Social/Behavioral - Expedited Review
Modification Approved

DATE: May 12, 2023

TO: Nirmala Lekhak
FROM: Social/Behavioral

PROTOCOL TITLE: UNLV-2022-148 Loving-Kindness Meditation among Adults 50 years and older
SUBMISSION TYPE: Modification

ACTION: Approved
APPROVAL DATE: May 11, 2023
REVIEW TYPE: EXPEDITED REVIEW

Thank you for submission of materials for this proposal. The Social/Behavioral has approved your study. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission. Only copies of the most recently submitted and approved/acknowledged Informed Consent materials may be used when obtaining consent.

Modifications reviewed for this action include:

changes to the sample size.

PLEASE NOTE:
Should there be any change to the study, it will be necessary to submit a Modification for review. No changes may be made to the existing study until modifications have been approved/acknowledged.

All unanticipated problems involving risk to subjects or others, and/or serious and unexpected adverse events must be reported promptly to this office. All FDA and sponsor reporting requirements must also be followed where applicable.

Any non-compliance issues or complaints regarding this protocol must be reported promptly to this office.

All approvals from appropriate UNLV offices regarding this research must be obtained prior to initiation of this study (e.g., IBC, COI, Export Control, OSP, Radiation Safety, Clinical Trials Office, etc.).

If you have questions, please contact the Office of Research Integrity - Human Subjects at IRB@unlv.edu or call 702-895-2794. Please include your study title and study ID in all correspondence.

Office of Research Integrity - Human Subjects
4505 Maryland Parkway . Box 451047 . Las Vegas, Nevada 89154-1047
(702) 895-2794 . FAX: (702) 895-0805 . IRB@unlv.edu

INFORMED CONSENT

Department of Nursing

TITLE OF STUDY: LOVING-KINDNESS MEDITATION AMONG ADULTS 50 YEARS OR OLDER

INVESTIGATOR(S): NIRMALA LEKHAK, PHD, RN

For questions or concerns about the study, you may contact Dr. Nirmala Lekhak at **702-895-5983 or** via email at **nirmala.lekhak@unlv.edu.**

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact **the UNLV Office of Research Integrity – Human Subjects at 702-895-0020 or via email at IRB@unlv.edu.**

A description of this clinical trial is 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.

It is unknown as to the level of risk of transmission of COVID-19 if you decide to participate in this research study. The research activities will utilize accepted guidance standards for mitigating the risks of COVID-19 transmission: however, the chance of transmission cannot be eliminated.

PURPOSE OF THE STUDY

You are invited to participate in a research study. The purpose of this study is to understand the use of loving-kindness meditation for adults 50 years and older. We are also trying to understand your experiences and challenges when participating in this study. This study involves intervention of loving-kindness meditation.

PARTICIPANTS

You are being asked to participate in the study because you are 50 years or older. If you are not able to consent fully, you will not be able to participate in the study.

PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following: answer some questions related to your demographic characteristics (such as gender, age, marital status, etc.) and health. We will also collect your contact information, which will be separated from the main study questions. The contact information will only be used to communicate with you to make appointments for future sessions and to teach you how to practice meditation daily. This contact information will be locked in secure UNLV research office. One of our research staff will contact you for an appointment. After you sign this informed consent form, during our first appointment, we will collect your demographic information and ask some questions regarding your health and well-being. This

information will be collected using an online software called Qualtrics. However, you will have option to use paper and pen to answer the questions as well. If you use paper and pen, we will transfer the information to Qualtrics. Before you answer these questions, our research staff will enter the STUDY ID for you in the Qualtrics software or paper/pen questionnaires. Information collected in Qualtrics do not contain your personal identifying information and will be password protected. This session will happen at mutually agreed upon space. We will make sure the space is secure and that no one can hear our conversation. We will be there to answer any questions you may have regarding the questionnaire. This session should not take more than 60 minutes. Your time will be compensated with $25 for this session. We will then randomize each participant to two groups, first group will get the meditation training first and after a month second group will get the same training.

When it is time for your meditation training (second session), we will show you a recorded video that will provide you with orientation and training to practice daily meditation. The meditation will be recorded by a certified meditation trainer. We will also provide you with a guided meditation practice in an mp3 player. You do not have to return the mp3 device after this research study is over and additional $10 will be provided for time compensation. The training session will happen in a group in a lobby or media room. After the training is over, we will be available to answer any questions. At the end, we will collect some data on your health and wellbeing and your thoughts about the training and meditation practice. This session should not take more than 60-90 minutes.

We also ask you to practice meditation at least once a day for 20-25 minutes using the mp3 device we give you. You will be taught how you can use the mp3 player. We will also call weekly to check in and answer any questions you may have. You will also be provided with a journal folder with some questions (daily and weekly questions), that we request you fill out daily (and weekly for weekly questions) after your guided meditation practice, which should not take more than 10 minutes. This completed journal, which captures your general feeling and experiences regarding the meditation practice, will be collected at end of the month. Around end of one month of your own guided meditation practice, we will contact you again for data collection. This session should not take more than 30 minutes. At this session, we will compensate you with $30. At this time, we may ask for 4-5 volunteers to participate in a focus group meeting, which will be around 90 minutes and compensated with $25. If all participants agree to meet face to face, we will meet at a mutually agreed venue to understand more about your experiences and any suggestions you may have for improving the intervention and future such studies. This focus group meeting will be audio recorded given that all participants unanimously agreed to it. Confidentiality cannot be guaranteed in this small group setting. However, the audio recording will be deleted once it is transcribed without any personal identifying information.

We will ask you to continue with you daily meditation practice using the mp3 player. This time there will be no weekly calls and we will do a follow up again at a month. At month follow up, we will call to set up an appointment for another set of data collection. This session should not take more than 30 minutes and will be compensated with $20.

If you are in a second group, then we ask you to continue doing activities you regularly do, and we will call in a month to schedule a meeting for data collection (compensated with $20) and then for the meditation training. We will follow the same timing and compensation as we did with the first group except there will be no focus group.

BENEFITS OF PARTICIPATION

There may be direct benefits to you as a participant in this study. You will receive training in loving-kindness meditation. Research has indicated the benefits of this practice in reducing stress. And we hope to learn about your experiences during and after the meditation practice. There are different types of meditation practices available for free on YouTube that may be beneficial as well.

RISKS OF PARTICIPATION

There are risks involved in all research studies. This study may include only minimal risks. Meditation practice may arouse thoughts and we recommend not paying attention to those thoughts and bringing your awareness back to the guided meditation. You may feel uncomfortable during the meditation practices as you become more aware of your thoughts and emotions. This is expected and guided practice will help you return back to meditation practice. Should doing meditation becomes challenging, you can stop the practice and come back at a later time. Sometime keeping eyes open and lowered may help. Please write about these experiences in your journal and give us a call to discuss these challenges. Some of the questions might make you feel uncomfortable, and you have the right to refuse to answer those questions. There may be some inconvenience in the time required to complete the task. We encourage taking breaks as needed.

COST /COMPENSATION

There may not be a financial cost to you to participate in this study. The study will take minimum of 30 minutes of your time for each session. Some session might take longer and is explained above. You will be compensated for your time. First intervention group will receive $85 in total, and second group will receive $105 because of one month wait and one extra data collection. For those, who participate in focus group, they will receive $25 more. This money will be divided between sessions. We may need to provide your identifying information, such as name, gender, mailing address, and date of birth, to our research payment system for compensation purposes. This information will not be linked to your study data.

CONFIDENTIALITY

All information gathered in this study will be kept as confidential as possible. The personal identifying information such name, address, and phone number will be collected in the beginning, so we can contact you for future sessions. This information will not be linked with the data collected for the research purposes and will be stored in a locked facility at UNLV for three years after the completion of the study. After the storage time, the personal identifying information gathered will be destroyed. However, anonymous group data that are separated from any identifying information may not be destroyed. Anonymous data that are not linked with personal identifying information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You are encouraged to ask questions about this study at the beginning or at any time during the study.

PARTICIPANT CONSENT:

I have read the above information and agree to participate in this study. I have been able to ask questions about the research study. I am at least 18 years of age. A copy of this form has been given to me.

Signature of Participant Date

Participant Name (Please Print)

Audio/Video Taping:

I agree to be audio or videotaped for the purpose of this research study.

Signature of Participant Date

Participant Name (Please Print)

Submission Type: Modification Date: 6-13-2025

IRB #: UNLV-2022-148
Title: Loving-Kindness Meditation among Adults 50 years and older
Creation Date: 5-4-2023
Status: Review Complete
Principal Investigator: Nirmala Lekhak

Modification

IMPORTANT REMINDER

Any changes to the study **must** be included in a modification submission, *including but not limited to*:

- Any changes to the **study title** or **purpose of the research,**
- Any changes to the **number of subjects** or **target subject population**, including but not limited to age, race, disability status, and gender,
- Any changes to **currently approved study procedures, recruitment materials, informed consent process or forms,** or **surveys//interview guides/assessments.**

Make your changes in the appropriate sections of the IRB protocol application smartform, including replacing any attachments (e.g. recruitment materials, consent forms, surveys/interview guides/assessments, etc.) being updated.

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*required

Modification Summary

Briefly describe the proposed modification(s) and explain why each change is needed.

I am seeing increased interest in my study, so to be safe I would like to increase the study sample size from 60 to 100. Given the benefit of the intervention and interest from the eligible community members, it seems fair to increase the sample size and not exclude any interested eligible members.

I am also increasing focus group number. We will ask for 8- 10 volunteers and divide them into two groups of 4-5 participants. As the sample size increases, I would like to make sure that focus group is representative of the sample as well, so I would like to increase focus group participants.

These changes have been made in the protocol as well.

*required

Assessment of Risk

Indicate whether the proposed modification increases risk to participants enrolled in this study.

✓ This modification ***does not*** increase risk to participants enrolled in this study.

This modification ***does*** increase risk to participants enrolled in this study.

About Cayuse Submission System

The Cayuse submission system is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark at the top-right corner of each section.

You do not have to finish the application in one sitting. **Be sure to click the "Save" button periodically.**

UNLV IRB

- You must have a formal approval letter from the IRB before beginning data collection.
- The Social and Behavioral IRB meets on the first Thursday of each month and the Biomedical/School of Medicine IRB meets on the third Tuesday of each month. Applications that need review by the Board should be submitted at least four weeks prior to the meeting.
- Protocols are reviewed in the order they are received.

Information to have available

- Study Recruitment Document(s)
- Detailed Study Information
- Consent Form(s)
- Questionnaires, Interview Guides, and other Data Collection Instruments
- Facility Authorization/Acknowledgement Letters

- Agreements (IRB Authorization Agreements, Volunteer Agreements, Data Use Agreements, etc.)
- Funding and/or Sponsor Information

*required

I have read the information above and I am ready to begin my submission.

✓ Yes

Is this human subjects research?

*required

Does your proposed project fit the definition of "research" defined as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"?

- ✓ Yes
- No

*required

Does your proposed project include activities using "human subjects" defined as a "living individual about whom an investigator (whether professional or student) is conducting research"?

- ✓ Yes
- No

Collaborative Research

*required

Is this a multi-institutional/collaborative study?

Multi-institutional/collaborative studies are research conducted in conjunction with an institution or with personnel not affiliated with UNLV.

- Yes
- ✓ No

Funding

*required

Do you have funding for this research study?

- ✓ Yes
- No
- Pending

Funding Source

Please search for your funding source. If the sponsor is not found, enter the information in the text field below.

National Institute of General Medical Sciences

Provide the sponsor if it is not found above.

the National Institute of General Medical Sciences, National Institutes of Health under grant number U54 GM104944

*required

What is the funder type?

- ✓ Federal
- State Government
- Sponsor
- Foundation
- Department/College
- Other

PLEASE NOTE: Once you obtain additional funding, a modification will need to be submitted.

Key Personnel Information

Key Personnel

***NOTE**: If you cannot find a person in the people finder, please contact the ORI-HS Office.*

ORI-HS has moved to a "key personnel" model, in which protocols only need to list the PI, Student Researcher (if a student is conducting the research as part of their own capstone/thesis/dissertation), and at least one Primary Contact (this defaults to the individual completing the form, but this can be any individual(s) who need edit/direct access to the protocol application). The PI will be responsible for keeping a record of all research team members and ensuring that all have completed the required CITI training and any other study requirements in a Research Team Member Log or documented elsewhere in their own study records, which does not need to be submitted to the IRB for review.

Ultimately, it is the PI's decision to decide who constitutes key personnel. However, ANY persons working on the protocol listed must complete CITI training. In addition, it is the PI's responsibility to verify that the training has been completed.

*required

Principal Investigator

One individual must be designated as the principal investigator(PI). The PI must be UNLV faculty. Students are not eligible to fill this role.

Click on the people finder below to search a name. You must provide the name of the PI here in order to complete submission.

Name: Nirmala Lekhak
Organization: Nursing Instruction
Address: 4505 S. Maryland Pkwy. , Las Vegas, NV 89154-3018
Phone: +1 (702) 8955983
Email: nirmala.lekhak@unlv.edu

*required

What is your role in the study?

Select all that apply

- ✓ Recruiting
- ✓ Consenting

✓ Administering study procedures

✓ Handling Identifiable data/specimens

Other

*required

Did you apply for and receive PI Eligibility Exception?

The policy of UNLV is that only full-time academic faculty members (appointments at 50% or more) may serve as PIs. Exceptions can be granted and PI status conferred on a case-by-case basis for individual research projects.

Yes

✓ No, I qualify for automatic PI status

*required

Primary Contact

This will auto-populate to the person completing the form. If someone else should be identified, please use the people finder below. Add additional persons who may need access to protocol information here.

Name: Nirmala Lekhak
Organization: Nursing Instruction
Address: 4505 S. Maryland Pkwy. , Las Vegas, NV 89154-3018
Phone: +1 (702) 8955983
Email: nirmala.lekhak@unlv.edu

*required

Student Researcher

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*Add the student **only** if they are conducting this research to satisfy graduation requirements such as Thesis, Dissertation, Senior Capstone, etc. Only **one** student may be listed here. Additional students can be listed under Primary Contact if they are conducting this research to satisfy graduation requirements.*

Yes

✓ No

Note: All study personnel will need to complete the following:

The human subject training course: "Social/Behavioral Research" or "Biomedical Research" course offered through CITI. Must be taken within the last five years.

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*required

Conflict of Interest

Do you or any investigator(s) participating in this study have a financial interest related to this research project?

Yes

✓ No

Does the PI or any member of the research team have an authoritative role over the research subjects (e.g., PI is the instructor of the course being recruited to participate).

Yes

✓ No

Research Participants

Subject Enrollment

*required

Select the age range of participants that will be enrolled in this study.

Check all that apply

- fetus
- birth to less than 18 years old
- ✓ 18 years and older

*required

Describe the different populations that will be recruited and enrolled

Provide the inclusion/exclusion criteria for each population.

Loneliness is a serious public health problem that affects more than 35% of older adults. Given that the study is testing an intervention to reduce loneliness and its implications among older adults, we will only include **adults 50 years of age or older**. We will be recruiting adults aged 50 and older living in Southern Nevada.

Inclusion criteria: *adults age 50 years or older living in Southern Nevada*
Exclusion criteria: *cognitive or language barriers that would be determined by whether they are able to understand and repeat information from informed consent. If we determine they are not able to provide informed consent, they will be excluded from the study.*

*required

Maximum number of subjects

Enter the total maximum number of subjects to be recruited and enrolled

100

*required

Provide the enrollment breakdown number for each participant population

For example: n= 5 teachers, n = 30 students

n= 50 intervention, n=50 waitlist control

*required

What are the selection criteria for research participants?

Include sample size calculations, if applicable.

Adults age 50 years or older, who are willing to participate will be recruited unless they have a significant cognitive or language barrier that will prevent them from successfully answering the study questionnaires.
We will use a randomized controlled trial (RCT) with waitlist control to determine the intervention's feasibility, acceptability, and initial efficacy. Although the proposed study is a feasibility pilot study, we will investigate the preliminary efficacy of the intervention. Therefore, the sample size for this current pilot study was estimated based on four repeated measurements: (baseline, right after intervention, post-intervention (at one month), and follow-up (at second month). Using an estimated effect size (Cohen's f= 0.2), an alpha of 0.05, and a power of 90%, for a repeated measure ANOVA between-within effects, with two groups and four measurement time points, the sample size was determined to be 46. This sample size was then increased by 33% to allow for attrition, to give the total sample of 60. The sample size was determined using G*Power (v. 3.1.9.7).

Given the interest from the community, we are increasing our sample size to 100. We do not want to exclude eligible community members who might benefit from participating in the study. This will help increase the study power as well.

*required

Vulnerable Populations

Please check the population(s) that will be enrolled. Check all that apply.

- Pregnant Women/Fetuses/Neonates
- Minors with Parental Permission
- Minors Who can Consent Themselves, emancipated minors/pregnant minors...
- Prisoners
- Other
- ✓ None of the Above

*required

Are you excluding your populations based on gender, race or ethnic origins?

- Yes

✓ No

*required

Would your population be considered decisional/cognitively impaired?

Yes

✓ No

*required

Recruitment

Describe how subjects will be recruited.

We, either the PI or research assistant (CITI-trained), will be recruiting adults aged 50 or older living in Southern Nevada. The research team will recruit 100 older adults from different senior homes or institutions that serve older adults, such as the Osher Lifelong Learning Institute (OLLI) at UNLV, with approximately equal numbers of participants **(n = 50)** in each RCT condition. Senior housing and OLLI staff will help advertise our study to their residents/members by posting flyers or emailing the flyer (they will not be involved in recruitment, data collection, or answering questions; they will direct the potential participants to us for any research-related questions). The research team will also directly work with the onsite manager of the senior apartments to post our flyers, promote our study, and recruit from the sites. Once the research team has received approval from the apartment manager, we will have a table in the lobby to recruit potential participants, we will also post flyers in the lobby area so interested participants can directly call the PI. The PI will ask the apartment complex to provide a facility authorization letter once approval to use the facility is received.
Recruitment will occur face-to-face at the older adult's apartment complex (probably in the lobby area, where we will obtain potential participants' contact information) or via phone (if potential participant call us with interest to participate). We will also use the OLLI site for recruitment, and approval to use the facility will be sought. During the recruitment phase, research team is only collecting potential participants name and contact information for screening visit.

At the end of the intervention, we will also recruit **8-10** volunteers from the study to participate in **two focus groups (each with 4-5 participants)** to further collect qualitative data on the feasibility of the study. During the final data collection at the end of the fourth week research team will ask the participants if they would like participate in a focus group interview. We will randomly choose **8-10** participants from the interested pool of the participants.

Describe the type of documents used (e.g., flyers, email, verbal announcements, etc.).

Study flyer will be used to advertise the study. Advertisement emails will be sent to apartment staff and OLLI staff to email it to their residents/members.

Attach recruitment materials here

Attachments are required because links can be changed or removed.
LKM Recruitment Flyer 2023.pdf

Email script v.3.docx

*required

Purpose

State the purpose of the study in lay terms.

Note: DO NOT copy and paste directly from your grant proposal, dissertation prospectus, clinical protocol, etc.

The purpose of the study is to examine whether the intervention (Loving kindness meditation) is feasible and acceptable among adults 50 years or older. The second aim is to examine the preliminary efficacy or impact of the intervention on reducing loneliness, depressive symptoms, and anxiety and improving compassionate love and cognitive function among this population group.

*required

Objectives

Briefly describe your research questions and the objectives of this study in lay terms. State what you hope to learn from the study and assess the importance of this new knowledge. What do you aim to achieve through this research?

Note: DO NOT copy and paste directly from your grant proposal, dissertation prospectus, clinical protocol, etc.

Objective 1: To evaluate the feasibility of implementing loving-kindness meditation (LKM) among older adults. Research Question 1: Is LKM intervention feasible and acceptable among older adults? We hope to find that intervention is feasible and acceptable among this population. We will also gather data on challenges and how to improve/refine this intervention for future research through a focus group interview. Objective 2: To examine the preliminary effectiveness of the LKM in increasing positive emotions such as compassionate love. Research Question 2: What is the preliminary effect of the LKM on compassionate love?Hypothesis: Older adults will show an increased compassionate love (Self-compassion scale) after 30 days of intervention.Objective 3: To examine the preliminary impact of the LKM in reducing loneliness and improvement in cognitive function and mental health.Research Question 3: What is the preliminary effect of the LKM on loneliness, depressive symptoms, anxiety scores, and cognitive function? Hypothesis: Older adults will show a reduced feeling of loneliness, depressive symptoms (CESD) and anxiety (PROMIS anxiety scale), and improved cognitive function (PROMIS cognitive function scale) after 30 days of intervention.

*required

Research Methods

Describe ALL the study procedures that human participants will undergo for purposes of the research.

Keep this in mind - If you are:

- *Observing participants - describe the setting and what you will document*
- *Asking participants to complete a survey - describe how the survey will be distributed*
- *Interviewing participants - describe how you will interview them and what the setting of the interview will be*
- *Audio or video recording - describe how the audio/video tapes will be used and how confidentiality will be maintained*
- *Conducting secondary analysis - describe the data source and provide a list of the variables that will be obtained and analyzed*

Include:

- *Time commitment for each participant including if there are multiple visits (e.g., 30 minutes per week for 3 weeks for a total time of 1.5 hours)*
- *Explain what will happen if the participant no longer wants to participate and they are no longer interested in being in the study. What will happen to data that has already been collected?*
- *Describe what will happen to the data after it is collected and analyzed. If data is presented publicly, will it be identifiable or de-identified?*

*required

How will you conduct this study?

Clearly describe any procedures used during the conduct of the study for each participant population. A step-by-step description is recommended.

A randomized controlled trial with a wait list control will be used in this research. The principal investigator will be involved in every aspect of the research and will train two research assistants to collect data and provide recorded orientation and intervention to participants. To develop orientation and intervention videos, PI will collaborate with Dr. Donna Costa, who is certified in a variety of mindfulness meditations. Dr. Costa will not have any interaction with the participants. She will help the PI design the intervention and record the meditative practice. The PI will record the orientation video in collaboration with Dr. Costa. The delivery of these recorded videos to the participants will be done by trained research staff. Some portion of orientation will be in person as well.

First, our community collaborators such as Osher Lifelong Learning Institute (OLLI) and senior

housing apartment will help with advertisement of the study via emailing their members our study flyer. We will also set up a table at these community partners sites for prospective participants to sign up. Once we have enough interested participants **(100 adults,** 50 years and older), we will set up an appointment with them to discuss our study. At this time, our research staff will explain the informed consent and after the potential participants fully consent to understanding the research procedure, its risks and benefits, we will ask them to sign the informed consent, copy of which will be given to them. Unless there is a significant language or cognitive barrier that makes it difficult for the potential participants to answer the questionnaires, no interested older adults will be excluded. Participants' capacity to consent would be determined by asking them if they understood the information about the study and the benefits and risks of participating in the study. The trained research staff will also respond to their questions about participating in the study. The potential participants will be told that they can withdraw from the study at any time if they choose. They will be told that the data they provide will be held confidential and they will not be individually identified or in any way associated with specific responses they supply. This will happen face to face in the participants' apartments in common private spaces such as a computer room or a community room or OLLI classroom, where we can privately talk with participants. We will take approval from the apartment manager and OLLI staff to use such a facility.

Then, participants' baseline data for screening will be collected before randomization. Randomization will be done based on participants race, gender and socio-economic statuses resulting with comparable demographic status in both intervention (n=50) and control group (n=50). Baseline data includes questionnaire on demographic information and measures of loneliness, depressive symptoms, anxiety, self-compassion, and cognitive function (see attached Study questionnaires LKM). The baseline data collection will occur one on one in a common private space in the apartment or OLLI classroom to protect participants privacy and for research staff safety. To further strengthen our staff's safety, they will travel in pairs to collect data and provide intervention. Participants will fill out the questionnaire on their own using either their own smart phone, paper and pen (for which data will be transferred to Qualtrics), or research iPad (however, study ID section will be entered by the research staff and participants are asked to fill out rest of the questionnaire). Our research staff will be there to answer any questions participants may have. We will offer rest/break periods as needed during the data collection sessions. Data will be collected using Qualtrics software, which will be password protected, which will ensure the protection of the participants' data. We may use paper pencil for data collection when needed and transfer the data to Qualtrics. We will destroy the paper data once the data has been cleaned and ready for analysis. The paper questionnaire will have Study ID section same as Qualtrics and personal data will not be collected during baseline or other data collection session. The only time personal information is collected during participants sign up, and this information will be safely locked in PI’s office cabinet and will only be used to contact participants for future data collection sessions.

Except for demographic information, other data and some intervention evaluation questions will also be collected at the end of the intervention, at 4 week and 8 week. There will be one extra data collection for control group before they get their intervention at 4 week. If for any reason participants refuse to participate during any part of the study, we will collect the reasons for their premature dropping out of the study. Some of the questions that will be asked to those who drop out of the study prematurely are in “Guide for Quantitative Data Collection” attachment.

The intervention primarily involves orientation and mindfulness practices such as proper posture, breathing techniques. We will also teach them the importance of the intervention and daily

practices, how to deal with thoughts that may arise during the meditation practice, and encourage them to write about their daily meditation experiences in the diary provided to them. We will also teach them loving-kindness meditation and provide them with guided meditation on an MP3 device, which they do not have return upon completion of the study. The orientation and intervention will happen in the lobby area, common space, or OLLI classroom in a group setting. The LKM recording will consist of mindfulness practice where they are guided to focus on compassion and kindness for themselves and others. Recording for both brief orientation and LKM are attached. After intervention session is over, participants are encouraged to practice guided meditation daily using the mp3 device for 20-25 minutes on their own at time appropriate for them. They will be encouraged to write their experience in the diary after the practice, which can take from 5 to 10 minutes daily. The diary will be a small folder with some questions to guide their entries daily. Please see dairy or journal requirement attachment for more information. The diary will be given to the participants after the intervention training. There will be weekly reminders via phone call to practice meditation daily and write their experiences in the diary. Weekly call will be around 5-10 minutes weekly for four weeks.

The orientation is about 10-20 minutes (with both in person and recording) and recorded LKM training is about 30-35 minutes (video links provided under interview section as attachments). We will also have a Questions and Answers session, which could take up 10-20 minutes. Participants will be then given the link to fill out the post intervention questionnaires on their own and if they request paper and pen version, those would be available as well.

After 3 weeks of intervention, we will call to set up an appointment to meet both intervention and control group to collect data for 4 week data collection. At this data collection session, we will also collect 30-day journal folders. At this time, we will also ask for 8-10 volunteers for focus group study (we will have two group of 4-5 participants) and once we have their permission, we will set up another appointment for focus group interview, which may take up to 90 minutes at either OLLI campus or apartment's media room. We will also set up an appointment for control group for their LKM training after collecting time 2 data from them. We will do a month follow-up again at 8 week for intervention group and 4week post-intervention data collection for control group.

There are three areas of outcome measures we are aiming to determine: feasibility, acceptability, and initial efficacy:

(1) feasibility of collecting measures of self-compassion, loneliness, depressive symptoms, anxiety, and cognitive function; (2) acceptability of the intervention (i.e., satisfaction, adherence, recruitment, and retention rates); and (3) initial efficacy (i.e., changes in loneliness along with self-compassion, depressive symptoms, anxiety and cognitive function at immediately post-intervention, at 30 and 60 day follow-up). We will evaluate feasibility through participants' satisfaction, their continued use of intervention after the study completion, how appropriate the intervention was for them, their positive or negative effects associated with the intervention. We will also assess their active and continual participation, retention rates, participation rate, and missing data on collected measures. We will also conduct two focus group with 4-5 participants in each group at the end of the study to determine the feasibility of the study and how we can further improve the intervention for future research. PI will transcribe the qualitative interviews.

*required

What is the anticipated time commitment involved for each study procedure (e.g. 30 minutes for the survey, 1 hour for the interview, etc.)? What is the total time that each participant will spend in the entire study?

Describe the duration of study participation (i.e. the anticipated amount of time commitment required for each subject), the length and number of study visits, and the timetable for study completion.

Describe, in timeline sequence, the activities participants will be asked to perform specifically for the research, and how much time each activity will take. Attach your schedule of assessment, if applicable.

Each session with participants will take about 30-60 minutes. Please see attached schedule of assessments for a detailed anticipated amount of time commitment.
The total time that each participant will spend in the entire study would be around 300 minutes. The focus group will have additional 90 minutes.

Baseline data collection: 60 minutes
Orientation and intervention and data collection: 60-90 minutes
Post intervention data collection at 4 week: 30 minutes
Time 2 control group data collection: 30 minutes
Follow-up data collection at 8 week: 30 minutes
Daily meditation practice: 20-25 minutes
Daily journal entry: 5-10 minutes.
Weekly call: about 5 -10 minutes
Focus group interview: 90 minutes (2 different groups)

Schedule of assessment (if applicable)

Schedule of assessments v.3.docx

*required

What is the anticipated completion date for the study?

12-31-2023

*required

Study Procedures

Check all that apply

✓ Survey/Questionnaires

Attach survey(s)/questionnaire(s)

Participants personal information.docx

Study questionnaires LKM.V4.docx

How will these be administered?

✓ Online

✓ Hard copy

Telephone

Other

✓ Interviews

*required

Attach script

Guide for Quantitative data collection v2.docx

Orientation Guide.docx

LKM Mindfulness Orientation Video

LKM Intervention Video

✓ Audio Recording

*required

Provide details of activities to be recorded and who will be recorded.

Whole focus group interview will be audio recorded, given all the participants unanimously agree to it. Focus group guide is attached below.We will ask the following before hitting the record button: "May I tape the discussion to facilitate its recollection? (if yes, switch on the

recorder, everyone should be comfortable being recorded, and we will not collect identifying information during the focus group and deter participants from using their names) (if no, we will write the notes to the best of our ability and ask questions as needed)."

Video Recording

✓ Diaries or Journals

*required

Provide details of diary or journal entry requirements.

Each participant in the intervention group is asked to write about their experience right after their daily meditative practice. We encourage them to answer all questions but answering any question is voluntary. These questions will guide the daily entry: How was your experience during the meditation? How long did you meditate today? Explain how you felt following the guided recording? What is your general emotion after the practice? What do you feel was the most challenging during the meditation practice or to continue the practice? Weekly Entry: Along with the daily entry, there would be extra questions for weekly entry: How is your behavior impacted by meditation? Do you have better controlled over your emotions? How do you feel for yourself and others now? Have you made any lifestyle modifications, such as better eating and drinking habits? Please explain. Has your sleep improved?

Still Photography

✓ Focus Group

*required

Attach focus group script or guide.

Focus Group Interview Guide.docx

*required

How many participants will be in each focus group?

5

*required

Provide the number of times each participant will take part in a focus group.

1

Observation

Secondary Analysis

Other

*required

Project Site(s):

Where will you conduct this study?

NOTE: If the project site is other than UNLV or online, a Facility Authorization Letter must be submitted for each site. You can find a template letter here.

✓ UNLV campus

*required

Specify which campus:

Maryland Campus

Shadow Lane/Medical Campus

✓ Other

*required

Please specify

Osher Lifelong Institute

External Collaborating Site(s) (e.g. collaborating site where study procedures are being conducted)

External Public Site(s) (e.g. coffee shop, library, etc.)

CCSD School(s)

International Site(s)

Online

✓ Other (e.g., Non-CCSD schools)

Provide a signed Letter of Authorization.

UNLV Letter of Support HHOVV.pdf

OLLI letter of support.pdf

Facility authorization letter Mcknight apartment.pdf

*required

Is this study a clinical trial?

NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

✓ Yes

*required

Provide the CT.gov number (NCTID).

NCT05350449

Attach a study protocol.

No

Informed Consent

*required

Describe the consent process.

Include:

- Who is obtaining consent?
- When and where will consent be obtained?
- How will the consent form be distributed to the participant?
- If obtaining signed consent, how will you collect the signed consent form?
- Who will be providing consent? (e.g., the subject, the parent, etc.)
- If minors are subjects, include how parent permission and assent will be obtained.

NOTE: If identifiable information will be published, shared or disseminated, the consent form must describe this for the subject.

- Who is obtaining consent?: PI or trained research assistant with CITI training. The research assistants will be hired after funding support.
- When and where will consent be obtained?: Participants' home or mutually agreed upon venue. We will make sure that the venue is a private and secure area.
- How will the consent form be distributed to the participant?: A copy of the consent form will be provided to the participants. We will explain the information of the consent form to the participants, give them time to read and ask any questions. Once we are sure that participants understood the study and procedures involved, we will ask them to sign the informed consent. a copy of which will be provided to them.
- If obtaining signed consent, how will you collect the signed consent form?: It will be collected face to face.
- Who will be providing consent? (e.g., the subject, the parent, etc.): The subject will be providing the consent.

*required

Select all that apply for your consent process

Informed consent (with signature)

✓ *Note: Signed consent may be a physical signature on a hard copy consent form, an electronic signature, or a typed name (for non-FDA regulated research).*

Check all that apply

Parent Permission Form(s)

Assent Form(s)

✓ Informed Consent Form(s)

Informed Consent Form(s) with HIPAA authorization.

Attach informed consent forms here.

Research-InformedConsentForm.v6.docx

Waiver of Documentation of informed consent (i.e. waiving the requirement to obtain signed consent)

Note: A Waiver of Documentation of Informed Consent is when you are still conducting a consent process, but you are not obtaining signed consent.
Examples: verbal consent, clicking a radio button to indicate consent, providing an information sheet, etc.

Waiver of informed consent

Note: A Waiver of Informed Consent is when you are not conducting a consent process at all.

Alteration of informed consent (use for deception/incomplete disclosure of purpose).

*required

Compensation

Will subjects be paid or otherwise compensated for research participation?

NOTE: UNLV has implemented the Forte Research Payments System as the central system to electronically manage incentives for UNLV research participants. The system will pay research participants via VISA credit card, check, or direct account deposit. Please contact hscomp@unlv.edu if you have questions about the use of Forte, to begin the process, or want to receive a waiver in order to use an alternative payment method.

✓ Yes

Describe the amount and nature of any compensation to subjects. Include gifts, research credit, gift cards, etc.

Participant Incentives (amount listed is per participants): Intervention Group: $25 per participants for baseline data collection; mp3 device with micro sd card (total of $35 value for guided meditation, and they will keep the mp3 device and return is not expected) after orientation and first intervention training; $ 10 per participants after LKM intervention training; Post intervention data collection and 30 day diary entries will be compensated with $30. At one month follow-up data collection, participants time will be compensated at $20 per participants. Control Group: $25 per participants for baseline data collection; $20 per participants after time 2 data collection before intervention. During intervention, mp3 device with micro sd card will be provided. $10 per participants after LKM intervention training; Post intervention data collection and 30 day diary entries will be compensated with $30. At one month follow-up data collection, participants time will be compensated at $20 per participants. Focus Group: $25 per participants for 90 minutes interview.

No

*required

Indicate the method of payment.

✓ Forte System Gift Card

The Forte Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth). In the consent form, please include that participants may be asked to provide their name, gender, email, mailing address, and date of birth for compensation purposes. Specify if these identifiers will or will not be linked to their study data.

Research Credit

Other

*required

When and how is the compensation provided to the subject?

Most studies require partial compensation be given for partial participation. Please address this in your answer.

The description how much compensation is provided above. We will provide them with described amount at each face to face meeting by adding designated amount in their Forte prepaid card. For partial participation, partial compensation will be provided. For example, they will receive $ 25 for baseline data collection and will not receive further compensation if they did not participate after the baseline data collection. If they took the training on intervention but chose to decline at time 2 data

collection, they will be allowed to keep mp3 player and sd card but will not receive $10 as no data will be collected. If participants did not complete the journal at all but provided data for time 3 data collection, they will receive $20 for data collection but not whole $30.

Study Procedures

*required

Will the study involve administering and/or collecting data from any of the following?

Check all that apply.

- [ ] Drugs
- [ ] Devices (includes software and mobile applications)
- [ ] Biologics
- [ ] Medical Records
- [x] None of the above

Participant Protection

*required

Do you consider this research study to be:

✓ Minimal Risk (something that a normal person would expect to encounter in their daily life).

More than Minimal Risk (this level of risk could place participants at risk of civil or criminal liability; damage their financial standing, employability or reputation; or place them at risk of emotional or physical damage).

*required

Potential Risks

Examples of risk include physical risks, psychological risks (such as stress, discomfort, or invasion of privacy) and social risks (such as jeopardy to insurability or employability).

Describe immediate risks, long-term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.

Expected risks to the subject are minimal due to the relaxed nature of the intervention. They may have difficulty practicing meditation at the beginning and some thoughts may arise, but with time, it usually gets better.
They may have discomfort when answering some questions. However, participants can take as many breaks during answering questions as they wish, and they can skip the questions that make them uncomfortable or stop participating in the study.

Describe any potential legal, financial, social, or personal affects on subjects of accidental data disclosure.

As we are not collecting any protected health or financial information from the participants, we do not anticipate any personal, financial, social, or legal effects on the subjects. Without having both identifiable documents and study data, there is very minimal chance of data disclosure. Moreover, we are collecting data in Qualtrics, which is always password protected.

What procedure(s) will be utilized to prevent/minimize any potential risks?

Given the potential risk information we have, we will make sure to teach our participants about potential risks and how to handle them should they arise. We will ask the participants to write down these experiences in their daily diaries, and if it starts to bother their daily activities, we will ask them to stop the practice.

Participants may feel uncomfortable during their meditation practices as they become more aware of their thoughts and emotions as they become more mindful of their surroundings and body responses. During the orientation session, participants will be instructed on how to deal with these thoughts safely. Participants will be encouraged to keep their eyes open if closing them feels uncomfortable. They will also be told that thoughts are normal, but guided meditation will help them focus back on the meditation. If they cannot focus back on the meditation, then that is normal as well. We will let them know that their comfort is important and should they feel any discomfort, they can stop the meditative practice and come back at a later time. They also have the option to stop the intervention at anytime and withdraw from the study.
Should they have any discomfort with answering the questions, they can skip the questions. They also have the option to stop the study at anytime.
They will be encouraged to approach the PI to discuss any concerns. The PI's mobile telephone number and email will be provided to the participants during the orientation to contact the PI.

*required

Potential Benefit to Participants

Do not include compensation here.

None (it is acceptable to have no benefit)

✓ Direct benefit to participant

*required

Describe

There may be direct benefits to you as a participant in this study. You will receive training in loving-kindness meditation. Research has indicated the benefits of this practice in reducing stress. And we hope to learn how the intervention is impacting your health.

Benefit to society

Other

*required

Privacy and Confidentiality

How will you protect the subjects privacy during research activities?

Privacy refers to the environment in which data are collected from participants and the individual's interest in controlling the access of others to themselves (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard, collecting only the minimum necessary PII to carry out the research, etc.).
We will be collecting data and implementing the intervention either at the participant's home or a mutually agreed upon venue. We will make sure the mutually agreed upon venue is private and secure so that the risk of being overhead is zero. After the data collection, the indefinable data will be locked in a briefcase before transferring the paper records to the UNLV secure file cabinet. Since the main study's de-identified data are collected in Qualtrics, the data will be password protected.

We will conduct focus group interviews via phone conference call or in person. After the recording is started, we will ask participants to only use their first names. We will let the participants know that once the recording is transcribed, the audio recording will be destroyed and the transcription will not have any identifiable information. Moreover, pseudo names will be used instead of their real names.

What precautions will be taken to safeguard *identifiable* data?

If identifiable data will be linked to the participant, describe how this will be presented in any written or oral materials related to the study.

If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

If you plan to de-identify the data, describe who will be responsible for the de-identification and how data will be de-identified so identifiers are not linked to the participant data.

Note: Data is considered to be anonymous when identifiable data is not collected at all. If identifiers are obtained, but are replaced with pseudonyms or participant ID numbers which can then be linked back to identifiers, then data is considered to be coded, not anonymous. If the data cannot be linked back to identifiers, then data is considered to be de-identified.

The only identifiable data that we are collecting are the participants' names and contact information in written form. We will assign a study ID to each participant and use that ID to collect data at different time points. The numerical ID is written at the top of the identifiable form. It is important to have this ID to link longitudinal data points. Only the PI and the research assistant collecting the data will have access to this information. **The list with participants' personal information will be stored in a secure UNLV PI's office in a locked cabinet.** The identifiable information will be destroyed in three years, and we will not be able to link the information back to the participants with the de-identified data. As no identifying information is collected in Qualtrics, destroying the identifiable information sheet will be sufficient to prevent being able to link the data to the participants.

*required

Who will have access to the *identifiable* data?

Check all that apply.

- ✓ Study personnel listed on approved IRB documents
- Funding agency for grant project
- Other

*required

Describe your plans for the storage/destruction of *identifiable* and *de-identified* data.

Specify how all forms of data (e.g. paper hardcopy, electronic, audio/video files/recordings, etc.) will be destroyed and/or kept at the conclusion of the study.

We will not destroy de-identified data. But identifiable data such as patient names and contact information will be destroyed after three years of data collection. Identifiable data are only used to contact participants to make appointments and link the different time points' data. Since this information will be in paper format, it will be locked on a secure UNLV site in a locked file cabinet and will be shredded at the end of the third year.

*required

Where will *identifiable* and *de-identified* data be stored?

For review/audit purposes, a copy of all records must be kept in a location accessible to the PI on UNLV property.

A USB Drive cannot be used for storage of the data. A HIPAA compliant storage solution must be utilized, accessible to both the student and PI. No PHI should be stored on a USB drive.

Indefinable paper records will be kept at secure storage location at UNLV school of nursing research office file cabinet. De-identified data are collected in online Qualtrics software. We will collect identifying information in paper separately, so it will be linked to Qualtrics data by subject code number. This code number is used to combine different time points data. When this data is downloaded in SPSS software, it will be stored in UNLV PI computer which is password protected. This will be accessible only to the PI and

UNLV research data sharing policy will be followed when sharing the de-identified data to a statistician, mainly for analysis purposes.

*required

How long will *identifiable* and *de-identified* data be kept?

Identifiable data will be destroyed after 3 years. De-identifies data may be kept forever for findings dissemination.