

Study title: Mindfulness and Diabetes Distress: Acceptability of Self-Led
Mindfulness-Based Intervention

Document Date: 11/22/2019

Approved by the University of Nevada, Reno Institutional Review Board on
12/13/2019

1. Parental Consent Form

University of Nevada, Reno
Parent Permission Information Sheet for Social Behavioral Research

Title of Study: Reducing Type 1 Diabetes Stress: An At-Home Workbook Study

Principle Investigator: Amy Hughes Lansing, PhD

Study ID Number: 1221205

Introduction

Your child is being invited to participate in a research study. Before you agree to your child's participation in the study, read this form carefully. It explains why we are doing the study; and the procedures, risks, discomforts, benefits and precautions involved.

At any time, you or your child may ask one of the researchers to explain anything about the study that you or your child do not understand.

Your child does not have to be in this study. Her/his participation is voluntary. If you do not agree for your child to participate, your child will receive the care she/he would have received if the study was not taking place.

Take as much time as you need for you and your child to decide. If you agree now but change your mind, you may withdraw your child from the study at any time. Just let one of the researchers know you do not want your child to continue.

Why are we doing this study?

We are doing this study to find out better ways to help teens with type 1 diabetes reduce stress.

Benefits of research cannot be guaranteed; however, we hope to learn if completing a workbook on mindfulness-based stress reduction can help reduce stress in teens with type 1 diabetes and improve their quality of life and disease management and outcomes.

Why are we asking your child to be in this study?

We are asking you to allow your child to participate because she/he is aged 13-17, has been diagnosed with type 1 diabetes, is attending or has completed high school and is not a ward of the state, or experiencing severe developmental delays or severe psychiatric disturbances.

How many people will be in this study?

We expect to enroll 65 participants at the University of Nevada, Reno.

What will your child be asked to do if you agree to allow your child to be in the study?

If you give permission for your child to be in this research study, she/he will be asked to:

1. Complete an online survey to answer questions about their health and wellbeing and share data from their glucometer as well as share their HbA1c test results from their medical provider.
2. Be randomized to complete the mindfulness based stress reduction workbook either at the time of starting the study or in 10 weeks after starting the study.
3. Complete another online survey after 10 weeks and share data from their glucometer and share HbA1c from medical provider.
4. Complete brief weekly surveys about the intervention during the 10-weeks they use the workbook.
5. Complete a final online survey after 20 weeks and share data from their glucometer and share HbA1c from medical provider.

How long will your child be in the study?

The study will take about six months of your child's time; she/he will participate for about 10 active weeks of workbook with two surveys and one additional online survey at 20 weeks.

What are your choices if your child does not volunteer to be in this research study?

If you and/or your child decide not to be in the study, your other choices may include:

- Getting standard treatment for your child's type 1 diabetes without being in a study.

What if you agree to have your child be in the study now, but change your mind later?

Your child does not have to stay in the study. There will be no changes to your child's medical care if you chose to leave the study. You may withdraw your child or your child may withdraw from the study at any time by contacting Amy Hughes Lansing at (775) 784-6828.

What if the study changes while your child is in it?

If anything about the study changes or if we want to use your child's information in a different way, we will tell you and your child, and ask if your child will remain in the study. We will also tell you about any important new information that may affect your willingness allow your child to stay in the study.

Is there any way being in this study could be bad for your child?

This study is considered to be minimal risk of harm. This means the risks of your child's participation in the research are similar in type or intensity to what your child encounters during their daily activities. If your child participates in this study she/he may experience boredom or people may find out that your child is in this study. We will keep electronic data in password protected and encrypted servers. We won't use your name on the files. Only people who work on the study will see your forms and we won't give out your name unless you tell us we can. The only other time we would give others information about you or your child is if we were worried about your child's safety or the safety of others.

What happens if your child becomes injured because of her/his participation in the study?

It is not expected that your child would become injured from reading a workbook on mindfulness based stress reduction. Some problems might happen that the researchers don't know about. It is important to let the researchers know if there is anything that you or your child don't like about the research study right away.

Will being in this study help your child in any way?

We cannot promise your child will benefit from being in this study but she/he may experience decreased stress from participating in this study.

Who will pay for the costs of your child's participation in this research study?

No costs are associated with participation in this study.

Will you (or your child) be paid for your child's participation in this study?

You will receive a gift card of up to \$50 for participation. Participants will receive \$10 for each time they complete the assessment measures (baseline, 10 weeks, 20 weeks). Participants will also receive \$10 for completing at least six of the ten weekly surveys assessing their use of the workbook over the ten-week intervention period. Participants who complete all of these surveys will receive an additional \$10, resulting in a maximum gift card amount of \$50.

Who will know that your child is in this study and who will have access to the information we collect about your child?

The researchers, University of Nevada, Reno Institutional Review Board, and US Department of Health and Human Services (DHHS) will have access to your child's study records.

How will we protect private information about you and your child, and the information we collect about your child?

We will treat your identity and that of your child with professional standards of confidentiality and will protect your and your child's private information to the extent allowed by law. We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. We will not disclose any information you provide without written permission. All child responses and data are kept strictly confidential and we will not share answers on questionnaires or data. However, if we are concerned about your child's safety or safety of another person, we may need to contact the appropriate authorities.

We keep your records and all electronic data in locked files and rooms. We use an ID number on files and data, and not your name. Our computer files are password protected and data is stored on encrypted servers.

We will not use your name or your child's name or other information that could identify you or your child in any reports or publications that result from this study unless you provide written permission.

Do the researchers have monetary interests tied to this study?

The researchers and/or members of their families have no monetary interests tied to this study.

Who can you contact if you have questions about the study or want to report an injury?

At any time, if you have questions about this study or wish to report an injury that may be related to your child's participation in this study, contact Amy Hughes Lansing at (775) 784-6828.

Who can you contact if you want to discuss a problem or complaint about the research or ask about your child's rights as a research participant?

You may discuss a problem or complaint or ask about your child's rights as a research participant by calling the University of Nevada, Reno Research Integrity Office at (775) 327-2368. You may also use the online *Contact the Research Integrity Office* form available from the [Contact Us page](#) of the University's Research Integrity Office website.

Agreement to be in the study

If you agree to allow your child to be in this study, you must click yes below.

☐ Yes, I agree to allow my child to participate in this study.

☐ No, I do not agree to allow my child to participate in this study.

2. Participant Consent/Assent Form

**University of Nevada, Reno
Social Behavioral Research Consent/Assent Information Sheet**

Title of Study: Reducing Type 1 Diabetes Stress: An At-Home Workbook Study

Principle Investigator: Amy Hughes Lansing, PhD

Study ID Number: 1221205

Introduction

You are being invited to participate in a research study. Before you agree to be in the study, read this form carefully. It explains why we are doing the study; and the procedures, risks, discomforts, benefits and precautions involved.

At any time, you may ask one of the researchers to explain anything about the study that you do not understand.

You do not have to be in this study. Your participation is voluntary. If you do not agree to participate, you will receive the care you would have received if the study was not taking place.

Take as much time as you need to decide. If you agree now but change your mind, you may quit the study at any time. Just let one of the researchers know you do not want to continue.

Why are we doing this study?

We are doing this study to find out better ways to help teens with type 1 diabetes reduce stress.

Benefits of research cannot be guaranteed; however, we hope to learn if completing a workbook on mindfulness-based stress reduction can help reduce stress in teens with type 1 diabetes and improve their quality of life and disease management and outcomes.

Why are we asking you to be in this study?

We are asking you to be in this study because you are aged 13-19, have been diagnosed with type 1 diabetes, are attending or have completed high school and are not a ward of the state or experiencing severe developmental delays or severe psychiatric disturbances.

How many people will be in this study?

We expect to enroll 65 participants at University of Nevada, Reno.

What will you be asked to do if you agree to be in the study?

If you agree to be in this study, you will be asked to:

6. Complete an online survey to answer questions about your health and well-being and share data from your glucometer as well as HbA1c from your medical provider.
7. Be randomized to complete the mindfulness-based stress reduction workbook either at the time of starting the study or in 10 weeks after starting the study.
8. Complete another online survey after 10 weeks and share data from your glucometer and your HbA1c from your medical provider.
9. Complete brief weekly surveys about the intervention during the 10-weeks you use the workbook.
10. Complete a final online survey after 20 weeks and share data from your glucometer as well as your HbA1c from your medical provider.

How long will you be in the study?

The study will take about six months of your time; you will participate for about 10 active weeks of workbook with two surveys and one additional online survey at 20 weeks.

What are your choices if you do not volunteer to be in this research study?

If you decide not to be in the study, your other choices may include:

- Getting standard treatment for your condition without being in a study.

What if you agree to be in the study now, but change your mind later?

You do not have to stay in the study. There will be no changes to your medical care if you chose to leave the study. You may withdraw from the study at any time by contacting Amy Hughes Lansing at (775) 784-6828.

What if the study changes while you are in it?

If anything about the study changes or if we want to use your information in a different way, we will tell you and ask if you want to stay in the study. We will also tell you about any important new information that may affect your willingness to stay in the study.

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This study is considered to be minimal risk of harm. This means the risks of your participation in the research are similar in type or intensity to what you encounter during your daily activities. If you participate in this study, you may experience boredom or people may find out that you are in this study. We will keep electronic data in password protected and encrypted servers. We will not use your name on the files. Only people who work on the study will see your forms and we will not give out your name unless you tell us we can. The only other time we would give others information about you is if we were worried about your safety or the safety of others.

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It is not expected that you would become injured from reading a workbook on mindfulness based stress reduction. Some problems might happen that the researchers do not know about. It is important to let the researchers know if you have any problems or concerns right away.

Will being in this study help you in any way?

We cannot promise you will benefit from being in this study but you may experience decreased stress from participating in this study.

Who will pay for the costs of your participation in this research study?

No costs are associated with participation in this study.

Will you be paid for being in this study?

You will receive a gift card of up to \$50 for participation. Participants will receive \$10 for each time they complete the assessment measures (baseline, 10 weeks, 20 weeks). Participants will also receive \$10 for completing at least six of the ten weekly surveys assessing their use of the workbook over the ten-week intervention period. Participants who complete all of these surveys will receive an additional \$10, resulting in a maximum gift card amount of \$50.

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The researchers, the University of Nevada, Reno Institutional Review Board, and the US Department of Health and Human Services (DHHS) will have access to your study records.

How will we protect your private information and the information we collect about you?

We will treat your identity with professional standards of confidentiality and protect your private information to the extent allowed by law. We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. We will not disclose any information you provide without written permission. All responses and data are kept strictly confidential and we will not share answers on questionnaires or data. However, if we are concerned about your safety or safety of another person, we may need to contact the appropriate authorities.

We keep your records and all electronic data in locked files and rooms. We use an ID number on files and data, and not your name. Our computer files are password protected and data is stored on encrypted servers.

We will not use your name or other information that could identify you in any reports or publications that result from this study unless you provide written permission.

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The researchers and/or their families have no monetary interests tied to this study.

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CONSENT/ASSENT to be in study

If you agree to participate in this study, you must click yes below.

☐ Yes, I agree to participate in this study.

☐ No, I do not agree to participate in this study.