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ClinicalTrials.gov
Unique Protocol ID 2022B0254

Informed Consent Form

Study Title: Mindfulness in Motion Targeted to Sustaining the Mental and Physical Resilience of First Responders and Health System Employees

Document Date: September 8, 2022
NCT07502092

Attached is the IRB approved informed consent.

Sincerely,

Beth Steinberg, PhD, RN
Primary Investigator

The Ohio State University Consent to Participate in Research

Study Title: Mindfulness in Motion Targeted to Sustaining the Mental and Physical Resilience of First Responders and Health System Employees

Protocol Number: 2022B0254

Researcher: Dr. Maryanna Klatt, PhD

Sponsor: Ohio Bureau of Workers Compensation

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose:

The purpose of this study is to deliver the Mindfulness in Motion (MIM) program to first responders (FRs) via a mobile app and evaluate the immediate and sustained effects of the intervention on symptoms of burnout, stress, resilience, work engagement, and physical function for FRs. The previously stated measures will be measured before and after the MIM program is given. This app provides the platform for daily mindfulness practice, and your feedback and information will help us to continually improve the daily practice platform to maximize the benefits of the program for all participants utilizing the app.

Procedures/Tasks:

The Mindfulness in Motion (MIM) program allows participants to contribute to the ongoing research and enhancements of the program through surveys and feedback questionnaires. An account was created for you following your program registration. This login will allow you to leave and return to the app as is convenient for you to complete all the daily and weekly content and surveys. Before proceeding to the remaining app content, you will need to confirm whether you provide consent for the data collected to be used for research purposes. The consent provided will cover all your activities on the app, but you will be able to withdraw consent by contacting the study principal investigator, Dr. Maryanna Klatt. Withdrawing consent would not impact the resources or program for the participant, the research team would simply remove your data in analysis or other analytics completed after the program. After making your consent selection you will be directed to the pre-program

survey. After submitting the pre-program survey, you will be directed to the program app introduction page before you can continue to the program content. Another pre-program activity is completing the Firefighter/EMS Validation Survey which asks a few brief questions on your certification number, effective date, certification city, date, and county, and card upload. This will be completed on REDCap, a secure OSU data collection server. Any data collected in this study will not be shared in any way with your employer nor your organization. This must be completed to receive any incentive from the Mindfulness in Motion program.

A couple of days after class session #7, the post-program survey, program evaluation, and additional resources will be available from the weekly content page. You will continue to be able to access the program app for approximately four weeks after the final class session.

Duration:

We are only seeking consent to use the data in our research that you will provide as a regular part of your participation in Mindfulness in Motion, no additional time is required for you to participate in the research. Regardless of if you consent for researchers to utilize your data in analysis, the program will be the same.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

You may have an improved experience with the program through your ability to access materials, including audio and video supplements as well as additional online resources, through the app.

. There is some risk of breach of confidentiality, however, the research team has put several measures in place to guard against this risk. To protect against this risk, all systems that store personal information such as your name or email address with your data will be stored on encrypted servers managed by Ohio State. Only study personnel will be able to access your data which will be stored behind an OSU Wexner Medical Center (OSUWMC) firewall on a secure server. The weekly content and questions are administered through a password-protected portion of the MIM app maintained by OSUWMC Information Technology (IT). The IT developers will have access to the app and information collected through the app but are not involved in the research. The information collected through the app will be stored behind the OSUWMC firewall on a secure server. Only study personnel will have access to the data downloaded from the app, which will be stored electronically on the secure OSUWMC server. In addition, our app has undergone thorough risk assessment and has been approved by OSU IT's Risk Assessment team.

Confidentiality:

The research team will work to make sure that no one sees your online responses without approval. The only information that will be asked of you is general demographic information, first and last name, and email address to register for the program. The mobile application that we will be using will not have access to your geolocation or other personal data tied to your phone or mobile device. The app development company will not have access to any of your data or share it with any third-party sources. Only members of the research team, that have completed the appropriate training will be able to view the research data. Your information will not be shared with any third-party apps. However, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Also, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Future Research:

Your de-identified information may be used or shared with other researchers without your additional informed consent. Additionally, we may have other mindfulness and well-being studies that you may be interested in. Please indicate below if you are interested in being contacted for future studies.

____ **Yes, I give my permission** to be contacted for future mindfulness or well-being research opportunities related to this study.

____ **No, I do not give my permission** to be contacted for future mindfulness or well-being research opportunities related to this study.

Incentives:

By law, payments to participants are considered taxable income. You will receive up to \$100 in the form Amazon gift cards for your participation in this study. To receive the incentives, you must fill out the validation survey so we may ensure the program and incentives are going to the proper audience.

The incentive payment schedule is listed here:

- \$25 Amazon Gift Card received after completing the pre-survey on the mobile app.

- \$50 Amazon Gift Card received after attending 6 out of 8 Mindfulness in Motion sessions and completing the post-program survey on the Mindfulness in Motion mobile app.

- \$25 Amazon Gift Card received after completing the 6-month follow-up survey on the mobile app.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By withdrawing consent from the study, you still will have access to the Mindfulness in Motion program material on the app. We will remove your data from the analysis completed at the end of the study. By agreeing to participate, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact **Dr. Maryanna Klatt at 614-293-3644 or Maryanna.Klatt@osumc.edu**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.

Please make your consent selection below:

- In addition to use of my responses entered in this app for further app development, I also consent to use of my responses entered in this app for research purposes and understand that my responses will be reported in aggregate as part of the study findings.
- I consent only to use of my responses entered in this app for further app development.

If you do not consent to either option, you will not be able to use the program app at this time. You can email Maryanna.Klatt@osumc.edu to delete the log-in created for this app if you wish. You may close your browser and return to the app later to make your consent selection, but you will need to confirm one of the two consent options before accessing the program modules.