Parental Informed Consent Form for Mindfulness-based Mobile Application to Reduce Rumination in Adolescents

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Adolescent Mobile App Study (RCT)
Parental Informed Consent Form Lawrence University

Introduction
You and your child have been invited to join a research project at Lawrence University’s Department of Psychology. The decision to let your child participate is up to you.

In this research project, we are investigating how a mobile app may help youth cope with their emotions. The participants will be about 150 adolescents between the ages of 12 and 15. We will be testing two different versions of the app, so half of the participants will be randomly assigned to get one version and half will be randomly assigned to get another version. Both versions involving paying attention to one’s emotions and will ask participants about how they’re feeling and what they’re doing each time they use the app. One version involves mindfulness exercises. Mindfulness means purposefully paying attention in a nonjudgmental manner. Participants in this version will get short, guided mindfulness exercises some of the time when they’re using the app.

The research has been approved by Lawrence’s Institutional Review Board, which protects human subjects. Participation is completely voluntary—you and your child may withdraw or decline to participate at any time without penalty. The researcher also has the right to withdraw your participation at any time. To withdraw, you or your child can simply inform the researcher. If you agree to participate, the following will occur.

What is Involved in the Project?
First, you and your child will come to the lab to receive the mobile app on your child’s device or one that we provide, and your child will be taught how to use the app by one of the researchers. We will go through an example of the questions during the lab visit so that your child knows what to expect during the course of the study. The active portion of the study will last three weeks, and your child will be notified three times per day to answer questions regarding their thoughts and feelings. If your child is in the mindfulness version, they will have the opportunity to do exercises suggested by the app (e.g., focusing on their feelings or listening to a guided audio recording). We will contact your child each week during the study to answer questions and encourage them. If your child borrows a mobile device, you will be asked to return it at the end of the study.

You and your child will also be asked to complete questionnaires during the lab visit. In addition, you and your child will be asked to complete questionnaires online three weeks after the lab visit and again 6 weeks, 12 weeks, and 6 months later.

Risks
To the best of the researcher’s knowledge, there will be no more risk of harm than would normally be experienced in daily life. The anticipated risks associated with your child’s participation in this research are minimal. The main risk is breach of confidentiality, though we will do our best to minimize the chance of this happening.

Benefits to Taking Part in the Project
We do not know whether your child will experience any direct benefits from participating. However, previous research has suggested that paying attention to one’s emotions may be beneficial. Others may benefit in the future from the information we find in this research.

As compensation, you and your child will each receive $15 in cash at the completion of the lab visit. At the completion of the questionnaires in 3 weeks, you will receive $5 and your child will receive at least $20. Your child can also receive up to $5 per week extra for using the app three times each day. You will receive $5 for each of the follow up questionnaires that you complete and your child will receive $10 for each of the follow up questionnaires that they complete. The total compensation is up to $115 per family ($35 for you and $80 for your child).

Confidentiality
Every effort will be taken to prevent anyone who is not on the research team from knowing that you or your child participated in the study and to ensure that all of the responses are confidential. No information that personally
identifies you or your child will be released or reported in any way unless required by law. When you and your child enter information into the app or electronic questionnaires, the data are associated with an ID number only. A master list linking the participant to their ID number will be maintained by the lead researcher and stored separately from the data. Individual participants will never be identified in published reports of these data. Only the lead researcher and her research assistants will ever have access to the data collected, because it will be locked in a file cabinet in our lab and/or stored on a private website that only the researchers in this study have access to. We will not share any of the information your child provides to us with you unless we find out your child is in danger of being harmed. In that case, we will work with you and your child to make sure they are safe.

This study is funded by the National Institutes of Health and is registered on Clinicaltrials.gov. We will post the general results of the study once it is completed. We will never post individual participants’ information.

Questions, Suggestions, Concerns, or Complaints
Before I give permission for my child to participate, I can ask any questions about the project that I have now.
- If I have any questions, suggestions, concerns, or complaints about this project, I can call Dr. Lori Hilt at 920-832-7050.
- If my child experiences any unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening, I will contact Dr. Lori Hilt.
- If I have questions about my child’s rights as a participant, I may contact the Chair of the Lawrence University IRB, Dr. Peter Glick at (920) 832-6707 or irb@lawrence.edu.

Permission for Child to Participate in Research Parent:
As parent or legal guardian, I authorize ________________________ (child’s name) to become a participant in the research project described above. I understand I will receive a signed copy of this consent form.

Child’s Date of Birth: __________

______________________________ Date ____________________

or Legal Guardian’s Signature Parent

______________________________ Date ____________________

Printed name of Parent or Legal Guardian

Parent Participant:
By my signature, I am affirming that I am at least 18 years old and that I agree to participate in this study. I understand I will receive a signed copy of this consent form.

______________________________ Date ____________________

Signature of participant

______________________________ Date ____________________

Printed name of participant

Person Obtaining Consent:
I have explained to the parent above the nature, purpose, risks and benefits of participating in this research project. I have answered any questions that may have been raised and I will provide the parent with a copy of this consent form.

______________________________ Date ____________________

Name of authorized person obtaining informed consent

Date