Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Adult Verbal Consent to Participate in a Research Study

Title of research study: ***Piloting an evidence-based mobile mindfulness practice to support self-management among Underserved and Racial Minority Adults with Pulmonary Hypertension***

Version Date: ***6/13/22***

Investigator: ***Tania Von Visger, Ph.D., APRN, CNS, CCNS, PCCN***

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to participate in a research study because you are an adult living with pulmonary hypertension. Because adults with pulmonary hypertension often experience stress related to high symptom burden, we ask for your consideration to be a potential participant in this study. The purpose of this study is to test the feasibility of a Mindfulness Meditation Program for PH (MMPH) for symptom reduction and quality of life improvement among patients experiencing psychological distress.

What should I know about a research study?

- Someone will explain this 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.

Why is this research being done?

The purpose of this study is to test the feasibility of the Mindfulness Meditation Program for PH (MMPH) explicitly tailored to address psychological stress commonly experienced among patients with PH. Current evidence indicates that adults with PH experience a high symptom burden making it challenging to manage self-care for optimal health and wellness. The limited social gathering resulting from the COVID-19 pandemic has led to the need to use technology to assist in the delivery of Mindfulness practice. Another purpose of this virtual program is to make the delivery of mindfulness practice easier to complete because it does not require traveling time and cost, unlike in-person meetings. There is a need to explore digital mental health resource delivery

method that is feasible, acceptable, and effective in alleviating stress and anxiety that are relevant to mental health and wellness.

Therefore, this study is being done to examine an MMPH's ability to deliver and help to address PH patients' current mental health needs during the current COVID-19 crisis.

How long will the research last and what will I need to do?

- We expect that you will be in this research study for approximately 16 weeks.
- You will be asked to complete the demographic questionnaires
- You will be asked to attend two instructor-led MMPH Zoom sessions (week #1 and week #4 – 60 min each)
- You will be asked to attend 6 instructor-led MMPH recorded sessions (week #2, #3, #5, #6, #7, #8 – 60 min each)
- You will be asked to complete several questionnaires at specified time intervals (at the beginning, middle, and end) depending on each questionnaire
- You will be asked to use the Mindfulness App (about 20 minutes/day)
- You will be asked to participate in a 30-40 min long individual interview via Zoom connection at the end of the 8th week.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

There are no foreseeable physical risks, discomfort, hazard, or inconveniences to you related to your participation in this research. However, there is potential physical harm if you use the M-App in situations that require total attention, such as driving or operating heavy machinery. There is an inherent risk of becoming so relaxed and drifting off into a sleep state, which may put you in danger during these activities.

There is a potential risk of emotional discomfort when answering survey questions about symptoms or feelings or while you use the M-App. Although unlikely, you may experience sensations of anxiety, depression, and worse physical symptoms. You will be instructed to rest and re-focus your attention on completing the survey in such a scenario. If needed, you should contact the research staff and be guided to a higher level of care.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you from taking part in this research. However, possible benefits may include relief from stress after participating in MMPH sessions or using M-App. Based on

existing literature reporting on the use of MMPH sessions and M-App, mindfulness practice can increase one's level of Mindfulness that can help with focus and attention, which may benefit your PH management progress. Participation in this study may benefit from stress and anxiety reduction, which can be helpful to your PH management and social interaction.

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

Participation in research is entirely voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team 716-829-2201, or by email at MMPHStudy@buffalo.edu. You may also contact the research participant advocate at 716-8884845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

How many people will be studied?

We expect to enroll 20 participants with PH conditions.

What happens if I say yes, I want to be in this research?

If you agree to participate, you will:

- Talk to the Research Staff for 45 minutes by Zoom Call during the time of enrollment. You will:
    - Discuss all study procedures and give verbal consent after reviewing this consent form
    - Complete a pre-intervention survey
- For the duration of your study participation, you will:
    - You will be asked to attend two instructor-led MMPH Zoom sessions (week #1 and week #4 – 60 min each)
    - You will be asked to attend 6 instructor-led MMPH recorded sessions (week #2, #3, #5, #6, #7, #8 – 60 min each)

- You will be asked to complete several questionnaires at specified time intervals (at the beginning, middle, and end) depending on each questionnaire ○ If you are in the first group, you will be asked to complete questionnaires eight weeks after the intervention completion
- If you are in the waitlist group, you will be asked to complete questionnaires eight weeks before the intervention begins
- Download and use the Mindfulness App according to the UB Mind user manual (about 20 minutes/day) for eight weeks
- Participate in an individual interview via Zoom meeting (30-40 min) with the Research Staff at your convenient time after completing the 8-week MMPH program. The interview will be audio recorded. We will delete the recordings one year after the study ends.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Complete the screening and baseline questionnaires by phone or Zoom
- Participate in MMPH sessions (Zoom connection and video-recorded sessions)
- Use M-App for an 8-weeks intervention period according to UB Mind user manual instruction
- Complete required questionnaires at specific time intervals within the M-App and REDCAP
- Participate in an individual interview via Zoom with the Research Staff Download M-App to your device.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. We will not hold it against you.

If you decide to leave the research, you can tell us if you want us to use or discard the data you have provided before deciding not to participate. Suppose you agree to allow us in the use of the data collected before your choice not to participate. In that case, the collected data will be handled and analyzed the same way as typical research data. If you object to our ability to use the data, we will attempt to destroy the data. Your decision to withdraw from participating in this study would not have foreseeable adverse effects on you.

Is there any way being in this study could be bad for me? (Detailed Risks)

The study would not have foreseeable adverse effects on you.

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Is there any way being in this study could be bad for me? (Detailed Risks)

The potential risks are:

- **Emotional discomfort:**

There is no known risk associated with this study. However, you may experience some emotional discomfort during your participation in the MMPH sessions and the questionnaire completion, MApp use, or individual interview with the Research Staff because of the sensitive nature of the topics being addressed.

We will provide you with information on mental health resources and support groups at the time of enrollment. If you feel extreme emotional distress, you will be encouraged to utilize community-based mental health resources within Western New York. The study PI will report the incident to your PH doctors and the IRB to assure your safety. We will follow the policies and procedures of the university.

- **Breach of confidentiality of information:**

There is a rare chance that your confidentiality may be compromised if someone outside the research team gains access to your data. Our research team is trained in procedures to protect your data. All Zoom participation and interviews with you will be undertaken in a safe and secure place, typically the conference room or private office with closed doors. We will remind you to complete a Zoom connection from the privacy of your residence. We will provide a Zoom password to you to ensure confidentiality and security. The researcher will immediately remove your name from the information you provide and replace it with a code number. We will keep de-identified data secured on password computer servers at the School of Nursing. The researchers will store your paper documents in locked cabinets in a locked office.

What happens to the information collected for the research?

We will collect and store your research information in a secured server, the UB box, in the Center of Nursing Research in the School of Nursing at Buffalo. Only data bank personnel will have access to your information.

We will make every effort to limit your personal information use and disclosure, including research study records. We will only disclose the information to people who 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 the University at Buffalo.

Even if identifiers are removed, your information collected as part of the research will not be used or distributed for future research studies.

The sponsor, monitors, auditors, and the IRB will be granted direct access to your research study records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Because this study is federally funded, we are required to post a summary of this research results at ClinicalTrials.gov. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.
This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal may include not participating in the MMPH sessions, not completing the questionnaires, M-App intervention, or focused group interviews. We may remove you from the study due to potential mental health risks determined by the study PI in a rare instance.

What else do I need to know?

For your participation in this study, you will receive up to a total of $90.00-worth of US Bank Prepaid Cards at four-time points.

- You will receive a $20.00 US Bank Prepaid Card at the midpoint of the MMPH program (after Week #4 completion). For the waitlist group, this will correspond with the middle of waiting for the program to begin.
- You will receive a $20.00 re-loaded to your US Bank Prepaid Card at the end of the MMPH program (after Week #8 completion). The waitlist group will correspond with the end of the waiting period and before the program begins.
- You will receive a $20.00 re-loaded to your US Bank Prepaid Card at the midpoint of the follow-up period (4 weeks after MMPH completion). The waitlist group will correspond with the middle of MMPH intervention or after Week #4 completion.
- You will receive a $30.00 re-loaded to your US Bank Prepaid Card at the end of the follow-up period (8 weeks after MMPH completion). The waitlist group will correspond with the end of MMPH intervention or after Week #8 completion.
- The only anticipated costs to participants relevant to the study include data charges from their phone carrier if they are not using a Wi-Fi service or go over the allotted data usage with their phone carrier.

Group	$20	$20	$20	$30
Intervention	MMPH Week #4	MMPH Week #8	4 weeks after MMPH	8 weeks after MMPH
Waitlist Control	Eight weeks before MMPH	Four weeks before MMPH	MMPH Week #4	MMPH Week #8

_____ You have had a chance to read and review the content of this Consent Form

_____ You have sufficient time to review the content of this Consent Form with the research staff

_____ You acknowledge that all of your questions related to this study participation have been answered by research staff to your satisfaction

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_____ You provide verbal consent to participate in this research study