

April 28, 2022

The Mental Health Effects of a Mindfulness App in Parents of a Child With Medical Complexity

NCT05925868

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The following informed consent is part of the electronic questionnaire that was approved by the Boise State University IRB.

Informed Consent

Principal Investigator: Dr. Cara Gallegos

You are invited to participate in a research study. This consent form will provide you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what will be expected of you as a participant, as well as any known risks, inconveniences or discomforts that you may have while participating.

Purpose and Background

The purpose of this research is to determine whether the use of a mindfulness app improves mental health outcomes in parents of a child with medical complexity. You are being asked to participate because you are parent of a child with medical complexity.

Procedures

If you agree to be in this study, you will participate in the following:

1. Use the Headspace mindfulness app (will be gifted to you)
2. Use a mindfulness app for at least 10 min, 4 days a week.
3. Answer surveys once/week.

Risks

The survey will include a section requesting demographic information. Your answers to these questions may make an individual person identifiable. We will make every effort to maintain confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank. Some of the survey and interview questions might make you feel uncomfortable or upset. You are always free to decline any question, take a break, or to stop your participation at any time. Should you feel discomfort after participating please contact your own health care provider or call the Idaho Care Line, 2-1-1 (a free statewide community information and referral service). Mental health resources are also included at the end of each survey.

Benefits/Compensation

The benefits of your participation in this study include receiving a \$75 Amazon gift card upon completion of all survey questionnaires.

Extent of Confidentiality

Reasonable efforts will be made to keep the personal information in our research records private and confidential. Any identifiable information obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by law. The members of the research team and the Boise State University Office of Research Compliance (ORC) may access the data. The ORC monitors research studies to protect the rights and welfare of research participants.

Your name will not be used in any written reports or publications which result from this research

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and data will be kept for at least 3 years (per federal regulations) after the study is complete and then destroyed.

Participation is Voluntary

Your decision to participate in this research study is entirely voluntary. You may withdraw from this research study at any time.

Questions

If you have any questions or concerns about your participation in this study, you may contact the Principal Investigator, Dr. Cara Gallegos at: 208-995-6633 or caragallegos@boisestate.edu. This study has been reviewed and approved by the Boise State University IRB. If you have questions about your rights as a research participant, you may contact the IRB, which is concerned with the protection of volunteers in research projects. You may reach the board through the Office of Research Compliance by calling (208) 426-5401 or emailing humansubjects@boisestate.edu.

Documentation of Consent

I have read this form and the descriptions of this research study. I have been informed of the risks and benefits involved and all of my questions have been answered to my satisfaction. I understand I can withdraw at any time. I voluntarily agree to take part in this research study.