



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:

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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:

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 finger 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 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 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 732-330-8871 and/or her Advisor, Dr. Linda Goodfellow at 412-491-6355. 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