

Consent to Participate in Research

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Title of Research Study: *Memory and Fear Study*

Principal Investigator: *James W. Griffith, PhD*

Supported By This research is supported by Northwestern's Osher Center for Integrative Medicine.

Collaborating Institutions: Trinity College Dublin, Maastricht University, and University of Cambridge

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to test if online mindfulness exercises helps reduce fear and anxiety related to memory loss.
- You will be asked to complete weekly online mindfulness activities for 3 weeks and answer study questionnaires before, during, and after the mindfulness program.
- We expect that you will be in this research study for about 9 weeks.
- The primary potential risk of participation is loss of confidential information.
- The main benefit of being in this study is learning and practicing mindfulness activities to help with fear and anxiety related to memory loss.
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are 55 years of age or older, have fear about memory loss, and are willing to complete online mindfulness exercises, study questionnaires, and a cognitive test.

How many people will be in this study?

We expect about 80 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the 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.
- You do not have to answer any question you do not want to answer.

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What happens if I say, “Yes, I want to be in this research”?

If you agree to take part in this research, we will ask you to complete a three-week self-guided online mindfulness program and complete study questionnaires before, during, and after the mindfulness program..

For this study, you will participate in an online three-week, self-guided mindfulness program. There will be two groups of study participants. Both groups will complete mindfulness and other activities online aimed to help with fear and anxiety about memory loss. One group will focus on mindfulness and meditation exercises and the other group will focus on mindfulness, meditation exercises, and goal setting. The group of study participants you will be assigned to will be chosen by chance, like flipping a coin. You will have a 50/50 chance of being assigned to any given group. You will be asked to log on to a website (using a computer or tablet) at least 4 times each week to complete activities. We estimate these mindfulness activities will take about 40-80 minutes to complete each week (10-20 minutes per day, 4 days of the week). You may revisit the online website and practice and use the mindfulness techniques as frequently as you want.

We will also ask you to complete questionnaires before, during, and after the mindfulness program. These questionnaires will focus on memory loss, well-being, quality of life, and mental health topics, such as anxiety and depression. We will ask you to complete a set of questionnaires 2 weeks before starting the mindfulness program. This set of questionnaires will take approximately 20-30 minutes to complete. During the mindfulness program, we will ask you to complete questionnaires each week after completing that week’s activities. The weekly questionnaires will take about 5 minutes to complete. After you complete all 3 weeks worth of mindfulness activities, you will complete a set of questionnaires that will take approximately 20-30 minutes to complete.

After you complete the mindfulness program, you will also complete one set of questionnaires and a set of open-ended questions to tell us more about your experience with the mindfulness program. Both of these study activities will take place about 4 weeks after you complete the mindfulness program. This set of questionnaires and open-ended questions will take approximately 30-45 minutes to complete.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits could include reduced fear and anxiety related to memory loss after learning and participating in mindfulness activities. You will have access to these activities after the study ends by requesting a pdf copy of the materials and audio files that we can email you or you will be able to revisit the website at any time for up to 3 years after the study is over. If you choose to revisit the website, you may complete the activities within the website but we will not collect any new data from your responses. We will also give you an information sheet with tips for keeping your brain healthy and active.

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

Some of the questionnaires will ask you about mental health topics, such as depression and anxiety, that you may find distressing. You may stop participation at any time or skip any questions, if you feel uncomfortable. If you experience any mental health distress during the study, you can contact the investigator of the study, Dr. Griffith. You can find his contact information under “Who can I talk to?”

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section of this document. If you have any other health concerns, we encourage you to contact your regular doctor or seek medical attention.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern University/Northwestern Memorial Healthcare. Your decision will also not affect any relationship you have with the institutions collaborating on this study, including Trinity University Dublin, Maastricht University, and University of Cambridge.

You can leave the research at any time and it will not be held against you. If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used.

How will the researchers protect my information?

All of your information will be stored on secure, encrypted Northwestern University servers that require multifactor verification to log on, meaning that anyone who wants to view the data will need to verify their identity in more than one way to access any data on the servers. Only members of the research team will have access to your identifiable information, such as your name, telephone number, email. After your participation is complete, your identifiable information will be stored separately from the rest of our research data to further protect your information.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- Collaborating researchers at other institutions who are involved with this study will have access to de-identified information only.
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.

We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

This research study will not use any tests or questionnaires to diagnose or treat any health conditions. Most tests done in research studies are only for research and have no clear meaning for

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health care. If the research results have meaning for your health, the researchers will not contact you to let you know what they have found.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

The researchers may contact you again as part of this research study.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data.

We would like to keep your identifiable information to contact you for future research studies with this investigator. We will ask for your consent to do so at the end of this form. If you give consent, we may contact you in the future for other research studies. You can be in this current research study without agreeing to future research use of your identifiable information.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

Will I be paid or given anything for taking part in this study?

You will receive an e-gift card for a maximum of \$80 for your participation in this study that will be emailed to you approximately 2-4 weeks after you complete the follow-up questionnaires.

You will be paid for each portion of the study you complete. You will be paid \$10 for each set of questionnaires you complete during the online mindfulness program, including the first set of questionnaires before the program starts. You will also be paid \$30 for completing the final set of questionnaires and the open-ended questions 4 weeks after completing the mindfulness program.

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator: James W. Griffith, PhD by email at j-griffith@northwestern.edu or by phone at 312-503-5345 or the study coordinator, Melissa Marquez by email at melissa.marquez@northwestern.edu or by phone at 312-503-7678.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

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- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

_____ _____ The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator.

Verbal consent:

Do you wish to participate? Record participant's response: Yes No

Participant name or study ID number (if not recording participant's name on the consent form to minimize risks to the participant, record study ID number instead): _____

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent Date