1. Consent Form
Reducing Disparities in the Treatment of Hypertension Using the OWL mHealth Tool

2. NCT Number
NCT03974334

3. Submitted
8/14/2020

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

FACT SHEET: Reducing Disparities in the Treatment of Hypertension using the OWL mHealth Tool (H00015619)

Who is conducting this study?

Clinical and research staff from the Department of Family Medicine and Community Health (DFMCH) at the University of Massachusetts Medical School (UMMS).

What is the purpose of the study?

You are being invited to participate because you have a current diagnosis of high blood pressure. Your participation will help us evaluate the effectiveness of an on-line technology (OWL) for self-monitoring and managing your hypertension and other cardiac risk factors.

Am I eligible to participate?

You are eligible to participate in the study if you:

□ have a current diagnosis of hypertension
□ are an English-speaking male or female of any race and ethnicity
□ are over the age of 18
□ are not currently pregnant or actively planning to become pregnant
□ are able to comprehend instructions and participate in the interventions
□ are able to access computer technology for utilizing the study intervention website

- Your participation is entirely voluntary.
- You do not have to be in this research study. If you join the study, you can stop or leave at any time with no change in the relationship you have with your medical providers.
- You will be told about any new information or changes in the study that could affect you.
- You can ask all the questions you want before deciding if you want to be in this study.

What is my expected time commitment?

We expect that you will be in this study for 8 weeks. Your approximate time commitment is one hour for pre-, mid-, and post- surveys, one hour for a focus group, six hours for small group sessions and cooking classes, and eight hours of using the weekly web-based platform.

What will I be asked to do?

We will ask you to provide information about yourself (age, gender, etc.) by completing a baseline questionnaire. The questionnaire will also ask general questions about your health, physical activity, diet, etc. You will be asked

to participate in an orientation session on how to use the OWL on-line technology and cooking demonstration. You will then be asked to use the OWL on-line technology at home and complete 8 weekly sessions to learn and practice skills that may help you manage your hypertension and other cardiac risk factors. You will be asked to attend a small group cooking class at week four of the intervention. At the end of 8 weeks, we will ask you to attend the final cooking demonstration and to complete a follow-up questionnaire and to participate in a focus group to discuss your experiences using the OWL technology. The focus group will be video and audiotaped. The video taping is optional; if you choose not to be included in the videotaping, you can still participate in an area of the room outside the scope of the video recording.

What are the risks or inconveniences of being in this study?

We anticipate that the risks or inconveniences will be minimal. These risks include slight embarrassment or discomfort in response to some health or personal information survey questions. You may also experience minor discomfort resulting from mild physical activity, a small risk of muscle strain from yoga poses, and feel lightheaded or sleepy from engaging in mindfulness/meditation activities. We will be audio and/or videotaping the cooking classes and the focus group at the end of the study, but you can choose to not be involved in the videotaping portion by sitting off screen. You may also feel uncomfortable sharing information in the group. We will do everything to make sure that your information is kept confidential.

One additional risk of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

Will being in this study cost me any money?

No, other than possible transportation or childcare costs you may incur to attend on-site meetings.

Will I be given any money or other compensation for being in this study?

You can receive $25.00 for completing 3 questionnaires and participating in the 8-week on-line learning and practice sessions using the mHealth OWL tool. You can also receive an additional $25.00 for participating in one focus group at the end of the study.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor may decide to discontinue your participation in the study even if you do not want to leave. This may happen if it is determined that the study may be harmful to you in some way or if the sponsor stops the study.

<u>If you have any questions or concerns about your participation, please call or email</u>:
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This research has been reviewed and approved by an Institutional Review Board. You can reach them at (508) 856-4261 or irb@umassmed.edu if you would prefer to speak with someone not associated with the study or have questions about your rights as a research participant.

To be completed by research staff member only.

This form was reviewed with the following participant by the following research staff member on the below listed date.

Did the patient provide verbal consent? □ Yes □ No

Study ID: _____

Research Staff Member: _____

Date of Review: _____