of thinking – recorded track

Mindful movement is the practice of moving your body intentionally with care and attention to what is happening with each movement.

Mindful movement – recorded track

Module 6 – Review & Tips for Maintaining Mindfulness Practice
Key Concepts
Breath
Awareness and Compassion
Listen to recordings
Mindfulness in a Moment and in Everyday Living

DUQUESNE UNIVERSITY

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

PARENTAL PERMISSION AND CONSENT FORM FOR YOUR CHILD TO PARTICIPAT IN A RESEARCH STUDY

TITLE:	Mindfulness Based Stress Reduction (MBSR) for Adolescents with Type 1 diabetes (T1D)
INVESTIGATOR:	Denise E. Van Sant – Smith, MSN, RN, CNE PhD Candidate, Duquesne University School of Nursing Bayville, NJ 732 330 8871 vansantsmithd@duq.edu
ADVISOR:	Dr. Linda Goodfellow Associate Professor of Nursing Duquesne University 312 Fisher Hall Pittsburgh, PA 15282 412-396-6548 goodfellow@duq.edu
SOURCE OF SUPPORT:	This study is being performed as partial fulfillment of the requirements for the PhD degree in Nursing at Duquesne University.
PURPOSE:	Your child is being asked to participate in a research project that seeks to investigate the effects of learned Mindfulness Based Stress Reduction (MBSR) on psychosocial and physiological measures of wellness in adolescents with T1D. MBSR is about learning to focus on the present which helps people to stop worrying about the past or the future. This may help your child feel less stressed.

In order to qualify for participation, your child must be 12 to 17 years old with Type 1 diabetes and have access to a computer with internet access.

PARTICIPANT PROCEDURES

MBSR is about paying attention and focusing on the present moment without negative judgment. It is also about learning how to stop worrying about the future and/or fixating on the past. MBSR has been used to help many different people with varying medical and/or psychological issues to feel more comfortable and less stressed. We want to see if it will do that for adolescents with Type 1 diabetes.

To participate in this study, your child will be randomly assigned to either the intervention or control group. Both groups answer the questionnaires and do fingerstick blood tests of their HbA1c. The control group participants do not go through the modules to learn MBSR right away. Should your child be assigned to the control group, they will have the opportunity to learn MBSR after their data have been collected. Having the control group will help us compare the results of the control group and the intervention group to determine whether MBSR helps adolescents with Type 1 diabetes.

If your child has been assigned to the intervention group, you and your child will receive instructions on MBSR via an online, age-appropriate website. You and your child will have access through this log in to the website. The website will include six modules for your child to learn MBSR. Once your child has completed the training, your child will be asked to practice mindfulness each day for approximately 10-15 minutes. Email/text reminders will be sent to your child.

Regardless of whether your child was assigned to the MBSR intervention group or the control group, your child will be asked to complete two questionnaires at the beginning of the study about their quality of life; how he/she feels; and questions about their mindfulness experience. These questionnaires will be administered two additional times including 6 weeks after they learn about mindfulness in the online modules and then again at the end of the study. It will take approximately 25 minutes each time they are asked to complete these questionnaires. Your child

will also be asked to complete a demographic form and Perceived Stress Scale one time at the beginning of the study.

You will be asked to assist your child in collecting a drop of blood from their finger two times to measure their HbA1c at the beginning of the study and at the end of the study. Each HbA1c test will determine your child's average blood sugar over the previous 90 days. The HbA1c test kits will be provided to you at no cost via U.S. Mail and the results of the test will be available to you in 5 minutes. You will be asked on both occasions to provide those results to the researcher via e-mail. These are the only requests made of you or your child.

RISKS AND BENEFITS:

There are minimal risks associated with participation but no greater than those encountered in everyday life. There may or may not be any direct benefits in participation. However, your child will have the opportunity to learn a stress management technique that may help them reduce stress associated with Type 1 Diabetes. In addition, you and your child will have the benefit of knowing that your participation in this study may help other nurses and health care providers to provide care to children with Type 1 Diabetes

COMPENSATION:

Your child will be compensated with a $15.00 *itunes* or *Amazon* gift card for agreeing to participate and completing the demographic survey, the stress scale, the first two questionnaires and the HbA1c test at Time 1. The gift card will be sent via U.S. Mail upon confirmation of the receipt of HbA1c results. At the end of the study, participants will be given an additional $25.00 *itunes* or *Amazon* gift card upon receipt of the completed questionnaires and second HbA1c test results. The gift card will be sent via U.S. Mail upon confirmation of the receipt of HbA1c results.

Participation in the project will require no monetary cost to you.

CONFIDENTIALITY:

Your child's participation in this study and any personal information that is provided will be kept confidential at all times and to every extent possible.

Your child's name will never appear on any survey or research instruments. All written and electronic forms and study materials will be kept secure. Their response(s) will only appear in statistical data summaries. Any study materials with personal

identifying information will be maintained for three years after the completion of the research and then destroyed.

RIGHT TO WITHDRAW: You and your child are under no obligation to participate in this study. Either or both of you are free to withdraw your consent to participate at any time by contacting Denise Van Sant- Smith via phone at 732-330-8871 or via e-mail at vansantsmithd@duq.edu. Should you decide to withdraw your participation or your child's participation, any iinformation already provided will be destroyed.

SUMMARY OF RESULTS: A summary of the results of this research will be supplied to you, at no cost, upon request.

VOLUNTARY CONSENT: I have read the above statements and understand what is being requested of me and my child. I also understand that our participation is voluntary and that we are free to withdraw our consent at any time, for any reason. On these terms, I certify that I am willing to allow my child to participate in this research project.

I understand that should I have any further questions about my participation in this study, I may call Denise Van Sant – Smith, MSN, RN 732-xxx-xxxx and/or my Advisor, Dr. Linda Goodfellow. Should I have any questions regarding protection of human subject issues, I may call Dr. James Phillips, Acting Chair of the Duquesne University Institutional Review Board, at 412-396-1886.

_____   _____

Participant's Signature   Date

_____   _____

Researcher's Signature   Date

139

DUQUESNE UNIVERSITY

600 FORBES AVENUE   ♦   PITTSBURGH, PA 15282

ASSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

TITLE:	Mindfulness Based Stress Reduction (MBSR) for Adolescents with Type 1 diabetes (T1D)
INVESTIGATOR:	Denise E. Van Sant – Smith, MSN, RN, CNE PhD Candidate, Duquesne University School of Nursing Bayville, NJ vansantsmithd@duq.edu
ADVISOR:	Dr. Linda Goodfellow Associate Professor of Nursing Duquesne University 312 Fisher Hall Pittsburgh, PA 15282 goodfellow@duq.edu
SOURCE OF SUPPORT:	This study is being performed as partial fulfillment of the requirements for the PhD degree in Nursing at Duquesne University.
PURPOSE:	You are being asked to participate in a research project. This project will teach you how to do mindfulness using an online website. We are interested to see whether Mindfulness Based Stress reduction will help you reduce any stress that you may have due to your diabetes. In order to be a participant you must be 12 to 19 years old with Type 1 diabetes and be able to use a computer with internet access.
PARTICIPANT PROCEDURES:	Participation in this study means you will have access to a website that teaches you about Mindfulness Based Stress

Reduction which is also called MBSR. Learning how to do MBSR helps you pay attention to the present moment and not worry about the past or the future so much. Some people have found that it helps them feel more comfortable even in stressful situations.

Before you begin participating in this study, we will have a computer program decide whether you will be in the group that learns MBSR now or learns it later. Whether you learn MBSR now or later, there will be questions on certain topics like how you feel about diabetes and about mindfulness.

To participate in this study and learn about mindfulness, you will receive instructions through six different learning sections on the website. Once you have completed the training, you will be asked to practice some of the mindfulness lessons you learned each day for approximately 10 – 15 minutes. Email/text reminders will be sent to remind you to do this.

In addition, you will be asked to answer questions about yourself, about what you think about your life and about mindfulness. They are questions about your opinions and what you think. They are not tests. You will be given these questions before you learn about mindfulness, right after you are done learning about it and 90 days after you learned about it on the website. It will take you about 20 minutes each time you are asked to answer the questions.

Also, you will be asked to do the HbA1c test. You will do this blood test at the very beginning and at the very end. This is the small sample of blood from a finger stick that will give us your average blood sugar over the last 90 days. We will ask your parents to help you do this test. It only takes about 5 minutes to get the results and we will ask your parents to email the results to us. You have probably done this test many times at the doctor's office. TheHbA1c test kits will be provided to you at no cost to you or your family and will be mailed to you.

RISKS AND BENEFITS: There are very few, if any risks in taking part in this study. You may or may not get some benefit from participating. However, you will have the chance to learn about a stress management technique that may help you reduce stress in your life or may help you manage some of the issues with having to deal with

diabetes. In addition, you have the benefit of knowing that your participation in this study may help other nurses and health care providers to provide care to other children and teens like you with Type 1 Diabetes.

COMPENSATION:
For participating in this study, you will get a $15.00 *iTunes* or *Amazon* gift card once you do the first part which includes four questionnaires and the HbA1c test. The gift card will be mailed to you at your home. At the end of the study you will also be given an additional $25.00 *iTunes* or *Amazon* gift card after you complete two questionnaires and your parents send us the second set of HbA1c test results. This second gift card will also be sent to you in the mail.

Participation in the project will not cost you or your parents any money.

CONFIDENTIALITY:
Your participation in this study and any personal information that you provide will be kept safe at all times. No one will ever know that you were in the study or what you told us.

Your name will never appear on any survey or research instruments. All written and electronic forms and study materials will be kept safe and secure. Your response(s) will only appear in statistical data summaries. Any study materials with personal information about you and about what you wrote on the questionnaires will be kept by us for three years after the research is complete and then it will be destroyed.

RIGHT TO WITHDRAW:
You are not required to be a part of this study. You can say you don't want to stay in the study even after it starts. You can contact the researcher by phone or e-mail to say you do not want to participate any longer. You would contact: Denise Van Sant-Smith via phone at 732-330-8871 or via e-mail at vansantsmithd@duq.edu.

SUMMARY OF RESULTS:
A summary of the results of this research will be supplied to you, at no cost, if you request it.

VOLUNTARY CONSENT: I have read the above statements and understand what is being asked of me. I also understand that my participation is voluntary and that I can stop at any time, for any reason. On these terms, I am willing to participate in this research project.

I understand that should I have any further questions about my participation in this study, I may call Denise Van Sant – Smith, MSN, RN 732-xxx-xxxx and/or my Advisor, Dr. Linda Goodfellow at 412-xxx-xxxx. Should I have any questions regarding protection of human subject issues, I may call Dr. James Phillips, Acting Chair of the Duquesne University Institutional Review Board, at 412-396-1886.

_____   _____

Participant's Signature   Date

_____   _____

Researcher's Signature   Date

DUQUESNE UNIVERSITY

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Mindfulness Based Stress Reduction (MBSR) for Adolescents with Type 1 diabetes (T1D)

INVESTIGATOR: Denise E. Van Sant – Smith, MSN, RN, CNE
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ADVISOR: Dr. Linda Goodfellow
Associate Professor of Nursing
Duquesne University
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Pittsburgh, PA 15282

goodfellow@duq.edu

SOURCE OF SUPPORT: This study is being performed as partial fulfillment of the requirements for the PhD degree in Nursing at Duquesne University.

PURPOSE: You are being asked to participate in a research project that seeks to investigate the effects of learned Mindfulness Based Stress Reduction (MBSR) on psychosocial and physiological measures of wellness in adolescents with Type 1 Diabetes. MBSR is about learning to focus on the present which helps people to stop worrying about the past or the future. This may help you feel less stressed.

In order to qualify for participation, you must be 12 to 19 years old with Type 1 diabetes, with no cognitive impairments, and have access to a computer with internet access.

PARTICIPANT PROCEDURES:

MBSR is about paying attention and focusing on the present moment without negative judgment.   It is also about learning how to stop worrying about the future and/or fixating on the past. MBSR has been used to help many different people with varying medical and/or psychological issues to feel more comfortable and less stressed. We want to see if it will do that for adolescents with Type 1 diabetes.

To participate in this study, you will be randomly assigned to either the intervention or control group. Both groups answer the questionnaires and do a fingers stick blood test of their HbA1c. The control group participants do not go through the modules to learn MBSR right away. If you are assigned to the control group, you will have the opportunity to learn MBSR after your data has been collected. Having the control group helps us compare the results of the control group and the intervention group to determine whether MBSR helps adolescents with Type 1 diabetes.

If you are assigned to the intervention group, you will receive instructions on MBSR via an online, age-appropriate website. You will have access through this log in to the website.   The website will include six modules to learn MBSR. They are each less than 30 minutes. Once you have completed the training, you will be asked to practice mindfulness each day for approximately 10 – 15 minutes. Email and or texts will be sent to remind you about the modules and practicing.

Regardless of whether you are assigned to the MBSR intervention group or the control group, you will be asked to complete two questionnaires at the beginning of the study about your quality of life; how you feel; and questions about your mindfulness experience. These questionnaires will be administered two additional times including 6 weeks after you learn about mindfulness in the online modules and then again at the end of the study. It will take approximately 25 minutes each time you are asked to complete these questionnaires. You will also be asked to complete a demographic form and Perceived Stress Scale one time at the beginning of the study.

You will be asked to perform a finger stick HbA1c home test kit twice: at the beginning of the study and at the end of the study. The HbA1c test kit determines your average blood sugar over the previous 90 days. The HbA1c test kits will be provided to you at no cost via U.S. Mail and the results of the test will be available to you in 5 minutes. You will be asked on both occasions to provide those results to the researcher via e-mail. These are the only requests made of you.

RISKS AND BENEFITS: There are minimal risks associated with participation but no greater than those encountered in everyday life. There may or may not be any direct benefits in participation. However, you will have the opportunity to learn a stress management technique that may help you reduce stress associated with Type 1 Diabetes. In addition, you will have the benefit of knowing that your participation in this study may help other nurses and health care providers to provide care to adolescents with Type 1 Diabetes.

COMPENSATION: You will be compensated with a $15.00 *iTunes* or *Amazon* gift card for completing the demographic survey, the stress scale, the first two questionnaires and the HbA1c test at Time 1. The gift card will be sent via U.S. Mail upon confirmation of the receipt of HbA1c results. At the end of the study, you will also be given an additional $25.00 *iTunes* or *Amazon* gift card upon receipt of the completed questionnaires and second HbA1c test results. The gift card will be sent via U.S. Mail upon confirmation of the receipt of HbA1c results.

Participation in the project will require no monetary cost to you.

CONFIDENTIALITY: Your participation in this study and any personal information that is provided will be kept confidential at all times and to every extent possible.

Your name will never appear on any survey or research instruments. All written and electronic forms and study materials will be kept secure. The response(s) will only appear in statistical data summaries. Any study materials with personal identifying information will be maintained for three years after the completion of the research and then destroyed.

RIGHT TO WITHDRAW: You are under no obligation to participate in this study and you are free to withdraw your consent to participate at any time by contacting Denise Van Sant- Smith via phone at 732-330-8871 or via e-mail at vansantsmithd@duq.edu. Should you decide to

withdraw your participation, any information already provided will be destroyed.

SUMMARY OF RESULTS: A summary of the results of this research will be supplied to you, at no cost, upon request

VOLUNTARY CONSENT: I have read the above statements and understand what is being requested of me I also understand that participation is voluntary and that we are free to withdraw our consent at any time, for any reason. On these terms, I certify that I am willing to participate in this research study.

I understand that should I have any further questions about my participation in this study, I may call Denise Van Sant – Smith, MSN, RN 732-xxx-xxxx and/or her Advisor, Dr. Linda Goodfellow at 412-xxx-xxxx Should I have any questions regarding protection of human subject issues, I may call Dr. David Demonico, Chair of the Duquesne University Institutional Review Board, at 412-396-1886.

_____   _____

Participant's Signature   Date

_____   _____

Researcher's Signature   Date