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Official Title: Walk With Me (WWM) for Perinatal Grief

Principal Investigators: Camille C. Cioffi, Ph.D., Maria Schweer-Collins, Ph.D., and David Smith, Ph.D.

Oregon Research Behavior Interventions Strategies, dba Influents Innovations

Award No. R43 MH126788

Final Version Dated: 6/1/2021

Informed Consent for Participation in Walk with Me for Perinatal Grief Study

Study Title: Walk with Me for Perinatal Grief
Principal Investigator: Camille C Cioffi, PhD; Maria Schweer-Collins, PhD; David Smith, PhD
Sponsor: National Institute on Mental Health R43 MH126788

SUMMARY

We are inviting you to take part in a research study. You do not have to be in the study if you do not want to. You can also decide to be in the study now and change your mind later.

This study is about developing a mobile phone-based intervention to support parents who experience pregnancy and early infant loss including but not limited to miscarriage, medical termination, neonatal loss, or still birth.

If you take part in this study, we will ask you to participate in the intervention our team of researchers has developed to see if it helps support you through your grieving process. We will also ask you to complete three surveys on your grief and your mental health one survey will be completed now, one will be completed in 1 month later and one will be completed in 2 months.

The most serious risks related to being in this study are that you might experience additional distress from participating or trying an intervention that has not been tested before. You may experience distress from the app content.

The main benefits of being in this study are that the intensity of grief you experience or the trauma symptoms you experience may be reduced as a result of participating. You might also experience comfort by using some of skills taught in the mobile app and by reading about ways you can honor your experience.

We plan to make the results of this study public but we will not include your name or other identifying information.

We would like you to ask us questions if there is anything about the study that you do not understand. You can call us at 541-434-1566 or email jessica.olson@influentsin.com.

You can also contact the Office for the Protection of Human Subjects with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 484-2123 or by email at kathryn@ori.org.

There are more details about the study in the following pages.

Informed Consent for Participation in Walk with Me for Perinatal Grief Study

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STUDY DETAILS

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

You are invited to participate in a research study which will provide a supportive mobile phone application to support parents who have experienced a perinatal loss such as a miscarriage, medical termination, neonatal fatality, or stillbirth. It will also provide healthcare professional training to improve care experiences for bereaved parents. This study is being conducted by Camille C Cioffi, PhD, Maria Schweer-Collins, PhD, and David Smith, PhD of Influents Innovations in Eugene, Oregon and is funded by the Nation Institute on Mental Health R43 MH126788. We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to participate in the study.

2. WHAT WILL YOU BE ASKED TO DO IN THIS RESEARCH STUDY?

If you decide to participate, you will be asked to first complete a baseline survey that assesses how you are currently feeling related to your loss. You will receive $50 for completing the survey. The survey will take about 20 minutes to complete.

After completing the survey, you will be given access to the mobile application prototype, free of charge, to use on your device. Over the course of one to two months, we ask that you spend time using the modules we have developed. Our app will track how often you use it and which modules you spend time using. At 1-month and 2-months, you will complete surveys on your current feelings related to your loss and report on what you thought of the mobile application so we can improve the experience for future users. You will receive $50 for completing each follow-up survey. The follow-up surveys will also take approximately 20 minutes to complete. You will receive $150 in total if you complete all three surveys.

3. WHAT ARE THE RISKS AND WHAT WILL BE DONE TO REDUCE THE RISKS?

There are some possible risks involved for participants. These are:

Psychological risk resulting from distressing content in the app and possible embarrassment in disclosing sensitive personal information. You can choose not to answer any survey item and you can ask questions about what we are asking you. You may also experience psychological risk from possible discomfort or dissatisfaction during or assessment procedures. While the modules in the app include things that are meant to help you feel less distress (e.g., guided meditation, ways to help address distressing thoughts, examples of ways to help those around you understand your needs and the way you view your loss), you may have the opposite reaction as all people are unique in how they experience grief and loss. Some distress is also normal when thinking about experiences that are especially difficult. We hope that can help you to feel better psychologically supported, however, if you need additional psychological support, we have trained clinicians on our team who are on-call to support our staff in making decisions to address your needs. This might include referrals to local service providers. There may be a delay in the study team review of data so if you need support, you should call or email the study team or use one of the following hotlines to for immediate support.

National Suicide Prevention Hotline: 1-800-273-TALK (8255)
SAMHSA's National mental health and substance use Helpline: 1-800-662-HELP (4357)

Risks of loss of confidentiality. We will be getting personal information from you. There is always the possibility that someone who is not authorized might see it. We take the following precautions to prevent any unauthorized person from having any access to the information you give us:

a. Any information you give us will be kept strictly confidential. All information will be kept in locked electronic files. We will remove all names from all the information we get (except this consent form). ID numbers will be assigned to the information you give us, and only authorized staff will have access to the locked electronic file that links your name to your ID#.

   We have a "Certificate of Confidentiality" which is a legal assurance from the federal government, which will help us protect your privacy. In rare cases, identifiable records could be subpoenaed. If this happens, ORI's lawyer will work with the courts to protect your privacy. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

   A description of this clinical trial will be available on http://www.ClinicalTrials.gov . This website will not include information that can identify you. At most, the website will include a summary of the research results. At the very end of the project, we will post a study consent form to the same website. The consent form will not have names on it. You can search this website at any time.

Storage & Future Use of Your Information
We may keep information about you forever. We do not know what studies we might do in the future. We would like your permission now to use or share your personal information without having to ask you again in the future. We will only use your information in other studies about pregnancy and infant loss. We will remove your name and any other information that identifies you before we use it in a new study or share it with other researchers. There is still a chance that someone could figure out that the information is about you.

4. WHAT ARE THE BENEFITS OF THIS STUDY?

There are also some benefits to you for taking part in this research project. Your participation will help us improve the experience for other parents who have experienced a perinatal loss. You may also benefit directly from using the mobile application as it was designed to support bereaved parents. It may feel empowering to share about your experiences with our study team.

5. WHAT OTHER OPTIONS DO YOU HAVE IF YOU DO NOT TAKE PART IN THIS STUDY?

The alternative to participating in this study, is to receive services as usual in your community. Your participation in this study will not exclude you from receiving typical services from your healthcare provider.

6. WHAT HAPPENS IF YOU ARE INJURED?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call them at the number(s) listed below. If you have been injured because you are in this study, we will provide community referrals to support you. Influents Innovations is unable to pay for the treatment of research-related injuries.

7. DO YOU HAVE A RIGHT TO WITHDRAW FROM THE PROJECT?

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits you might otherwise receive. If you decide to participate, you can stop participating any time without penalty. If you decide not to participate, you will continue receive your usual medical treatment.

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call Jessica Liu at 541-434-1566 or email jessica.olson@influentsin.com. If you have questions about your rights as a research subject and/or research-related injury, call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900. You will be given a copy of this form to keep.

9. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature below indicates that you (1) have read and understand the information provided above, (2) that you willingly agree to participate, (3) that you may withdraw your consent at any time and stop participating at any time without penalty, and (4) that you have received a copy of this consent form.

Participant Name:_____

Participant Signature: _____

Date Signed:_____

If you are 18 or over please skip the next section and click Next below

Assent (ages 15-17)

Assent is being obtained as participant is under the age of 18 and the requirement for parental informed consent has been waived for participants who are minors.

I understand the research and the focus group as described above and I agree to participate.

_____ _____

Signature of Minor Date

_____

Printed Name

Consent/assent will be in Qualtrics and they will just check a box and fill in name and date