Duquesne University IRB
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Protocol Summary Form

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The Psychosocial and Physiological Effects of Teaching Mindfulness Based Stress Reduction (MBSR) to Adolescents with Type 1 Diabetes

Research Questions

Does a learned mindfulness based stress reduction program offered online increase mindfulness and improve quality of life in adolescents with Type 1 diabetes compared to a control group of adolescents with Type 1 diabetes?

Does a learned mindfulness based stress reduction program offered online result in the physiological benefit of reduced HbA1c measurements in adolescents with Type 1 diabetes compared to a control group of adolescents with Type 1 diabetes?

Purpose and significance of the study

The prevalence of Type 1 diabetes 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 (Tilden, Charman, Sharples, & Fosbury, 2005). The fact that Type 1 diabetes strikes most often in childhood also has significant implications for disease management. Considerable stress is associated in adolescents with Type 1 diabetes (Watts, O'Hara, & Trigg, 2010). It is imperative that nurses and other health care professionals find ways by which stress can be reduced in the service of improving quality of life.

Mindfulness-based stress reduction (MBSR) programs have been shown to enhance psychosocial and physical wellness (Prouix, 2003). Several studies have examined the use of MBSR in adolescents in various populations, but to date no study has been specifically designed for adolescents with Type 1 diabetes. In addition, several online programs and e-health systems have been utilized to enhance delivery of psychoeducation on diabetes management for adolescents with Type 1 diabetes (Wittemore, et al., 2013; Tercyak, Abraham, Graham, Wilson, & Walker, 2009).

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 Type 1 diabetes focused on well-known issues of adolescence such as peer pressure and relationships with family (Bernstein, Stockwell, Gallagher, Rosenthal, & Soren, 2013; Helgeson, Escobar, Siminerio, & Becker, 2010). 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, Boland, Davidson, Li, & Tamborlane, 2000); 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) and in delivery format such as online, web-based mindfulness training (Davis & Zautra, 2013). MBSR has 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 Type 1 diabetes.

Engel's biopsychosocial model will be used to guide this study. The model has frequently been used to address treatment of those with cancer and diabetes because biological, psychological and social components of these chronic illnesses have been found to have a significant impact on effective disease management. Based on the autoimmune nature and difficult psychomotor demands of Type 1 diabetes management, this study with a focus on adolescents with this chronic autoimmune condition, has the potential to provide important data about the relationship between stress and effective disease management. The significance of this nursing research study is in the potential for improving the quality of life and management of diabetes by reducing the HbA1c of adolescents with Type 1 diabetes through the use of MBSR. The use of MBSR could provide a stress management technique for this population that would improve management of diabetes leading to significant reductions in both physiological complications associated with diabetes and psychological stressors associated with the management and care of diabetes in adolescents.

Data from this study will advance the science of nursing and provide a better understanding of the challenges faced by adolescents with Type 1 diabetes, 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 provide diabetes health care professionals with evidence of a new and effective approach to improve care of adolescents with Type 1 diabetes. The specific aim of this study is to determine if a learned stress reduction method provided online will result in improvement of both psychosocial measurements of reported quality of life and physiological measurements of blood sugar control measured by HbA1c.

Research Design and Procedures

This study will utilize a between group repeated measures design to measure the effects of the learned MBSR intervention over time. MBSR will be the independent variable. Dependent variables include mindfulness, diabetic quality of life and HbA1c. Adolescents with Type 1 diabetes will be randomly assigned to an intervention group or a wait list/control group that will be offered MBSR after all data has been collected. The study will utilize a 2 (experimental versus wait-list control group) by 3 (pretest [Time 1], posttest [Time 2], and 3 month follow-up [Time 3]) to examine within and between group differences overtime on two psychosocial measures including mindfulness and quality of life. The physiological measure understudy, HbA1c, reflects glucose control over the previous three month period and will be measured at Time 1 and Time 3. MBSR training will be provided via an online website and secure data collection site called *MySweetMind.org*.

Instruments

Two questionnaires will be used to collect data on psychosocial measures at the three time points including: 1) Diabetes Quality of Life Measure for Youths (YDQOL) (Ingersoll & Marrero, 1991) (Appendix A) and, 2) Mindful Attention and Awareness Scale for Adolescents (MAAS-A) (Brown, 2011) (Appendix B). A researcher-generated demographic sheet (DDS) (Appendix C) will also be administered at Time 1 to describe the population. These questionnaires will be administered to the participants via a secure, online data collection site in both the experimental and control groups. In addition, HbA1c will be measured at the beginning of the study (Time 1) to measure blood glucose over the previous three month period and after three months of participation in the study (Time 3) in participants in both the experimental and control group

Diabetes Quality of Life Measure for Youths (YDQOL) (Appendix A) will be used to measure adolescents on life satisfaction, diabetes impact, worries about diabetes, school life and peers. The YDQOL has a Cronbach alpha of 0.92 (Ingersoll & Marrero 1991). The YDQOL will take approximately 15 minutes to complete.

Mindful Attention and Awareness Scale for Adolescents (MAAS-A) (Appendix B) (Brown, 2011) will be used to measure the effectiveness of mindfulness training in youths and has been found to correlate with psychological well-being and healthy self-regulation. Cronbach's alpha varies from .82 to .84 in adolescent populations. The MAAS-A takes approximately 10 minutes to complete.

The Demographic Data Sheet (DDS) was researcher generated (Appendix C) and includes 11 questions about the participants. This information will be used to describe the population understudy including age, gender, race, school grade and number of years with diabetes including date of diagnosis. Respondents will also be 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. The DDS will take less than 5 minutes to complete.

Glycated Hemoglobin test (HbA1c) (Appendix D) is a blood test requiring a venipuncture or finger stick. For this study, a finger stick will be self-obtained from each participant at Time 1 and Time 3. The instant HbA1c requires a drop of blood from the finger stick that provides results in 5 minutes. This measurement is useful because it is less affected by the day to day variations in blood glucose levels. The HbA1c is representative of average blood glucose over a 90 day period.

The HbA1c test kit will be 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 will be asked to put the card into a reader that provides the results in the form of an electronic read out within 5 minutes. Those with Type 1 diabetes are familiar with this process as it is a common diagnostic test performed in the Endocrinologist's office at each visit. It is also the same type of finger stick procedure these adolescents use to test their blood sugar as they regularly do approximately 4-8 times per day. The parents will then be asked to e-mail this information to the researcher at Time 1 and Time 3. Reminder texts and e-mails (Appendix E) will be sent to the participants in both the experimental and control group. Reminders will also be posted on the website.

Sample Selection and Size

The population under study will include adolescents with Type 1 diabetes between the ages of 12 and 17. To participate, adolescents will need to have the ability to read English at a sixth grade level with no cognitive impairment and have access to a computer and the Internet. A power analysis was conducted using a medium effect size of 0.25, power of .80 with alpha set at .05 using a two tailed test of significance; thus, a total sample size (N) of 86 (n=43), per group will be needed.

Recruitment of Subjects

Recruitment fliers (Appendix F) will be posted at pediatric endocrinology offices in New Jersey. In addition, email invitations will be sent through the Diabetes Education and Camping Association (DECA). The primary recruitment method will be 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 will be provided at intake and outtake days of the camp to the parents and campers. Both parents and camper will be given a postcard with the website address and general information about participating. Secondly, eleven Pediatric Endocrinology offices in New Jersey will be contacted in order to gain access to adolescent patients diagnosed with Type 1 diabetes. Physicians will be sent a letter (Appendix G) and asked to return an included post card if they are 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 (Appendix H) to adolescents and the parents of adolescents with Type 1 diabetes. Permission to recruit at these sites will be obtained. Additional recruitment activities will include word of mouth and announcements placed on the Internet via parent and child support groups.

Participants of this study will be able to participate in the privacy of their own home via a website for learning the MBSR program. Study participants will access the intervention through a developed website, *MySweetMind.org.* In addition, collection of all psychosocial data will occur via a secure online data collection site. HbA1c will be obtained via a self-collected finger-stick blood test at two specific time periods and the results will be sent by the participants' parents via email to the researcher for analysis.

Informed Consent Procedures

After obtaining approval from Duquesne University Institutional Review Board, recruitment activities will begin through the Diabetes Camp and several Pediatric Endocrinology offices.

Once a parent or adolescent contacts the investigator either by phone or e-mail, they will be screened via phone conversation for recruitment into the study by the researcher. Criteria for inclusion in the study is: (a) between the ages of 12 and 17; (b) ability to read English at a 6th grade level; (c) diagnosis of Type 1 diabetes; (d) no cognitive impairment as reported by parent; and (e) access to a computer and internet. Existing blood sugar control will not be used as inclusion or exclusion criteria. If the potential participant qualifies for the study, both adolescent and parent will be given the log in information.

The website will be accessible only through log in and is a private website; additional security was added by purchasing secure sockets layer (SSL) encryption for the website. A secure connection is created between the participant and the server which provides compliance with HIPPA regulations and confirms the security of the data. Potential participants and parents will be able to gain access to the content of the *MySweetMind.org* website through contact with the investigator once they obtain log in instructions via phone or e-mail.

Upon logging in to the website, the process of obtaining parental permission/consent and participant assent will begin. Once potential participants have had a chance to review the content and better understand the research study and what will be expected of them, they will have the opportunity to ask any additional questions online, via e-mail, or via telephone conversation with the researcher. Once all questions have been answered, assent and parental permission/consent forms will be sent via mail and returned via a prepaid envelope. Once obtained, participants and their parents will be given the online access code to the *MySweetMind.org* website. All assent forms and parental permission/consent forms will be stored in a locked cabinet in the PI's home office.

MBSR Online Intervention

The principles of MBSR will be divided into 6 main modules delivered in the online, web-based format via the website*: MySweetMind.org* (Appendix I*)*. Participants will be given a password to access a 6 week module-based site to learn Mindfulness Based Stress Reduction adapted for adolescents. This adaptation of MBSR is based on the work of Dzung X. Vo, MD, FAAP and Jake Locke, MD as presented in the book (2015) written by Dr. Vo, *The Mindful Teen*. The major topics included in each module are as follows: Module 1- Introduction to Mindfulness, Mindful Eating; Module 2 – Sitting Meditation; Module 3 – Body Scan; Module 4 – Mindfulness of Thinking & Everyday Mindfulness; Module 5 – Loving Kindness Meditation & Mindfulness Movement; and, Module 6 - Review & Tips for Maintaining a Mindfulness Practice. The key concepts for each module are shown in Appendix D. The website, *MySweetMind.org*, is currently under construction. The design will be user friendly, attractive and age appropriate. Each of the modules listed above will have short video vignettes (5-10 minutes) describing the content for current module. As the participant enters each module they will see images, hear music and voice descriptions which describe the mindfulness concept for that module. Also, the participant will see a written outline of the material that can easily be printed out, if the participant chooses to. In addition, suggestions for practice of the material will be given for each module. As the participant completes modules, they receive tokens representative of that completion which move forward as progress is made through the modules. The website is being designed to work on smaller devices such as phones and tablets as well as a computer.

Collection of Data and Method of Data Analysis

Upon initial access of the website, the participant will be asked to first complete the DDS, YDQOL and MAAS questionnaires delivered online and submitted online. In addition, the participants will be asked to test their HbA1c using a finger stick home testing kit that will be

sent via US mail to the parents of the adolescents who have agreed to participate. The parent of the participant will be asked to e-mail the results of the HbA1c to the PI.

Once all Time 1 data have been obtained, the participant will begin to go through the modules learning mindfulness. Within the website, the participant will be prompted to go to the diary page where the time spent on each module and time spent practicing the concepts of it will be recorded. This diary data will be accessible to the researcher. At the end of the 6 weeks allotted for the Module progression, the participants will be asked to take the YDQOL and the MAAS-A questionnaires again online. They will be encouraged to practice the mindfulness modules for 10-15 minute daily which will continue to be available. At Time 3, the participants in both the experimental and control groups will be asked to take the YDQOL and the MAAS-A questionnaires again one last time. The HbA1c test kit will also be sent to the home again and the results of this test will be emailed to the researcher. Those randomly assigned to the control group and thus, not yet had the opportunity to learn MBSR will be asked to take the YDQOL and MAAS-A questionnaires again at Time 2 and then the YDQOL and MAAS-A along with another HbA1c at Time 3. Once all data has been collected from those participants randomly assigned to the control group, participants will be offered the MBSR intervention.

Participants will be given a $15.00 *iTunes or Amazon* gift card for completing the first three questionnaires and the HbA1c test at Time 1. The gift card will be sent via U.S. Mail upon confirmation of the receipt of the HbA1c results and completion of the questionnaires. At the end of the study, participants will be sent via U.S. Mail an additional $25.00 *iTunes* or *Amazon* gift card upon receipt of the second HbA1c test results and completed questionnaires.

Procedures for the participants randomized to the control group will follow the same procedures as noted above except that they will not have access to the MBSR learning modules until the end of the three month data collection period. Those who were placed in the control group will be provided the opportunity to access the website and utilize the modules to learn mindfulness after all data have been collected and the intervention was shown to be effective in at least one variable measured.

Planned Analysis

Descriptive statistics will be 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 will be 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 will be tested to determine whether or not parametric testing can be done. Although parametric testing is planned, it may be that the equivalent nonparametric test will be used to analyze data. In addition, a correlational matrix will be created to determine whether any two variables co-vary at > 0.65. Two way repeated measures Analysis of Variance (RM-ANOVA) will be used to answer the research questions.

Interactions with Subjects and Subjects' rights

In the development of this study, careful consideration was given to maintain the 7 principles as outlined within the NIH document concerning treatment of research subjects. Specific to the

interactions with subjects, a fair subject selection will be utilized, IRB approval and informed consent will be obtained. Additionally, respect for enrolled subjects will be demonstrated by checking on their well-being as they participate, maintaining confidentiality and sharing results with them once the study is complete. Those subjects who are in the control group will also be given the opportunity to learn MBSR at the completion of data gathering since it has been shown in many populations to be a benefit and advantage to individuals with varied health conditions.

All information gathered including data, parental permission/consent and assent forms will be stored in a locked cabinet with careful attention to the privacy of participants and security of all materials. The website will be accessible only through log in and is a private website; additional security was added by purchasing secure sockets layer (SSL) encryption for the website. A secure connection is created between the participant and the server which provides compliance with HIPPA regulations and confirms the security of the data. Only the researcher and advisor will have access to the data collected.

Appendix A
Diabetes Quality of Life for Youths Questionnaire (DQOL)

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 How Often 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, school or household duties because of your diabetes?	[1]	[2]	[3]	[4]	[5]
B12:	How often do you find yourself explaining what it means to have diabetes?	[1]	[2]	[3]	[4]	[5]
B13:	How often do you find that your diabetes interrupts your leisure time activities?	[1]	[2]	[3]	[4]	[5]
B14:	How often are you teased because you have diabetes?	[1]	[2]	[3]	[4]	[5]
B15:	How often do you feel that because of your diabetes you go to the bathroom more than others?	[1]	[2]	[3]	[4]	[5]
B16:	How often do you find you eat something you shouldn't rather than tell someone that you have diabetes?	[1]	[2]	[3]	[4]	[5]
B17:	How often do you hide from others the fact that you are having an insulin reaction?	[1]	[2]	[3]	[4]	[5]

		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]

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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
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	Never	Seldom	Sometimes	Often	All the Time
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]

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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

Reminder Text/email content:

Hello,
This is a reminder that the HbA1c test kit has been sent. Please take 5 minutes to obtain and email these results. Thank you.

Please email or text with any questions.

Thanks,
Denise
732-330-8871 cell

Duquesne University IRB
Protocol #2015-10-14
Approved: 11-19-2015
Expiration Date: 11-18-2016

Appendix F

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

Invitation to Participate in a Research Study

Adolescents ages 12-17 with Type 1 Diabetes

This study will examine the effects of
Mindfulness Based Stress Reduction (MBSR)

This Mindfulness program may help positive youth development and resilience by teaching core mindfulness practices. Participants learn valuable strategies to focus on the present and stop worrying about the past or future.

The research is done via an online, age-appropriate website. Participants will be required to have access to a computer and the Internet. Participants will receive a $15 *iTunes* or *Amazon* gift card for completing the first part of the study and then an additional $25 iTunes or Amazon gift card at the end of the study.

For additional information please contact:
Denise Van Sant – Smith, MSN, RN, PhD candidate
Duquesne University School of Nursing
732-330-8871
vansantsmithd@duq.edu

Appendix G

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.org.

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. My cell phone number is 732-330-8871

Sincerely,

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

Duquesne University IRB
Protocol #2015-10-14
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Expiration Date: 11-18-2016

Appendix H

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_____
_____

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Appendix I

Key Concepts for www.mysweetmind.org 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

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