INVESTIGATOR STUDY PLAN - REQUIRED

1. Study Protocol
Reducing Disparities in the Treatment of Hypertension Using the OWL mHealth Tool

2. NCT Number
NCT03974334

3. Submitted
8/14/2020

INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE
Reducing Disparities in the Treatment of Hypertension using the OWL mHealth Tool (H00015619)

2. EXTERNAL IRB REVIEW HISTORY*
NA
This study has not been submitted to an external IRB.

3. PRIOR APPROVALS:
NA

4. OBJECTIVES*
This is a one-year study with a no-cost extension until 7.31.20. The objectives are:
1) To engage 26 socio-economically diverse subjects (2 cohorts of 13) with a current diagnosis of hypertension in beta testing an on-line mHealth platform (Our Whole Lives: an e-Health toolkit) that is being adapted to help manage and reduce high blood pressure and other cardiac risk factors by introducing mindfulness skills and lifestyle modification.

2) To identify barriers and facilitators of using OWL at home for self-monitoring and self-management of blood pressure and other cardiac risk factors. This is an 8-week pilot study that will assess the usability of a refined e-health platform for managing hypertension and other cardiac risk factors. There will be three in-person medical group visits to provide feedback on the refined system.

3) To redesign the OWL Orientation Session (OWL-O) by engaging 10 subjects from our existing OWL-H cohort(s) to quantitatively beta test and to complete a qualitative interview/focus group on an adapted version of the Orientation Session, based on their previous feedback.

5. BACKGROUND*
Nearly 80 million adults in the United States have high blood pressure. Few studies have specifically targeted minority populations with hypertension.[1,2] Subject preferences, access to care, and socioeconomic/cultural determinants all add layers of complexity to this type of research. Dr. Gardiner developed and tested OWL for Chronic Pain (OWL CP) in subjects with chronic pain and chronic conditions with funding from the Patient Centered Outcomes Research Institute (2013-2017).[3] OWL CP was also tested in a sample of 46 with funding from the Aetna Foundation.

Preliminary results from the Aetna foundation study showed a reduction in cardiac risk factors such as systolic blood pressure, stress, unhealthy eating, and sedentary behavior among subjects participating in the self-management program delivered by the OWL platform.[4] OWL uses an innovative online community and self-management program to provide access to stress reduction, mind-body techniques, nutrition, exercise, and peer support. OWL provides educational materials including videos of clinician-led talks (stress reactivity, nutrition, movement, etc.). OWL also provides subjects a facilitated community blog, private journal, peer support, and an extensive resource library. OWL can be successfully accessed on a cell phone, tablet, or desktop.

For this study, we refined the OWL CP platform to specifically address cardiac risk factors and hypertension, creating OWL for reducing Hypertension and Cardiac Risk Factors (OWL-H). Due to the proposed mixed methods, a transdisciplinary team reviewed quantitative and qualitative outcomes and will assist with refinement to the system. Based on preliminary findings and the availability of additional funding, we are taking the opportunity to make much-needed updates to the OWL-H website, particularly the Orientation Session, in order to increase the usability and user experience of the site. These changes will aid our team's long term plans of a large RCT to test the OWL-H platform's success in reducing hypertension and cardiac risk factors.

6. INCLUSION AND EXCLUSION CRITERIA*

We consented 25 subjects with self-reported high blood pressure. We collected baseline data on 24 subjects and 22 completed the protocol for the study (two participants were lost to follow-up and 1 withdrew). We will reach back out to those 22 subjects and plan to recruit 10 to complete beta testing and a qualitative interview/focus group on the updated Orientation Session. As these 10 participants will have already met the below listed criteria recently, and we are asking them to beta test the new Orientation Session only (and not collecting new data from the participants, we will not rescreen them.

Inclusion criteria:

1. Male and female subjects of all races and ethnicities who are English-speaking adults over the age of 18 and who have a current diagnosis of hypertension. OWL is currently only available in English.
2. Subjects' physical and mental health status will be sufficient to be able to comprehend instructions and participate in the interventions.
3. Subjects must be able to access computer technology (cellular phone, desktop, laptop) and the internet to utilize the online OWL-H platform.

Note: We will be videotaping the 3 cooking demonstrations (to take place during the group medical visits) to add this content to the OWL-H platform. This has been added to our fact sheets. We will ask patients to sign a release to allow us to film them during the cooking classes. If they choose not to consent to filming, they will still be able to take part in the class off camera.

Exclusion criteria with rationale:

1. Serious underlying systemic or co-morbid disease, including psychotic or manic symptoms, which preclude physical or cognitive ability to participate in the intervention. The risk-benefit ratio of the interventions for these individuals may be potentially higher than acceptable.
2. Active substance abuse, given that individuals who have active substance abuse pose a higher risk both to themselves and other members of the groups.
3. Beginning new hypertension treatments in the past week or planning to begin new hypertension treatments in the next few weeks or planning a major medical event in the next few weeks, which would interfere with accurately determining the effect of the intervention on impact in this study.

4. Subjects who are pregnant or actively trying to become pregnant will be not included in this study given that the risk-benefit ratio of this intervention may be higher than acceptable for these individuals due to the potential onset of non-study related gestational diabetes and/or gestational hypertension. Determination of pregnancy status will be based upon subject self-report.
5. Subjects who are not willing to participate in the intervention or attend the group visits/interview/focus group.

7. STUDY-WIDE NUMBER OF SUBJECTS*
NA

8. STUDY-WIDE RECRUITMENT METHODS*
NA

9. STUDY TIMELINES*

This is a one-year open feasibility pilot study with an extension until July 2020. Planning and recruitment activities took place during months 1-3. In months 4-8, two cohorts participated in beta testing of the on-line OWL-H platform eight-week modules followed by a focus group convened at the end of the online component. During each cohort, we invited the subjects to 3 group visits to re-enforce the key content of OWL-H and answer questions on how to use the OWL system and get feedback about the system. During those visits, the subjects will also be invited to participate in three cooking classes that will be videotaped. These videos will be uploaded into the OWL-H system in months 9 to 12. Data analysis will be completed during months 9-12. Concurrently, during months 9-12, we will be re-enrolling 10 repeated subjects to beta test an updated version of the OWL-H Orientation Session. Once testing and data collection are complete, we will analyze and send our findings to BrightOutcome to make any final needed updates to the Orientation Session.

Time Line – one year

	Q1	Q2	Q3	Q4
IRB completed	X			
Revision and Addition of new content to OWL by Bright outcomes and Dr. Gardiner	X			
Beta Testing of OWL by Bright outcomes and Dr. Gardiner	X			
Recruitment		X	X	
Pilot testing of the new OWL-H		X	X	
Focus Group		X	X	
Revision of OWL-H				X
Preliminary Data Analysis				X
Re-Consent of 10 OWL-H Subjects				X
OWL-O Focus Groups/Interviews				X

Full Data Analysis				X
Final Revision of OWL-H				X
Preparation of Grant Proposals				X
Publications				X

10. STUDY ENDPOINTS*

Our primary outcome is successful refinement of the OWL platform, based upon participant utilization and focus group feedback, to deliver information on self-management of hypertension and other cardiac risk factors, and to encourage self-monitoring of blood pressure.

Specific Aim 1 - To pilot test the OWL-H platform for 8 weeks with 26 patients with hypertension (2 cohorts) to refine its utility for home self-monitoring (number of times patients record home blood pressure and input this data onto OWL and engagement of self-management tools (i.e. # of logins, # of mind body sessions completed, # of times modules accessed each day)). Hypothesis 1: Eighty percent of patients will log in and record their blood pressures.

Specific Aim 2 - At the end of each cohort, conduct a focus group to obtain information about: 1) the barriers and facilitators of using the OWL platform and using OWL to self-monitor blood pressure at home, 2) satisfaction with OWL, 3) how OWL helped with reduction of number of cardiac risk factors (e.g., smoking, eating habits, perceived stress, and amount of exercise and health-related quality of life).

Specific Aim 3 – Using the previously collected feedback from the above aims, make key updates to the OWL Orientation Session. Re-consent 10 participants from the original OWL-H project to beta test and participate in a focus group/interview on the updated session, either on the UMMS campus or through a secure teleconference platform like Zoom. Implement changes as needed based on that feedback and testing.

11. PROCEDURES INVOLVED*

Recruitment

Primary OWL-H Project: Subjects were recruited from the Worcester area with a focus on the adult primary care clinics.

Subjects self-referred or were referred by their primary care provider. Subjects were contacted by the study RC via phone or e-mail to schedule a convenient time to complete the screening consent, review study objectives, and review eligibility criteria. An individual's name and contact information was kept separate from collected and stored data by utilizing a password protected spreadsheet on a school server and the OnCore patient and study tracking system. This information will be destroyed when feasible (the spreadsheet will be deleted immediately following completion of the study time period).

A HIPAA waiver was requested and approved to perform a medical record review to confirm eligibility, which was used to enroll the first 11 enrolled subjects in the study. The RC conducted a medical record review by querying the subject in EPIC by name and birthdate. The RC then

confirmed that there was a high blood pressure medication listed on the medication chart and there was a diagnosis of hypertension on the problem list. With the current criteria not requiring a medication use, and self-reported instead of an official diagnosis of hypertension, a chart review is no longer required.

Once eligibility was determined, the study RC contacted the subject by phone or in-person to review the study fact sheet, obtain verbal consent for participation using that fact sheet, and to go over the HIPAA authorization and photo consent forms. The staff member who explained the study fact sheet and obtained verbal consent signed and dated the bottom of the fact sheet to provide confirmation of received consent. A copy of the study fact sheet, HIPAA authorization (for participation in group medical visits), and photo consent forms were provided to the subject prior to first group visit through the avenue of their choice (e.g., blank copies sent through email for their reference; hard copies mailed; or hard copies provided at individual in-person meeting). If possible, signed copies of the forms were collected prior to the first group visit. If not possible, they were collected during the check-in process at the first group visit. Before or during the first group visit, subjects were administered a baseline questionnaire (socio-demographic and general health information). Subjects were given the option of completing the questionnaire online (REDCap database) before the first group visit; in-person with a study staff member at an individual meeting or during the first group visit; or over the phone with a study staff member. No data was collected without completed consents from the subject.

OWL-O: The study RC will re-contact OWL-H participants that completed the entire protocol (i.e., were not lost to follow-up or withdrew) to make them aware of this project extension and ask whether they would like to participate in the updated orientation testing. Those that desire to will be consented with the OWL-O Beta Addendum Consent Fact Sheet. The study RC will sign and date the fact sheets to provide confirmation of consent.

OWL-H Orientation to Intervention (Week 1 – 8/21/19 and 10/30/19)

Eligible subjects were asked to participate in 3 in-person sessions. Participants had three options for data collection. They could fill out the baseline questionnaire online (REDCap) prior to the orientation, in-person with a study staff member prior to orientation, or during the first thirty minutes of the orientation. They also completed their photo consent and HIPAA authorization forms during that time, if it was not completed before this first group visit. Participants had baseline weight, height, waist circumference, pulse, and blood pressure readings completed at the orientation in a private room.

As part of this first group visit and cooking class session, a tutorial on how to use the OWL technology was demonstrated, participants were given their login information, and all participants were taught to take their blood pressures. As participants arrived, they were given the OWL-H Group Visit Check-In Form, which asked them basic questions about healthy lifestyle habits, any changes in medication, pain and mood rating, etc. This form was strictly for guiding the group leader (PI Dr. Paula Gardiner) in her discussion with each patient individually, to track any potential AEs throughout the study, and to help guide the discussion. While this form collected data that assisted in the conduction of our research project (e.g., identifying potential AEs), any information identified as needing to be kept (again, solely the case for AEs

or a note to file for a medication change (as the goal was for participants' meds to stay the same during the course of the study, though we in no way would ask them to go against their doctor's advice)) was recorded on a different form. This Group Visit Check-In Form was stored separately from any recorded data in a locked filing cabinet in a locked study staff member's office and was shredded after review by the PI and research staff (for potential mention of any AE or needed NTFs. If a potential AE was discovered using this form, the PI discussed it with the patient in private at each group visit, then completed the study adverse event log form (which, as previously approved by the IRB and in line with HRP-801, will guide the decision of when it needs to be reported to the IRB) if it was determined to be an adverse event.

Each participant received a blood pressure cuff and was asked to sign the Blood Pressure Cuff Return Agreement. All participants were observed taking their blood pressure prior to leaving the session with their cuff. Finally, we conducted and video recorded a cooking class on healthy food choices for reducing HTN during this time. Any subjects who did not consent to being video recorded were able to sit out of the scope of the camera during this presentation.

Mid-Session Feedback Group Visit (Week 4 – 9/11/19 and 11/20/19)

During week 4, subjects first filled out the OWL-H Group Visit Check-In Form, then completed the Midpoint Survey to answer questions about use of the OWL technology and to get feedback. They then participated in a short educational discussion regarding what they had learned so far using OWL. A second cooking demonstration took place during this session, which was video recorded, excluding on film anyone who did not consent to be video recorded. Any adverse events were recorded by the RC and PI.

Final Session (Week 8) and Focus Group (10/9/19 and 12/18/19)

During week 8, subjects again filled out the OWL-H Group Visit Check-In Form and participated in a group visit and cooking class to reinforce key content and provide certificates of completion. During this visit, a follow-up weight, height, waist circumference, and blood pressure were obtained and entered into REDCap. At the completion of the group visit, subjects were asked to complete a follow-up questionnaire, to return their blood pressure cuffs, and to participate in a one-hour focus group discussion with a facilitator who collected information about their experiences using OWL. If subjects did not come to the group, they were asked to come in to meet with the RC to obtain this data and return their cuff.

Updated OWL Orientation Testing and Feedback Session (Spring 2020)

Based on feedback collected from the OWL-H project surveys and focus groups (for both cohorts) and the availability of extra funding from our sponsor, we are making needed updates to the OWL-H Orientation Session to increase usability of the platform. Specifically, we plan to create tutorial videos that will be embedded in the session to familiarize participants with the various aspects of the OWL-H platform. We will also use this funding to create new Resource Section content (e.g., Healthy Shopping Guide, How to Eat Healthy When Eating Out, and lists of specific local resources for hypertension management), based on previous participant feedback.

Ten subjects who previously consented to be part of the OWL-H project and completed the entire protocol will have the opportunity to take part in the quantitative beta testing and qualitative focus group/interview data collection for this updated Orientation Session. They will be asked to attend a research session, which will be held in a computer lab on the UMass campus or remotely by using a teleconference platform like Zoom, to complete a structured quantitative beta testing of the new session content. They will then be asked to participate in a semi-structured focus group/interview to collect qualitative feedback on the updated session. This research session should not last more than 2 hours.

OWL-H Platform

OWL is maintained on a HIPAA compliant server. All patients were given a username and password that was not linked to their real name or any health information. We will do the same for the OWL-O research session(s). At the orientation class for the OWL-H project, participants were given a blood pressure cuff for home use to monitor their blood pressure throughout the study. They were taught to use their blood pressure cuffs and were asked to measure and record blood pressure readings prior to logging into OWL.

The OWL platform is set up so that upon login a box appears to collect the participants daily blood pressure and pulse values, as well as information on their HTN medication use (if taking medication). For the OWL-O research session(s), participants will be given false values to enter in this daily reading box. The OWL-H intervention included watching a weekly 10-minute health topic video and interacting with a 15 to 20-minute meditation or body scan or gentle mindful movement at home. Additionally, there was a participant blog for participants to interact on. This was monitored daily by the research staff and Dr. Gardiner. For the OWL-O session(s), participants will be asked to only interact with the login screen, daily reading box, Orientation Session, and new education content.

12. DATA AND SPECIMEN BANKING*
NA

13. Data Analysis and Management*

The data collected from the study will be used to further adapt/revise the OWL-H technology for use in a larger study. We are using preliminary findings to update the OWL Orientation Session and will collect further data through focus groups/interviews and beta testing in order to further improve and revise that session, as needed. We are basing the sample size for both projects on the number of subjects whose feedback we need to revise the system.

Qualitative data will be gathered from focus groups held at the end of each 8-week session and the end of the OWL-O research session(s). Qualitative data analysis methods will be used to identify themes from questions related to website utilization, including identification of barriers, facilitators, and practice techniques.

Quantitative data was collected from baseline, midpoint, and follow-up assessments and include socio-demographic, health status, and general health knowledge and high blood pressure. Only study staff included on the IRB project have access to the raw data. Data analysis will include the initial calculation of descriptive statistics (means, proportions, and standard deviations) and baseline to follow-up measurement analysis including T tests and chi squares for normally distributed data. Quantitative data regarding the updated Orientation Session will be

collected during the OWL-O session(s) using a structured beta-testing tool that measures usability.

Data was collected on the utilization of the OWL website, use of home practices, use of mindfulness practices, and any adverse events since beginning to use OWL. Data regarding the use of the OWL website was also gathered—length of time spent on each page, number of times the patient logs in, links the participant clicked on, activities used on the website (such as listening to the body scan recording or watching health videos), any text which was inputted on the website, and any content that was downloaded.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

Since OWL-H was a minimal risk study, we did not be developing a formal data safety monitoring committee, but instead had the below data safety monitoring plan. Performing activities suggested on the website had a slight possibility of causing participants to have muscle soreness from doing mindful movement or to feel light-headed or sleepy from the mindfulness/meditation activities. All participants were warned of these risks and told they were able to discontinue any activities as soon as they felt discomfort. Dr. Gardiner monitored all blood pressure readings at all group visits and daily on the platform and referred subjects with blood pressure readings of >160/100 to the emergency room, as needed. Since all patients were either on HTN medications or did not meet the threshold to take medications, as recommended by their PCP, we did not anticipate that patients' blood pressures would meet this criterion.

OWL-O (Spring 2020)

As participants of OWL-O will only be conducting a beta test and interview regarding the updated Orientation Session and not being asked to do any physical activities or provide blood pressure readings, the above risks are not associated with the OWL-O session(s). However,participants are able to contact the principal investigator, Dr. Paula Gardiner, for advice on any potential study-related problems that might arise. Dr. Gardiner will regularly review any issues brought by subjects to the study staff, looking for systematic trends suggestive of risk and clinically important issues. Participants were and will be told during the consent process that they are study volunteers, and that they do not have to answer any study questions which make them uncomfortable. They were and will be reminded of this information by the Research Coordinator if a question on any study surveys appears to make the participant uncomfortable. The RC will contact Dr. Gardiner regarding any safety concerns.

All written data and forms were and will be stored in a locked file cabinet that is accessible by the Principal Investigator and study team members only. All computer files were and will be password protected on a UMMS server, and all study subjects will be designated by a unique ID number only (the same ID will be assigned to the repeat OWL-O participants as they had in OWL-H). Any data downloaded for analysis will be scrubbed for identifying information by a study staff member before being exported from REDCap. Study subject's unique identifiers were and will be linked to their name only in a password protected spreadsheet on a school server and on the secure OnCore system. Data will be handled with the same confidentiality accorded to patient's medical records. All project staff have been trained in procedures to ensure patient confidentiality.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

The principal investigator or sponsor may discontinue participation in the study even if the subject does not want to leave. This may happen if it is determined that the study will produce negative effects, or if the sponsor stops the study.

16. RISKS TO SUBJECTS*

The potential risks to subjects are minimal. These risks include slight embarrassment or discomfort in response to some health or personal information survey questions and potential loss of privacy and confidentiality. Subjects may have felt/feel uncomfortable sharing information in the focus group/interview at the end of the study. Subjects may also experience minor discomfort resulting from mindful movement, a small risk of muscle strain from mindful movement, and feel lightheaded or sleepy from engaging in mindfulness/meditation activities (though these risks do not apply to OWL-O).

Subjects who choose to participate in the focus group/interview at the end of the OWL-H 8-week session can choose not to answer any questions or not to participate in videotaping. Focus groups were audio and video-taped, and the tapes were destroyed after information was transcribed. Subjects participating in the OWL-O sessions must consent to having their on screen participation video recorded (not their likeness, only the computer screen) and their audible feedback audio recorded, as this will be key in capturing usage/usability and feedback data as the beta testing and focus group are occurring. They may choose not to answer any questions they wish but must participate in both the beta testing and focus group/interview in order to complete study requirements. This is all stated in our OWL-O consent fact sheet.

Protections Against Risk

All subjects were and will be informed of potential risks during the consent process. Subjects were and will be advised to discontinue activities as soon as they feel discomfort, though this risk is unlikely during the OWL-O session(s). Potential risks to confidentiality of data collected throughout the study were and will be addressed as follows: All written data and forms were and will be stored in a locked file cabinet that will be accessible only to relevant study staff. All computer files with protected health information were and will be password protected, and all study subjects were and will be designated by a unique ID number only. The master list linking subject identities with their ID numbers was and will be kept on a password protected spreadsheet on a school server and on OnCore. Data was and will be handled with the same confidentiality accorded to subject's medical records. Specific procedures protecting participant confidentiality include staff training in procedures to ensure confidentiality. All reports did and will preserve the subjects' anonymity. Any breach of confidentiality will be subject to a root cause analysis and preventive measures taken as appropriate.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

Participation in this study may provide subjects with practical knowledge for monitoring and self-managing their high blood pressure. Additionally, participants may gain experience in meditation techniques.

18. VULNERABLE POPULATIONS*

NA

19. MULTI-SITE RESEARCH*
NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*
NA

22. SETTING

We primarily recruited subjects from the adult primary care medicine clinics at the UMass Medical School. Outreach to Worcester-area community health centers was initiated due to recruitment difficulties. All recruitment procedures did and will strictly adhere to HIPAA regulations. The group visits, cooking classes, and focus group meetings took and will take place at the medical school in a room with a closed door to ensure confidentiality. Focus groups were and will be audio and videotaped. Transcripts were and will be retained on a password protected server. All tapes were and will be destroyed after transcripts have been reviewed and verified for accuracy. Video tapes of the cooking classes will be uploaded to the OWL-H website.

23. RESOURCES AVAILABLE

Principal Investigator: Dr. Paula Gardiner is Associate Research Director and Associate Professor in the Department of Family Medicine and Community Health, and Medical Group Visit Program Director in the Center for Integrated Primary Care. As PI, she will provide research leadership and oversee study implementation. She will supervise all research staff, monitor budget activities, communicate with Institutional Review Board (IRB) staff, and complete all IRB required reports.

Co-investigator and Cooking class Instructor: Barbara Olendzki, RD, MPH, Associate Professor and Director of the Center of Applied Nutrition will devote effort to the OWL-H study. She will be responsible for providing three healthy cooking classes.

Research Coordinator: Ariel Villa will devote time to study activities. She will facilitate all facets of study implementation including recruitment, subject consent, training, and creation of data tracking systems.

24. LOCAL RECRUITMENT METHODS

We recruited a total of 25 subjects with a current diagnosis of hypertension for the OWL-H project and plan to re-enroll 10 of those participants for OWL-O. We will strictly adhere to HIPAA regulations. OWL-H recruitment materials, including flyers, brochures, and patient handouts, were distributed to and made available to potential subjects receiving health care services in the adult primary care medicine clinics located at UMass Memorial system. Subjects were able to self-refer or be referred by their primary care provider. Outside recruitment will not be necessary for OWL-O, as it is a repeated subjects design.

For OWL-H, research staff coordinated a meeting with primary care providers to review study procedures, risks and benefits to subjects, and data collection methods. The presentations

educated providers and staff about OWL, broadly defined the inclusion criteria, detailed methods of recruitment, and encouraged providers to distribute flyers and brochures to their patients with hypertension. All questions were answered thoroughly by the investigator. Subjects who were referred by their provider at the time of their medical appointment or who self-referred were contacted by the study RC. The RC provided subjects with a study fact sheet and obtained verbal consent.

OWL-H subjects received $25.00 for completing baseline, midpoint, and follow-up questionnaires and an additional $25.00 for participating in the focus group. OWL-O subjects will receive $50.00 for completing beta testing of the updated Orientation Session and a focus group/interview session on the same.

25. LOCAL NUMBER OF SUBJECTS

We recruited 25 subjects who were eligible to participate. Of those, 22 completed the entire protocol. From those 22, we plan to recruit 10 to beta test the updated OWL Orientation Session.

26. CONFIDENTIALITY

All participating subjects were and will be assigned a specific study code. We did and will use the REDCap secure online database to gather and store participant data. Subjects were and will be assigned a project identification number to protect privacy. Data is and will be stored in locked cabinets in a designated locked research office. Data is and will also be stored on UMMS privacy/password protected servers. Only study staff on a strictly need-to-know basis will have access to data.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

OWL-H research subjects had the opportunity to complete pre-, mid-, and post-study data on-line via REDCAP or in-person. Collection of baseline and follow-up physical data (vitals, weight, height, waist circumference) was conducted in a private room by research study staff. Refused or Declined choices on all surveys allow for voluntary skipping of questions.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

NA

29. ECONOMIC BURDEN TO SUBJECTS

There may be minimal costs to participate (i.e. childcare, transportation). As needed, both OWL-H and OWL-O have funds in the budget to assist with patient transportation and parking costs.

30. CONSENT PROCESS

For OWL-H, subjects who were referred by their clinician at the time of appointment and expressed interest in participating in the study were contacted by the study RC at that time to confirm eligibility and obtain verbal consent. Since both projects are minimal risk, a fact sheet was and will be provided to all potential subjects in lieu of a formal written consent. The RC did and will obtain verbal consent from subjects interested in participating to confirm eligibility. If eligible, the study protocol was and will be explained along with potential risks and benefits and measures taken to protect privacy and confidentiality. All questions were and will be answered to subject satisfaction.

For OWL-H, if the subject was unable to meet with the RC at the time of their appointment, alternative arrangements suitable to the subject were made. For subjects who self-referred, the study RC contacted subjects by phone to confirm eligibility to participate and to go over the study fact sheet and obtain verbal.

We consented individuals according to inclusion/exclusion criteria, and will continue to do so for OWL-O. Research study staff were trained to follow all consent procedures as outlined in SOP HRP 802: Investigator Guidance: Informed Consent.

During the orientation class and focus group session of OWL-H, participants reviewed and discussed the guidelines about confidentiality. As participants are not providing any clinical or personal information during the OWL-O research session(s), and will have consented to be part of a group beta-testing session and focus group, this will not be done for OWL-O.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

This is a minimal risk study, and we did and will obtain verbal consent to determine eligibility using a study-specific fact sheet.

32. DRUGS OR DEVICES

NA

References

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