

#### **University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical Research Institute on Addictions 1021 Main Street | Buffalo, NY 14203 UB Federalwide Assurance ID#: FWA00008824

Title of research study: Reducing loneliness among aging populations using mindfulness-based interventions. Version one.

Version Date: 08/27/2025

Investigator: Justin Giambruno

<u>Key Information</u>: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

# Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are age fifty, or older. You have experienced loneliness in the past, and/or currently experiencing loneliness. Your mindfulness practices do not occur on a daily basis.

# What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

# Why is this research being done?

This research is meant to explore if mindfulness is effective in decreasing loneliness among aging populations. The research is testing the effectiveness of using an online training program to teach mindfulness skills. The research is also testing the effectiveness of teaching mindfulness online as an implementation strategy for clinical settings.

# How long will the research last and what will I need to do?

We expect that you will be in this research study for six weeks. Prior to beginning the research, you'll be asked to complete the UCLA loneliness scale (Version 3) and the Five-Facets Mindfulness Questionnaire. You will be asked to learn about and practice mindfulness using an online website. The research will be conducted over a six-week period. You will be asked to practice the skills within each module, consisting of approximately twenty-five minutes of practice, at least five days every week. Practice time will differ from week to week as the time necessary to complete each practice differs between weekly modules. After completion of the

six-week modules, you'll be asked to complete post intervention surveys which include the UCLA loneliness scale (Version 3) the Five Facets-Mindfulness Questionnaire, implementation survey, and open-ended questionnaire. During the entirety of the six-week program, approximately seven hours and fifteen minutes should be set aside for completion.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

### Is there any way being in this study could be bad for me?

This study presents minimal risk to participants.

More detailed information about the risks of this study can be found under "Is there any way being in this study could be bad for me? (Detailed Risks)"

## Will being in this study help me in any way?

Research has demonstrated that mindfulness-based interventions can decrease loneliness among varying demographics. We cannot promise any benefits to you or others from your taking part in this research. No monetary reimbursement is provided for participation in the study.

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Your alternative to participating in this research study is to not participate.

**<u>Detailed Information:</u>** The following is more detailed information about this study in addition to the information listed above.

#### Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Justin Giambruno at (838) 207-9742 or jigiambr@buffalo.edu. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email <a href="mailto:ub-irb@buffalo.edu">ub-irb@buffalo.edu</a> if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

# How many people will be studied?

We expect approximately ten individuals for this research study.

# What happens if I say yes, I want to be in this research?

- You will be asked to log onto our website openheartsandminds.com. On the website you
  will be asked to complete a preliminary questionnaire. The questionnaire includes
  background questions regarding mindfulness, loneliness, and demographic information.
  On the website there will be a link to the questionnaire, which will redirect you to the
  Oualtrics website.
- After completing the preliminary questionnaire, the sole investigator will email you a participant ID that will be used during the entirety of the research.
- You will be asked to complete questionnaires and surveys. Surveys will be completed during the first week, the fourth week, and week six.
- You will log onto the openheartsandminds.com website where you will be asked to complete online modules weekly. You will also be asked to practice mindfulness skills weekly. You have the option to complete a daily meditation log, which can be helpful to encourage your mindfulness practices and will not be reviewed by anyone.

Weekly module practices:

Module one – Education about loneliness and mindfulness

Module two - Body scan and sitting meditation

Module three - Mindful yoga

Module four - Walking meditation

Module five - STOP exercise and turning towards meditation

Module six - Lovingkindness meditation

• After completion of the mindfulness modules, you will be asked to complete post-study questionnaires on the sixth week of the study. These questionnaires will measure loneliness, mindfulness skills, and the effectiveness of implementation strategies.

# What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Complete weekly online modules, which include educational and formal practice. You will also be asked to complete survey and questionnaires associated with the intervention and implementation process. Please make sure that you can understand English proficiently and have a reliable internet connection.

# What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you decided to discontinue your participation in the study, your data will not be included in the final analysis of the research study.

# Is there any way being in this study could be bad for me? (Detailed Risks)

During research there is the potential that information collected confidentiality may be at risk. Whenever you are participating in research there is always a slight possibility for minimal discomfort. For anyone who is experiencing discomfort, they can contact the principal investigator – Justin Giambruno (jjgiambr@buffalo.edu) (838) 207-9742.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

All participant information will be kept on a secure online database. All information will be deidentified, meaning that all your information will be under your participant ID. Your study information will not be used for future studies, even if information that identifies you is removed.

# Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include - Incompletion of the mindfulness modules on a weekly basis.