STUDY TITLE:

Improving emotional well-being and quality of life in older adults experiencing dementia-related fear.

Short study title: Memory and Fear Study

PRINCIPAL INVESTIGATOR:

Name: James W. Griffith, PhD
Department: Medical Social Sciences

VERSION DATE:

17 February 2021

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☐ Children (you must **complete Appendix A** in addition to this protocol document if you plan to enroll children) ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☒
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	☐

1.0 Purpose and rationale of the study:

Many older adults worry about developing dementia. Evidence suggests that dementia has become the most feared health condition among people over the age of 50, surpassing heart disease, cancer and stroke [1]. Evidence also suggests that dementia-related fears negatively affect health and well-being through vicious cognitive-behavioral cycles [2-4]. Individuals who worry about developing dementia often fixate on what they perceive to be symptoms of the condition, such as every time they forget a name. This excessive self-monitoring is fatiguing and can actually increase cognitive failures, which compounds the initial fear. Over time, these experiences of anxiety and failure can undermine motivation and engagement in healthy activities, which leads to social withdrawal and other negative consequences such as accelerated cognitive decline [5].

Interventions that disrupt these vicious cognitive-behavioral cycles could afford immediate improvements in dementia-related fears and mental health, as well as long-term benefits (e.g. curtailing cognitive decline [6]). Crucially, mindfulness-based interventions have been shown to improve health and well-being outcomes in other conditions, such as chronic pain and fatigue, by improving individuals' ability to acknowledge negative thoughts and feelings without fixating on them [7-9]. However, few studies have investigated the use of mindfulness-based interventions in the context of dementia-related fear. In addition, extant interventions are often modified from pre-existing psychological interventions (e.g. mindfulness-based cognitive therapy). These approaches therefore require a high level of support and specialist training to administer. In addition, they lack relevance for older adults experiencing sub-clinical levels of dementia-related anxiety, who may be at risk for dementia. To address these limitations, we will use newly developed web-based technology to deliver a low-intensity intervention to help older people manage dementia-related fears in daily life.

We will develop a web-based mindfulness plus activation intervention tailored to mitigate dementia-related fears and improve well-being in a sample of older adults experiencing heightened dementia-related fear. This three-week program will focus on (1) mindfulness-based exercises to identify and monitor dementia-related fears and (2) behavioral-based exercises to overcome maladaptive fear avoidance (FA-mindfulness). An active control group will receive a typical meditation intervention. Therefore, this project will (1) determine the impact of the FA-mindfulness on dementia-related fear and maladaptive avoidance, (2) maximize convenience by developing a web-based intervention program and (3) investigate a low-cost approach to promote health-related outcomes in older adults.

We will conduct a randomized control study to determine the impact of a tailored, web-based mindfulness program to reduce anxiety and increase quality of life in older adults experiencing dementia-related fears, relative to a conventional meditation program. A group of older adults experiencing elevated dementia-related fears will randomly receive either the FA-mindfulness program or a mindfulness meditation-only control condition. Outcome measures will be administered at five time points (pre-, baseline, interim-, and post-intervention as well as at 3-month follow up). We predict greater reductions in dementia-related fear and avoidance (e.g., avoiding cognitively demanding situations) in the FA-mindfulness group relative to the comparison group (Hypothesis 1). This outcome will be measured using the fear-avoidance of memory decline (FAM) questionnaire [2], developed by us. We also predict greater improvements in mental health (i.e. anxiety, depression) and psycho-social functioning (i.e. quality of life, social functioning, fatigue) in the FA-mindfulness group relative to the comparison group (Hypothesis 2). This outcome will be measured using the World Health Organization Well-Being Index (WHO-5) [10],the PROMIS-29 scale [10] and the Geriatric Depression Scale (GDS-15) [11]. We also predict that fear will lead to a reduction in cognitive fatigue, and thus, improved cognitive performance in the FA-

mindfulness relative to the comparison conditions (Hypothesis 3). Cognitive performance will be measured using the Montreal Cognitive Assessment (MoCA), which can be administer remotely if needed [13]. A final objective will be to identify mechanisms through which FA-mindfulness program facilitated improvements in psycho-social functioning. Our theoretical framework suggests that maladaptive avoidance behaviors, relating to fears of dementia, restrict meaningful engagement in beneficial activities, which negatively impacts daily functioning. Therefore, we predict that treatment-related changes in fear-avoidance tendencies will predict improvements in psycho-social functioning overtime (Hypothesis 4)

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Inclusion criteria

1. 55 years of age or older
2. Elevated dementia-related fear as measured by the FAM scale (score of 61 or higher)
3. Able and willing to provide informed consent
4. Able to read/write in English
5. Willingness to be randomized to intervention group
6. Willingness to complete three weeks of self-guided intervention, questionnaires and cognitive tests
7. Access to internet for completion of questionnaires and intervention materials
8. Current United States resident

Exclusion criteria

1. Diagnosis of mild cognitive impairment (MCI), Alzheimer's Disease or dementia by a health care provider
2. Impaired cognitive or neurologic function as determined by the MoCA blind (score of <18 out of 22) [12, 13, 14]
3. Unstable medical condition (hospitalization in the last 6 weeks or repeated ER visits)
4. Severe depression (GDS-15 cut-off score of 12 or higher) [15]
5. Current treatment for anxiety or depression
6. Current participation in another psychotherapy
7. Current use of psychiatric medication
8. Current substance use disorder
9. Inadequate vision or hearing to interact with study materials

3.0 Sample Size:

We will recruit two groups with 40 participants in each (N = 80). The randomization will be stratified by age (female vs. male). These group sizes are powered to observe a significant interaction between time (within-person) and treatment (between-group)

using a mixed model. Assuming a medium-sized (d = .4), group sizes of 21 are powered at 80% to observe a significant group-by-time interaction (alpha = .05, calculated using G*Power). These group sizes are relatively consistent with guidance in the literature [24], suggesting that groups of 27 are powered at 80% to observe a significant group-by-time interaction.

4.0 Recruitment and Screening Methods:

Recruitment Methods:
We plan to recruit no more than 80 participants for this study. Potential participants will also be recruited through community-based outreach methods, digital and print advertising (e.g., flyers, web postings, such as Google Ads), and registries (e.g., Research Match). Additionally, the PI of this study, James W. Griffith, has a list of participants from previous research studies who have agreed to be contacted for future research conducted by this PI. Those who have participated in previous research studies in Griffith Lab, will receive either an email or phone call, depending on their contact preferences, describing the study. If a participant is interested, they will be directed to the online screening survey in REDCap to assess initial eligibility before a longer screening phone call.

Research Match is a secure online, national recruitment tool that is maintained by Vanderbilt University. ResearchMatch.org allows researchers to conduct feasibility or recruit potential study participants. Participants who are interested and released their contact information to the study team will be contacted via email to complete an online pre-screener to determine eligibility.

Screening Methods:
Screening for this study will be two-fold. First, participants will complete an online screener consent form and then, if they agree, an online screener will be administered via REDCap to collect demographic information and assess top-line inclusion/exclusion criteria.

The online screener will consist of the following:

1. General contact information form
2. Demographic information form (Age, gender, ethnicity, relationship status, employment status, years of education, income, family history of dementia and contact information).
3. Questions to confirm adequate hearing/vision required to complete the intervention materials.
4. Basic questions about internet accessibility
5. Current treatment for anxiety and depression, including psychotherapy and medications.

6. Current diagnosis of substance use disorder
7. Unstable medical condition
8. Diagnosis of MCI, Alzheimer's Disease, or Dementia
9. Fear and Avoidance in Memory Loss (FAM)
10. GDS-15

If participants are deemed eligible by the online screener, they will move on to the second part of the screening process. They will be called by a research coordinator for a more detailed screening to assess and verify their eligibility to enroll. At this phone call, the research coordinator will first obtain consent from the potential participant and remind them that after consenting they will need to complete additional screening questionnaires prior to enrolling in the study. After consenting, the coordinator will assess the participant's cognitive impairment using the Montreal Cognitive Assessment (MoCA) Blind, which allows the research coordinator to assess cognitive impairment remotely. Participants that score less than 18 points (out of a possible 22) on the MoCA Blind will be deemed ineligible for the study [12, 13, 14].

After completing both online and phone screening procedures, if the individual is eligible and still interested in participating, the coordinator will confirm their participation, randomize the participant, and begin sending them the weekly modules.

5.0 Research Locations:

Northwestern University

This study will be delivered remotely for participants who live in the Chicago area. We plan to use Northwestern University's iteration of REDCap to screen, e-consent, and store data for all participants in the study. The intervention will be delivered through a REDCap site that will be created to look like the intervention material packet. Research team members at NU will e-Consent all participants into the study as well as collect all screening data over the phone, including cognitive screening of participants using the MoCA Blind and administering the Geriatric Depression Scale (GDS-15).. Study participants will be able to contact NU research team members via phone or email for any questions or concerns throughout the duration of their participation in the study.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

Northwestern University is the lead study site for this research project and will be the only site recruiting participants. NU will create all protocols and modifications related to the study and notify research team members outside of NU. NU will be responsible for ensuring that all procedures are followed in accordance with the protocols that are approved by NU IRB.

Northwestern University

Northwestern University is the primary grantee for this study. NU IRB will review all research procedures for this study. All participants in the study will reside in the United States. Research team members at Northwestern University will obtain informed consent from all participants who enroll in the study. Research coordinators at NU will also conduct cognitive screening over the phone with participants as described in Section 4 above. Study participants can correspond with NU research team members by phone and email for any study-related questions or concerns throughout their participation in the study. Research team members at NU will be responsible for ensuring all sites follow protocol procedures. The sites hold biweekly project meetings that will continue throughout the duration of the study to ensure all protocol procedures are being followed correctly. Any deviations from the protocol will be reported to the NU IRB. NU personnel will also monitor data sharing to ensure only deidentified data is shared with collaborating institutions.

Trinity College Dublin, Maastrict University and University of Cambridge
Research team members located at Trinity College Dublin, Maastrict University and University of Cambridge will assist with development of intervention materials and consult on data collection and analysis. All data provided to research team members at these sites will be deidentified prior to sharing. Data will be shared by downloading deidentified spreadsheets from the REDCap database and then emailing the data via secure emails.

Data analysis may occur at other institutions, including Trinity College Dublin, Maastrict University, and University of Cambridge. These data will be deidentified prior to analysis.

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

All data collection will occur in the United States.

8.0 Procedures Involved:

This study is a two-group experimental design. The two study groups are (1) Experimental group that will participate in mindfulness, de-centering exercises plus behavioral activation activities and (2) Control group that will participate in mindfulness, de-centering exercises only.

The study consists of five total time-points. The baseline visit will occur 2 weeks prior to the start of the intervention. Participants fill out questionnaires two weeks prior to starting the intervention as well as weekly after completing the intervention activities. At the two-week pre-baseline visit, a research coordinator will screen participants for

eligibility, as described in "Recruitment and Screening Methods" section above. If eligible, they will complete the study questionnaires as described in Table 1 below.

A total of 80 participants will be randomized into the study. Participants will be randomized to one of two groups: (1) mindfulness and de-centering or (2) mindfulness and de-centering with behavioral activation. The randomization will be stratified by age (female vs. male). Randomization will occur on a 1:1 ratio and within strata (female vs. male). Participants will be randomized to one of the two interventions based on a predetermined list within each strata created using the blockrand package of R. Randomization will occur by blocks, with varying block sizes, in accord with recommended methods for RCTs. The randomization key will be linked to a unique study ID number, as well as to an intervention (mindfulness and decentering vs. mindfulness and decentering + behavioral activation).Participants will be aware that there are different arms they can be assigned to and will know which randomization group they are assigned.

The intervention will consist of three weeks' worth of sessions of mindfulness and de-centering exercises (and behavioral activation exercises for the experimental group). Each week of the intervention, participants will be asked to complete mindfulness activities 4 days of the week. These activities will take about 10-30 minutes to complete each day that an activity is assigned. Each week of the intervention will focus on psychoeducation and mindfulness lessons. Week 1 will consist of psychoeducation on memory loss, dementia, fear of dementia, and general health anxiety. Participants will also complete a beginner's mindfulness technique towards the end of the week. Week 2 will consist of psychoeducation about mindfulness and meditation. Participants will learn about and practice mindfulness techniques throughout the week. They will also complete written activities. During week 3, participants in the control group will continue practicing and using mindfulness techniques taught in week 2 of the intervention. The experimental group will learn about behavioral activation strategies and practice activities related to behavioral activation throughout the week. After completing each week's activities, participants will complete a short set of questionnaires. We expect that modules for the control and experimental groups to take about the same amount of time to complete. We estimate about 10-30 minutes each day that an activity is assigned because similar amount of audio files and activities are provided to each group.

All modules of the mindfulness intervention will be completed within REDCap forms designed based on the intervention materials developed with this protocol. The modules will consist of audio files, exercises (e.g., multiple choice questions, writing activities, meditation exercises, etc.), and summarization of concepts learned in each module. Each week of the intervention, participants will be emailed with that week's links to the assigned intervention modules. The links will be sent in the beginning of the week to the participant's specified email address. For each of the 3 weeks of the intervention, the participant will complete four modules that will each take between 10-

30 minutes to complete. Participants also have the option to review the modules that they have already completed. The links will remain active for the duration of their participation in the study and for up to 3 years after the study is complete. No data is collected directly from the individual within the modules. The modules are educational in nature and include activities to help participants practice what they have learned in each module. While the REDCap modules will include fields for participants to reflect on questions and their own thoughts, those responses will not be used as outcome data. Due to the nature of REDCap forms, research personnel will be able to view the information that participants have input into the forms but it will not be used for data analysis.

After completion of the follow-up visit, all participants will receive a handout that describes resources and lifestyle behaviors/activities they can do to help reduce their risk of developing dementia.

In addition to the intervention components, participants will be asked to fill out questionnaires at all time-points. Questionnaires administered during intervention weeks will be completed after the participant completes the intervention materials for that week. The Patient Expectation Scale is the only questionnaire that will be completed before the intervention during an intervention week.

After follow-up assessments (4 weeks after completion of the intervention), participants will be emailed a REDCap form that asks a series of open-ended questions about their experiences with the intervention. The purpose of these questions is to give participants the opportunity to share their experience with the intervention and their initial impressions on if the intervention seemed beneficial for them. These questions will cover the following topics:

1. Overall experience, including beneficial and difficult aspects, difficulty of completing the activities, and feedback on the length of each section.
2. Personal reactions to overall change in anxiety about memory loss
3. Plans to continue using mindfulness techniques learned in the intervention
4. Any recommendations or comments the participant has.

When participants are emailed the qualitative questionnaire described above, they will receive an email debriefing them about the study and who to contact if they have any follow-up questions.

Participants will complete the following questionnaires throughout the course of the study:

Name	**Description of instrument**
Fear and Avoidance of Memory loss (FAM) scale	To assess fear of memory loss. This scale is 24-items.

Fear of Alzheimer's Disease Scale (FADS)	To assess fear of Alzheimer's disease. This scale is 30-items.
Memory Failure Scale (MFS)	This measures memory failures that people tend to experience in everyday life. This scale is 12-items.
MoCA Blind	The Montreal Cognitive Assessment was developed to identify cognitive impairment in individuals. The MoCA BLIND is comprised of the same tasks as the MoCA FULL, except the visual items have been removed, which allows the assessment to be performed remotely over the phone.
PROMIS-29	To assess quality of life, social functioning, fatigue, anxiety, and depression.
World Health Organization Well-Being Index (WHO-5)	To assess overall well-being. This scale is 5-items.
Geriatric Depression Scale (GDS-15)	To assess severity of depression. This scale is 15-items.
Patient Global Impression of Change (PGIC)	To assess participant's impression of change in their fear and anxiety since the start of the intervention. This scale is 1-item.
Patient Expectations Scale	Single item to measure participant expectations for treatment.
Coronavirus Anxiety Scale (CAS)	The coronavirus anxiety scale (CAS) is a self-report mental health screener of dysfunctional anxiety associated with the coronavirus crisis. This scale is 5-items.

The table below indicates at which time-points these questionnaires will be administered:

Table 1. Summary of Study Procedures

	2-Weeks Pre-Intervention	**Intervention (3 sessions)**			**Post-Intervention (1 week after session 3)**	**Follow-Up (4 weeks after post-intervention)**
		1 (baseline)	**2**	**3**		
Online screen	●					
Demographics	●					
FAM	●	●	●	●	●	●
FADS		●			●	
MFS		●			●	●

PROMIS-29		●			●	●
WHO-5		●			●	●
MoCA BLIND	●					
GDS-15	●					
Patient Expectation Scale		● (before administering intervention)				
PGIC						●
CAS		●			●	●
Qualitative questionnaire						●

At the end of each set of questionnaires, we will ask the participants a few questions about their experience with that week's intervention activities. These questions will include:

1. On a 0 to 10 scale, how unhelp or helpful were the techniques this week? With 0 being not at all helpful and 10 being very helpful." (0-10 scale)
2. "Is there anything else you would like to tell me about the past 7 days, if so, please make a note here:" (open ended text box)

As a benefit to participant, we plan to allow all participants who have consented and enrolled in the study to access the website and activities provided during the intervention so they can continue to use them, if they would like. No new data will be collected from participants if they choose to revisit the website/materials. Participants may choose to answer the exercise questions within the REDCap but that data will not be used as outcome data. The REDCap website built for this research study will remain active for up to 3 years after study completion. Participants will also have the option to download pdf copies of the website or download the mp3 recordings of all audio files to save to their personal devices to use in the future. We will also include a zip file of all pdf versions of the intervention materials that we will email to participants, upon their request. After the study is completed, we will also post that zip file of the intervention materials to our research website (https://sites.northwestern.edu/griffithlab/) where participants can go to download the materials, if they choose.

9.0 Research with Vulnerable Populations (if children are the ONLY vulnerable population you plan to enroll, do NOT complete this section -- instead fill out Appendix A)

N/A

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

The consent process for this study will be two-fold. First, the participant will complete an online screening consent form to collect sensitive screening information. Then, if they are eligible, they will be contacted by a study coordinator to obtain full informed consent and complete screening and enrollment in the study.

The online screener consent will be administered via a Redcap form and will explain key information about the screening process. After potential participants review the online screener consent, they will have the option to “agree” or “disagree” to complete the online screening procedures. If a participant agrees and are deemed eligible by the online screener, a research coordinator will contact them by phone to complete the consent process. If a participant is deemed ineligible, based on their responses to the online screener, we will include an optional question at the end to ask if we can use the information they provided on the online screener to recruit them for future research studies.

If participants agree and are eligible from the online screener, they will then be contacted by a research team member for additional screening and consenting. The consent process for this study will take place over the phone between participants and research team members. The informed consent process is expected to take around 20 minutes to complete. This study is conducted entirely remotely and presents only minimal risk to the participant so therefore we are requesting a waiver of signed consent for this study. Instead, we plan to use a verbal consent process. Research team members will call participants to confirm study eligibility criteria and, if they are eligible, will obtain verbal consent from the participant. First, research team members will thoroughly explain the informed consent form to the participant, allowing them to ask any questions throughout the explanation with additional time after explanation of the study for additional questions. The participants will be free to take as much time as they need to decide whether or not to participate and/or to consult with friends/family about their decision to participate. Once all of the participant’s questions have been answered, the research team member will ask a short series of questions to determine consent comprehension. If the participant answers all consent comprehension questions correctly, the research team member will verbally ask them if they wish to consent to the study. If they say “yes”, the research team member will mark that on the e-Consent form housed in REDCap. The research team member who obtained consent will then print their name, sign their name, and date the form. The person who obtained informed consent will then email a copy of the verbal informed consent form to the participant for their records.

12.0 Waiver of Participant Signature on Consent Form:

This study is requesting a waiver of participant signature on the consent form because the study will be conducted remotely using phone and web-based sessions. In place of a participant signature on the consent form, we intend to use a verbal consent process for this study. The verbal consent process takes the burden off of the participants as they do not have to navigate to the consent form on a separate device as they remain on the phone with a study coordinator. Additionally, older populations often are limited in their technology literacy and find it difficult to sign using an electronic form. A study team member will follow a similar process to the standard informed consent process in order to obtain verbal consent. As described above, the study coordinator will thoroughly explain the form, allow adequate time for participant's questions, and, if requested, send a copy of the form to the participant so they can consult with friends/family about their decision to participate. This study will also ask a few consent comprehension questions prior to obtaining verbal consent to ensure that the participant understood the consent form information that was explained to them. In place of a signature line, the study coordinator will verbally ask the participant if they consent to the study.

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

Participants will be compensated up to a maximum of $80 for their participation in this study. Participants will be compensated based on the visits they complete. Compensation will occur at the end of the study. Participants will be sent e-gift cards for the total amount of their compensation within 2-4 weeks of study completion. If a participant withdraws or drops out, the participant will be paid for all completed time-points prior to their withdrawal/drop out based on the table below.

Time-point	Compensation amount
Baseline	$10
Week 1	$10
Week 2	$10
Week 3	$10
Week 4	$10
Follow-up	$30

15.0 Audio/Video Recording/Photography

N/A

16.0 Potential Benefits of this Research:

This study will not promise any direct benefits as a result of this research. Participants may experience a decrease in their fear or anxiety related to dementia after practicing the intervention techniques.

17.0 Potential Risks to Participants:

The main potential risk of this study is a breach of confidentiality. To combat this risk, we will store all identifiable information in a REDCap database that is only accessible by members of the study team. The study will also use questionnaires and mindfulness-based interventions to see if that type of intervention helps reduce anxiety or fear about dementia in older adults. These study procedures do not have significant risks beyond some discomfort in answer health-related questionnaires and participating in mindfulness-based activities. The intervention materials will be provided online so the participant will be able to access them privately and stop use at any time that they feel uncomfortable.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

This study will be conducted entirely remotely. Participants will interact with a research team member by phone twice over the course of the study. Once at the beginning of the study to complete screening procedures and the informed consent process and once at the end for a debriefing interview. During these phone calls, the research team will advise the participant to try to have a private space to answer questions and discuss the study procedures. The research team member will also conduct these phone calls from a private space to ensure participant confidentiality. All data collection will take place in a secure REDCap database hosted on Northwestern University's iteration of REDCap. Participants will be assigned a study ID# once they are enrolled in the study. Only research team members interacting with participants will have access to their identifiable information. All participant data will be deidentified prior to analysis.

Special procedures for ensuring patient confidentiality will be implemented. Data transmission and the distributed data systems will have multiple layers of security. All study data will be entered by research team members into the electronic data entry system, hosted on Northwestern University's interation of REDCap. This database will be accessed using password protected computers, will require research team members to log in to Northwestern's VPN using a username and password. All data containing PHI will be stored in the secure REDCap database. Within the database, each study subject will be assigned a unique identification number. Only this number will be used to identify subjects in any individual tabulation. The PHI that is collected will represent the

minimum necessary to successfully execute the study. Deidentified data from the study may be stored on the Northwestern shared drive, which is regularly backed up.

Only group-level data will be included in publications and presentations. If individual participated data are to be published, no identifying information will be included. Access to computerized data will be restricted to study personnel. Password authorization will be enforced. Previous use of this security system and a secured server indicates that this technique is very successful in assuring the protection of confidential information. The data will be stored on a secure server with restricted access. All study personnel who have access to patient data will be educated regarding the need to protect confidentiality and the procedures to be followed to ensure such protection. After the study is completed, the archived data will be stored on the secure, password protected Northwestern shared drive.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

This study will ask questions about depression and anxiety, for which good treatments do exist. In this study population, these mental health issues will be directly tied to anxiety/fear about dementia/cognitive slips. Therefore, we will provide a handout to every participant at the end of the study that gives helpful lifestyle behaviors and resources to help prevent cognitive decline. Giving this information to all participants ensures that no person will be missed, and also reduces any feelings of stigma that might arise if the person felt singled out based on their responses. While this study does not ask any explicit questions about suicidality or self-harm, if the participant was to mention an immediate threat to themselves or others, the research team members will be trained to assess suicidality. In the case that a participant mentions a significant threat of suicidality or self-harm, the PI of the study, James W. Griffith, is a licensed psychologist and he will be informed of any concern for follow-up. Any immediate suicidal intent will be treated as a life threatening emergency. We will involve emergency services from 911 if needed and request a crisis intervention manager for the situation. Participants will be notified that if they mention a significant threat of suicidality or self-harm, that emergency services will be contacted on their behalf.

20.0 Long-term Data and Specimen Storage and Sharing:

After study completion, participant data will be archived in the REDCap database and deidentified data will be archived on the secure Northwestern shared drive. Any data that is shared outside of the research team will be deidentified.

21.0 Qualifications of Research Team to Conduct the Research:

James W. Griffith, PhD. (Contact PI). *Associate Professor, Department of Medical Social Sciences, Northwestern University.*

The team will be led by Dr. Griffith, a clinical psychologist and researcher with expertise in behavioral interventions and advanced data-analytic techniques used for clinical trials, including growth curve models and mixed modelling. Dr. Griffith has over 70 publications in a variety of clinical areas including anxiety, depression and cognitive difficulties. He has contributed to the design, execution, and data analyses of clinical trials and large observational studies with aggressive recruitment goals. He is also a licensed clinical psychologist with extensive experience in cognitive-behavior therapy.

Francesca R. Farina, PhD. (Multiple PI). *Post-doctoral Research Scientist, Department of Psychology, Trinity College Dublin and Trinity College Institute of Neuroscience, Ireland.* Dr. Farina is an established researcher with expertise in aging, cognitive decline and dementia. She has successfully led a number of Irish Research Council funded-projects specifically focused on emotional well-being and quality of life in older adults at-risk for dementia. She possesses advanced training in study design, recruitment of vulnerable populations and statistics (e.g., predictive modelling). Dr. Farina will co-lead the project along with Dr. Griffith and Dr. Bennett. Dr. Farina will be actively involved at each stage of project.

Marc Bennett, PhD. (Multiple PI). *Investigator Scientist, Medical Research Council-Cognition and Brain Sciences Unit, University of Cambridge, UK.*
Dr. Bennett's research is on the development, prevention and treatment of anxiety during sensitive neuro-developmental periods, e.g., neuro-developmental delay, adolescence and later life. Dr. Bennett is also a post-doctoral researcher for the Wellcome Trust funded MYRIAD Project investigating the role of mindfulness-based training as a prevention strategy in adolescent anxiety and depression. Dr. Bennett is currently commissioned by the Wellcome Trust to author an Insight Analysis on Psychological Decentering as a core component of psychological treatments for anxiety and depression. Dr. Bennett will therefore assist in developing the FA-mindfulness based intervention and establishing the app-based delivery system.

Dr. Griffith, Dr. Farina and Dr. Bennett currently collaborate on a research line investigating the impact of fear-avoidance on health-related outcomes in older adults [2], so they are well placed to executive this project. Dr. Griffith is also currently supported by the National Institute on Aging to determine the impact of health literacy on dementia screening; this pilot project will allow him to expand this work into the domain of treatment to enhance the overall well-being of older adults

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