VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Sarah Jaser, PhD **Revision Date: 4/11/2022**
Study Title: Communication and Coping Randomized Trial
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
The purpose of the study is to test the effects of an intervention for mothers of adolescents with type 1 diabetes. We will be comparing a communication and coping intervention to an education intervention to see the effects on adolescents' diabetes outcomes. The reason for this study is that many mothers of adolescents with type 1 diabetes experience distress, and mothers' adjustment has been related to adolescents' outcomes.

You are being asked to participate in a research study because you are the parent of a child between the ages of 11 and 17 who has been diagnosed with type 1 diabetes for at least one year and is a patient at Vanderbilt's Eskind Pediatric Diabetes Clinic. You have also reported mild to moderate symptoms of depression or diabetes distress and you are a regular user of Facebook.

If you choose to participate, you and your child will complete surveys today and at the next few diabetes clinic appointments. You will be randomly assigned to either the communication and coping intervention or the education intervention. You will take part in individual phone calls and be invited to join a Facebook group for your intervention. There is only a small risk to be in the study, as we are mainly gathering information, and you may learn new strategies to help you manage your child's diabetes better.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:
If you agree to be in the study, you will be put into one of two groups: the communication and coping group or the diabetes education group. This will be done by chance (like the flip of a coin) – you can't choose which group you will be in. We will let you know which group you are in after you complete the surveys today and "friend" the study Facebook account.

You will be asked to complete surveys today and at your child's clinic visits in 3 months, 6 months, and 12 months. These surveys ask about your wellbeing and your feelings related to diabetes, parenting, and on your child's diabetes management and symptoms. It will take about 40 minutes to answer all the questions. We will also collect your child's A1C from their medical chart. We ask that you bring their meter(s) to clinic visits, so we can download their numbers.

You will also be asked to participate in a videotaped conversation with your adolescent today and at 6 months. You will be given a card with questions to guide your interaction, based on your answers to questions about

diabetes-related stress (e.g., "what happened the last time we had to remember diabetes supplies? How can we reduce this stress?") This conversation will last 15 minutes. We will transfer the video file from the encrypted tablet to a secure server.

At the start of the intervention, you will receive a binder with study materials. Mothers in the communication and coping group will receive a binder with information on coping and parenting strategies, and mothers in the diabetes education group will receive a binder with information on topics related to diabetes management.

You will receive 7 individual phone calls with a trained member of our research staff to discuss the information in the binders. Calls will last approximately 10-30 minutes. The first 5 calls will occur weekly, and the last 2 "booster" calls will occur monthly. The calls will be scheduled at a time that is convenient for you. These calls will be audio recorded.

All mothers in the study will also be added to a private Facebook group, where you will receive 1 post per day for 3 months. The posts will be on topics related to the group assignment (communication and coping or diabetes education). A moderator will view and respond to all comments made by Facebook group members.

In addition, during the active phase of the intervention (3 months), you will receive an email or text message link to a survey to measure depressive symptoms every 2 weeks. This information is collected to make sure study participants are safe.

Groups can be created on Facebook, and with the use of privacy settings, we can determine who can see the posts and who can participate. We will have the privacy settings on Facebook group in this study set to "secret" which means that people can only join if they are invited by the study team. All posts in the group are only viewable by invited members. These posts, or any comments you make on them, will not show up in your Facebook friends' newsfeeds. It is always a possibility that other group members could screenshot content and share the screenshots or to discuss what is happening in the group with other people, but we will ask all participants to in no way share any content in the group with anyone.

We will download data from the Facebook group including posts, comments, and reactions from you and other people in your group so that we can study this data to better understand how people participate and how people responded to our posts. We will not download any data from your Facebook profile or any post to your feed – just your posts, comments, and the posts/comments you reacted to in the study Facebook group. Facebook may ask you to indicate (for example, by clicking on a button) that you are OK with us collecting these data from Facebook.

Expected costs: n/a

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
This is a research study, so there is only a small risk to those who agree to take part, as we are mainly gathering information. You are free to skip any question that you feel uncomfortable answering and you are free to withdraw from the study at any time without penalty. All efforts, within reason, will be made to keep personal information used for research confidential, but total confidentiality cannot be guaranteed. Under Tennessee

law, the researcher(s) will not maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, including, but not limited to, physical, sexual, and emotional abuse or neglect. If any researcher has or is given such information, he or she may be required to report it to the authorities. If you indicate that your depressive symptoms are worsening over the course of the study, the PI or trained member of the study team will follow up with you to refer you to the appropriate level of services.

Compensation in case of study-related injury:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care your child would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you or your child money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study.
The benefits from the study include gaining a better understanding of how best to support mothers of adolescents with type 1 diabetes using social media.

b) The benefits you might get from being in this study.
The potential benefit from participating in the study is that you may learn new strategies to help you manage your child's diabetes better. However, there are no direct benefits to individuals for participating in the research study.

Study Results:
After you complete the study, we will email/mail you a debriefing letter (overview of study design and objectives). When the overall study is completed, we will mail/email a letter to all participants summarizing main findings and a link to results on ClinicalTrials.gov

Alternative treatments available:
The alternative treatment is usual medical care. If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits.

Compensation for participation:
Parent and adolescent participants will be given Amazon gift cards for completing surveys.

- $20 each at baseline.
- $25 each at 3 month data collection.
- $30 each at 6 month data collection.
- $30 each at 12 month data collection.

Parent and adolescent participants will also be given small gifts (mug, tote bag, flashlight) at baseline, 3 months, and 6 months.

Parents and adolescents will receive additional $20 gift cards each for completing the video collection at 6 month data collection.

Circumstances under which the Principal Investigator may withdraw you from study participation:
If you or your child become ineligible after enrolling in the study (e.g., new medical diagnosis), you may be withdrawn from study participation.

What happens if you choose to withdraw from study participation?
You are free to withdraw from the study at any time without penalty.

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact Sarah Jaser, PhD at 615-343-6775.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will do everything we can to keep your personal information in your research record confidential (which means private), but total privacy cannot be guaranteed.

All data will be coded with a number rather than names to keep it secret. Data will be stored in a secure location without any names on it. The results of these studies will not be part of any medical record, since they are not being done for patient care reasons.

If results of any of the surveys need to be shared with others, we will get permission from you first. All study papers will be kept for at least 6 years after the study is finished. After 6 years, all data related to this study will be destroyed.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to your child. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your child's PHI as described below.

As part of the study, Dr. Jaser and her study team may share the results of your study and/or non-study linked meter data and A1C, as well as parts of your child's medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the National Institutes of Health, the University of Connecticut Institutional Review Board, and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

The sponsor and/or Vanderbilt may give or sell your child's health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. Jaser and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Jaser in writing and let her know that you withdraw your consent. Her mailing address is 2525 West End Avenue, Suite 1200, Nashville, TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____

Date Signature of patient/volunteer

Consent obtained by:

Principal Investigator: Sarah Jaser, PhD **Revision Date: 4/11/2022**
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Date

Signature

Printed Name and Title