

CONSENT COVER PAGE

PROTOCOL TITLE: Belongingness in Nursing through Mindfulness – BEING Mindful: A Pilot Study

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The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for *Belongingness in Nursing through Mindfulness – BEING Mindful: A Pilot Study*

You are being invited to take part in a research study about Belongingness in Nursing through Mindfulness – BEING Mindful: A Pilot Study. Based on the brief screening questionnaire, you have been identified as potentially qualifying for this study.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if meditation and yoga will improve the sense of belonging among faculty and staff in the University of New Mexico (UNM) College of Nursing (CON). Your participation in this research will last about six (6) weeks.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The key reasons you may want to participate in this research are to increase your sense of well-being, give you an opportunity to practice mindfulness, and provide time for self-reflection. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

People with mobility issues or health problems may not feel comfortable with yoga. Because you will be participating with co-workers this may not be comfortable for some people. It will also require your participation in two (2) mindfulness sessions (either meditation or yoga) per week for six (6) weeks. You will be asked to wear a Garmin device on your wrist for the full six (6) weeks. For a complete description of the risks, refer to the Detailed Consent/Appendix

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. As an employee, if you decide not to take part in this study, you will not lose any services, benefits or rights, you would normally have if you choose not to volunteer. All HSC nurse faculty are staff may participate in the meditation and yoga without being part of the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Sharon Ruyak of the University of New Mexico Health Sciences Center, College of Nursing. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is slruyak@salud.unm.edu.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

We are only including nurse faculty and staff employed in the University of New Mexico (UNM Health Sciences Center who are 18 years of age or over.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the UNM, CON Research Laboratory Suite. You will need to attend 14 research sessions. This includes a pre-assessment session, 2 mindfulness sessions (meditation or yoga) per week for 6 weeks, and a post-assessment session. Meditation sessions will take approximately 30 minutes per session and yoga sessions will take approximately 45 minutes per session. The total amount of time you will be asked to volunteer for this study is approximately 8 hours for meditation participation or 14 hours for yoga participation.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate in this study, the following things will happen:

Consent: Allow researchers to describe the study to you and obtain your consent to participate. If you agree to participate in this study, you will be asked to read and sign this consent form.

Questionnaires: You will be asked to complete a structured questionnaire via the secure REDCap survey system at the beginning of the study and at the completion of the study. We will ask questions about your age, education, race/ethnicity, marital status, chronic health conditions, and emotional health. Some of these questions will be personal but it is important we understand your emotional health and possible stresses. If there are questions that you do not want to answer, that is OK. You do not have to answer them all and it will not affect your employment. This information will not be shared outside of the study team except as group data.

Mobile Ecological Momentary Assessment (mEMA):

Phone app assessment: You will be asked to download a mobile application (app) on your smartphone. You will use this app to answer short surveys on your phone about mindfulness three times per day for 6 weeks. This app will also collect information from the smart wearable device you will wear on your wrist. Your permission for the collection of data will be required in order to install the app on your smartphone. We will only collect data on your heart rate, movement, and sleep.

Smart wearable device: You will be asked to wear a smart wearable device on your wrist 24 hours a day for 6 weeks. The smart device will continuously send data to your phone during this time. The smart device will collect information about your heart rate, movement, and sleep. It is important you wear the device 24 hours a day, during the day and at night, so we can collect your heart rate during your daily activities and when you sleep as well as information on your sleep patterns. This information will be transferred automatically from your smart phone to secure data storage when you are in range of a WiFi network.

Intervention: You will be assigned to either the meditation group or the yoga group. We will assign individuals on 1:1 basis. If an individual is unable to participate in the yoga group, they will be assigned to meditation and the next two individuals will be assigned to the yoga group. You will be asked to commit to attend two sessions (either meditation or yoga) per week for six weeks total. Each meditation session will last approximately 30 minutes and each yoga session will last approximately 45 minutes. Meditation sessions will be conducted by trained instructors and yoga sessions will be taught by certified yoga instructors.

Participation in meditation sessions will include participating in semi-guided seated and walking meditation.

Participation in yoga sessions will include following along with poses and corresponding breathwork. During the sessions you will be cued about options for how to modify poses.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Overall, participation in this study may cause you some inconvenience. There is a small risk of loss of privacy and confidentiality associated with participating in the study. Procedures we will use to protect your information are described below.

Loss of Privacy: One of the main risks of being in the study is possible loss of privacy if the study procedures are not followed. However, we have put safeguards in place to protect your privacy.

Survey Completion: You will be complete a structured questionnaire with a research team member via the secure REDCap system. You will answer questions about your age, education, race/ethnicity, marital status, chronic health conditions, and emotional health. Potential risks include feeling uncomfortable reporting these feelings. If there are questions that you do not want to answer, that is OK. You do not have to answer all of them and this will not affect your employment. If this activity causes you to feel upset, we can offer information about resources that may be able to help you with these feelings. The interviews will last approximately one hour. This information will not be shared outside of the study team except as group data. At the completion of your participation in the study, you will be asked to complete an interview about your satisfaction with the intervention.

Phone app: You will be asked to install a mEMA app on your phone. All data collected from the mEMA app are encrypted before being pushed to the cloud-based storage database. Access to the database is restricted to authorized members of the research team.

Wearable smart device: Wearable smart devices are common and most people experience little inconvenience when wearing a device. If you experience discomfort or irritation you may remove the wrist device and contact the study team. Although it is unlikely, it is possible the smart device could record a health event when you are wearing it, such as an abnormal heart rate. It is important that you know that the wrist sensor device is not a medical device; it is only a research measurement tool and the data that it records is not being monitored in real-time by the study team. In the rare event that you have a health event while wearing the sensor, study staff will not be able to detect and report these events to you as they are occurring.

Because the data from the wearable smart device and phone app are sent wirelessly, invasion of privacy is a risk. We will make every effort to safeguard your information. The mEMA platform does not require you to enter any Personally Identifying Information. You will be given a unique identifying code to enter into your mobile app. All data collected from the mobile app are encrypted, which is a form of data

security that prevents unauthorized people from accessing it, before being sent to the company cloud-based storage data-base.

Yoga: Yoga is generally considered to be a safe form of physical activity when performed properly under the guidance of trained instructors. However, as with other forms of physical activity, there is always a chance that an injury may occur. Most common discomforts include muscle soreness, pain, fatigue, or emotional discomfort. We will ask you to complete an Exercise Participation Screener to determine exercise readiness. The certified yoga instructors are trained to provide guidance on modifications to make sure everyone can participate safely. In the rare event of an injury, research personnel will assist the participant to make an appointment at the UNM LoboCare Clinic.

Meditation: Meditation is generally not considered harmful. However, it is possible you may experience some discomfort while participating in meditation. Meditation can reveal uncomfortable thoughts or emotions. If you experience distress, a research team member will provide you with information related to the UNM Counseling, Assistance, & Referral Services (CARS). Physical discomfort may occur from prolonged sitting, for example, sore back, knees, hips, and feet). The meditation instructors can help you to make adjustments in how to sit properly for comfort and stability. Chairs will be provided for individuals with mobility issues that prevent them from sitting on the floor or for those who experience discomfort in meditation.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will receive any direct benefit from participating in this study. However, some people who engage in mindfulness practices like meditation and yoga experience improved wellness including decreased stress, improved balance, flexibility and strength, improved focus, improved self-awareness, and a greater sense of connection.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions that you have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. All information will be stored without your name associated with it. All surveys, questionnaires, and electronic data will not be associated with any personally identifiable information about you. The data will be stored on a secure site at UNM set up for research data. Only the researchers will have access to the information.

You should know there are some circumstances in which we may have to show your information to other people because it is required by law. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

We will make every effort to safeguard your data, but we cannot guarantee the security of data obtained through commercial survey companies. It is also possible the company, depending on the company's Terms of Service and Privacy policies, will use the data collected for research purposes for marketing or reporting purposes.

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. If you choose to leave the study you may still participate in meditation and yoga.

If you choose to leave the study early, you will be asked if you wish to withdraw authorization for use of the data collected to that point. However, any data that has already been deidentified and analyzed cannot be withdrawn.

The investigators conducting the study may need to remove you from the study. The researchers may decide to stop your participation without your permission if they think that being in the study may cause you harm, or for any other reason.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will not be covered by the University of New Mexico, the College of Nursing, or the research team. Medical costs related to your care and treatment because of study-related harm will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any payment for taking part in the study. However, you will receive 6 weeks of participation in mindfulness sessions (meditation or yoga).

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Generally, surveys and data from the Garmin device collected for research purposes are not meant to provide clinical information and cannot be used to make decisions about standard medical care. Because the investigators will not have access to information that identifies you, the research findings will generally not be provided to you.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 60 people to do so.

FUTURE USE OF YOUR INFORMATION

Your information for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name.

INFORMED CONSENT SIGNATURE PAGE

You are participating. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research subject

Date

Printed name of research subject

Printed name of [authorized] person obtaining
informed consent/HIPAA Authorization

Date

Signature of [authorized] person obtaining
informed consent/HIPAA Authorization

