



DUQUESNE UNIVERSITY

600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

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

- 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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- 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 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 your child feel less stressed.
- In order to qualify for participation, your child must be 12 to 17 years old with Type 1 diabetes, 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, your child 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. 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 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 completing the demographic survey, 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 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 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 732-330-8871 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