## Consent to Participate in Research



**Title of Research Study:** Randomized Controlled Trial of a Mindfulness-based Intervention in a Federally Qualified Center (FQHC)

**Investigator:** ***Inger Burnett-Zeigler, PhD, Department of Psychiatry and Behavioral Sciences, Feinberg School of Medicine, Northwestern University***

**Supported By:** This research is supported by Northwestern University and National Institute on Minority Health and Health Disparities.

## Key Information about this research study:

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

The purpose of this study is to see if a mindfulness intervention (M-Body) helps to reduce depressive symptoms and if this intervention can be run at a Federally Qualified Center like Near North Health Services Corporation. In addition, we want to see if this intervention is any more or less helpful than the usual care you would receive. For this reason, we are randomizing study participants to be in one of two conditions: 1) take part in the M-Body group or 2) receive usual care with the option to take part in the M-Body group after their part in the study ends. If you choose to participate in the study and are randomized to the M-Body group, you will be asked to attend 8 weekly 90-minute group sessions. Regardless of what condition you are in, you will be asked to complete surveys and interviews, have your blood pressure and BMI assessed, and collect a dried blood sample with a finger prick four times over the course of the study. You will be asked to do this before the start of the study and again and after two, four, and six months. The primary risk of participation is some negative emotions or reactions from talking about personal issues. The main benefit is the potential to decrease stress and improve depressive symptoms.

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

We are asking you to take part in this research study because you are between the ages of 18 and 65, speak English, and endorsed feelings and behaviors that are consistent with depressive symptoms.

## How many people will be in this study?

We expect about 330 people total will be in this research study. We expect there to be about 15 people in each M-Body group.

## What should I know about participating in a research study?

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

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

If you agree to take part in this study, you will be assigned to one of two conditions. The condition you are assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what condition you get. You will have a nearly one in two chance of being assigned to either condition. The two conditions are the M-Body group or Usual Care. If you are randomized to the Usual Care condition, you will be given the opportunity to participate in the M-Body group after six months.

**What is the M-Body group?**

The group will consist of 8 weekly 90 minute sessions held at a Near North Health Services Corporation (NNHSC) site. _Each session will include an introduction, check-in and review of homework, teaching, and skill practice. These sessions will be led by a trained healthcare provider from one of the Near North clinics, and may be attended by other study staff.

The group sessions will cover the following topics:

1) Simple Awareness
2) Attention and perception
3) Dealing with thoughts
3) Stress: Responding vs. reacting
4) Dealing with difficult emotions and sensations
5) Mindfulness and communication
6) Mindfulness and compassion
7) Developing a personal mindfulness practice

The principal investigator, Dr. Inger Burnett-Zeigler, will oversee the group and all study related activities. Group sessions will be audio or video recorded. This is to check to see that the group facilitator is following the protocol.

**What is the Usual Care Condition?**

If you are randomized to the Usual Care condition, you will get information about some of the depressive symptoms you endorsed when the research team first contacted you. You will be given the opportunity to ask questions of a sensitive and knowledgeable clinician. You may call the study team about increasing symptoms or urgent situations at any point in the study period. You may join a M-Body Group in six months after you have completed all assessments.

Regardless of which group are randomized to, you will be asked to come to a NNHSC site and complete questionnaires about your mood, stress, well-being and functioning at 4 time points: the start, the end, two months after the end of the group, and four months after the end of the group. In addition to completing the questionnaires at these visits, a trained researcher will interview you about your mental health, ask about the types of health services you have been using, measure your blood pressure and BMI, and collect a dried blood sample. To collect the sample, the trained researcher will clean one of your fingers with an alcohol wipe and prick it with a disposable and sterile micro-lancet like those used by diabetics. One to five drops of blood will be collected on filter paper and sent to a lab to be analyzed. These visits will take about 90 minutes each.

In addition to these in-person visits, in two months, four months, and six months, an independent researcher who does not know any study details will call you to conduct another mental health interview. This interview should last about 30 minutes. We expect that you will be in this research study for six months total.

By agreeing to participate in the study, you consent to allowing the research team to contact your primary care provider by phone after each assessment (baseline, 2, 4, and 6 months) with your study results. In the case of you expressing active suicidal intent, your primary care provider may be contacted at any time.

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

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improving depressive symptoms, functioning, well-being, and reducing stress. All study participants may benefit from the extra care provided by the study, which may help give you quality services more than your usual treatment.

Another potential benefit of your participation is to the community and society-at-large. This group may be a preferred option for some for depression treatment in primary care. Results of this study may help scientists to guide clinicians in improving depression treatments in primary care. Your participation may also contribute to the larger goal of creating a quality mind-body depression group for people like you.

Snacks/light meals will also be provided at group sessions. Please let the study team know if you have any food allergies before participation.

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

No serious negative effects should come from your participation in this study. You may feel some negative emotions or reactions from talking about personal issues. You may feel mild discomfort from the finger prick for the dried blood sample. Should this happen, you are free to tell the session leader if you would like to take a break.

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

Participation in research is voluntary. You can decide to participate or not to participate. If you are not eligible or interested in participating, you will be referred back to your primary providers and given information about other depression treatments.

## What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you wish to withdraw from the study, you will be asked to inform the research team. You may decide to withdraw from the study at any time. If you withdraw, no more information will be collected from you. When you tell the research team you wish to withdraw the research assistant or investigator (Dr. Burnett-Zeigler) will ask if the information already collected from you can be used.

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

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Your samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

A description of this clinical trial (NCT03620721) will be available at 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to a person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of potential child abuse, or intent to hurt self or others.

**Data Sharing:** De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include a severe worsening of depressive symptoms, suicidal intent, or an impairment in functioning such that you cannot participate in the research study.

## What else do I need to know?

Compensation: If you agree to take part in this research study, we will pay you up to $110 for your time and effort. You will receive a $20 gift card after you have completed the baseline assessment, and a $30 gift card after you have completed each assessment after your group ends (in two months, four months, and six months). Also, you will be reimbursed for public transportation costs (single use bus cards) associated with transportation to the sessions and assessments. Additionally, you will receive an instructional manual and audio CD, yoga mat, tote bag and pen if you participate in the M-Body sessions that are yours to keep.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has affected you in some way, talk to Dr. Inger Burnett-Zeigler who is the principle investigator for this research study. You can call her at 312-695-6711 on Monday-Friday from 9am-5pm.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

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

## Optional Elements:

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

| I agree | I disagree | |
|---|---|---|
| _____ | _____ | The researcher may use my video or audio recorded image in scholarly presentations or publications when showing my face or hearing my voice might serve to help other professionals understand the research. I may be identifiable as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification. |
| _____ | _____ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study. |

## Consent to Participate in Research



Signature for Adult 18 or older

Your signature documents your permission to take part in this research.

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent