GEMINI: Virtual Integrative Medical Group Visits for Managing Chronic Pain
Informed Consent Document
Version Date: 07/03/2024

CHA Cambridge Health Alliance	**INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study.

Study Title: GEMINI: Virtual Integrative Medical Group Visits for Managing Chronic Pain

Your name (Participant):	**Today's Date:**

Not including this study, are you taking part in any research now? ☐ **Yes** ☐ **No**

Name of Principal Investigator: Paula Gardiner MD

Name of Co-Investigator(s): Zev Schuman Olivier MD

Consent form version date or number: Version 4

Name and telephone number of study contact to call with questions:
Tori Blot Research Coordinator (781-873-9782)

CHA IRB Number: CHA-IRB 23-24-260	**Study Sponsor(s):** NIH/NCCIH

Key Information

- You will be asked to participate in an online self-management program called **OWL (Our Whole Lives)** for people who have chronic pain. **OWL** is hosted on a secure internet platform called **GEMINI.**
- In addition to engaging in OWL, you may be asked to do other tasks such as attending a weekly group visit on Zoom and interacting with a secure online community.
- Taking part in this study is voluntary. You have the choice to take part or not. You may leave the study at any time for any reason.
- You will be asked to participate in the study for 24 weeks.
- You will be asked to complete surveys before beginning the study, and then again at Week 10, Week 16, and Week 24. These surveys will be delivered online.
- You may also be asked to participate in an optional focus group or an individual interview.
- You may not benefit from this program. If you choose to participate, you may have moments where you feel stressed, embarrassed, or anxious. Despite strong efforts to maintain your confidentiality, if you participate in an online program, as with any activity on the internet, it is possible that your protected health information (PHI) may be exposed.

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Introduction

Please read this form carefully. This form tells you about a study called, "GEMINI: Virtual Integrative Medical Group Visits for Managing Chronic Pain." This study is being conducted by researchers at Cambridge Health Alliance, in Cambridge, Massachusetts, in conjunction with software developer Bright Outcome, in Buffalo Grove, Illinois. By engaging in the OWL program on the GEMINI platform, you are engaging with a tool managed by Bright Outcome.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in the study, you may leave the study at any time for any reason. If you don't want to take part, it does not change any part of the standard health care you may receive at Cambridge Health Alliance.

If you decide to take part in this study, you will be asked to sign this form. We will give you a copy of the signed form. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

This program aims to help you learn more about your chronic musculoskeletal pain. It is not, however, guaranteed that you will experience these benefits.

The National Institutes of Health (NIH) is providing funding for this research. If you have any questions about the research or about this form, please ask us.

We will tell you about new findings that may cause you to change your mind about being in this study.

Purpose of the Study

The purpose of this research study is to help you function better and test the efficacy of a non-medication internet-based solution for patients with chronic muscle or skeletal pain.

Approximately 212 participants will be in this study at Cambridge Health Alliance and surrounding neighborhoods.

Reasons why you have been invited to be in this study

To take part in this study, you have to meet the following criteria:

- You understand English well enough to understand procedures and questionnaires and provide informed consent.
- You are over the age of 18.
- You have chronic musculoskeletal pain.
- You have an average pain intensity of ≥ 4 in the past 7 days.
- You've reported having chronic pain for at least 3 months.
- You've experienced pain on at least half the days in the past 6 months.

Reasons why you may not be eligible to participate in this study:

To take part in this study, you must **NOT**:

- Be experiencing severe depression, current mania or psychosis, or suicidality
- Have chronic pain caused by cancer
- Be actively using heroin or cocaine in the past 3 months
- Have heavy alcohol use that interferes with the ability to participate
- Have cancer or serious underlying systemic or comorbid disease that prevents you from participating in the 24-week study.

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- Have a known or planned pregnancy

Period of Participation (how long you will be in this study)

If you choose to participate in this research study, you will first be screened to determine whether you are eligible for this study. If you are found to be eligible following an initial Eligibility Screening Session, you will be asked to review and sign an Informed Consent Form, and complete a Baseline/Screening Survey Session. Following completion of your Informed Consent Form Session and Baseline Survey Session, the study team will make a final determination of your eligibility.

PLEASE NOTE: There are several components and time points which are used to assess your eligibility to join this study. These are:

1. **Recruitment Screening Call**
2. **Informed Consent Session**
3. **Screening and Baseline Survey Session**

It is possible that you will be deemed ineligible at any of these 3 time-points. Eligibility determinations will be based on the safety and suitability for you to personally participate in this research. If you are deemed to be ineligible, it is because it may be unsafe or unhelpful for you to be enrolled in this particular study.

If you are deemed to be **INELIGIBLE** following your **Recruitment Screen call**:

- We will unfortunately be unable to enroll you in this program.

If you are deemed to be **INELIGIBLE** after your **Informed Consent Session**:

- We will unfortunately be unable to enroll you in this program. You will be paid for your time consenting ($20) dollars

If you are deemed to be **INELIGIBLE** following your **Baseline Survey Session**:

- We will unfortunately be unable to enroll you in this program, and you will be paid for your time spent completing a Baseline Survey Session($25) and $20 for the consent session.

If you are deemed to be **ELIGIBLE** following your **Baseline Survey Session**:

- You will be paid for your time spent completing a Baseline Survey Session($25), $20 for the consent session, and given a secure password to your personal OWL account.

- The total Period of Participation in this study is **24 Weeks.** You will be asked to engage with a mindfulness program called OWL for the **first 9 weeks**, potentially attending a 90-minute weekly **Live-Online Group** once a week for nine weeks during this time. You will be asked to complete **Follow-Up Survey Sessions at Week 10, Week 16, and Week 24**. These survey sessions may last up to 30 minutes. You will have the option of attending an **Online Focus Group(60 minutes) or Individual Interview(60 minutes) at Week 10**. You will be paid for time spent completing study surveys, and attending an optional focus group or individual interview. We will ask you **NOT** to participate if you expect to be hospitalized or cannot be on the internet during the study for a health problem or any other reason.

Procedures (what will happen during this study)

This study has 6 required (R) and 1 optional (O) components: Recruitment Screening Session(R), Informed Consent Session(R), Baseline Survey Session(R), Engagement with the OWL on the internet (R),

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Live-Online Mindfulness Group if Applicable(R), Follow-Up Survey Sessions(R), and an Online Focus Group/Individual Interview (O)

1. **Recruitment Screening Call(R):** Upon self-referral to this study, you will be contacted by a Research Coordinator to complete a Screening Session.
2. **Informed Consent Session(R):** If you are initially deemed to be eligible at the previous step, you will be asked to review and sign an Informed Consent Form during an Informed Consent Session.
3. **Baseline Survey Session(R):** After completing an Informed Consent Session, you will be asked to complete a Baseline Survey Session that will take about 30 minutes to complete.
    a. It is possible that after completion of your Baseline Survey Session, you will be deemed ineligible to participate. **Whether you are eligible or ineligible, you will be paid for your time spent completing a Baseline Survey Session.**
4. **Engagement with the OWL on the internet (R):** For 9 weeks, you along with other people in the study, will all have access to a mindfulness program within OWL, optimized for people with chronic pain.
5. **Live-Online Mindfulness Group(R):** You may be asked to attend a 90 minute weekly session once a week for 9 weeks via Zoom. If this is the case, this component is a **REQUIRED** weekly commitment**.**
6. **Follow-Up Survey Sessions(R):** You will be asked to complete follow-up survey sessions at Week 10, Week 16, and Week 24.
7. **Online Focus Group/Individual Interview(O):** You will be asked to participate in an **OPTIONAL** individual interview, or a one-hour focus group with other participants in the study who used the OWL website as well.

Collection of identifiable private information or identifiable biospecimens:

We will collect data that includes contact information. You can choose to leave the study and remove our access to your data at any time. The study team will have access to your data up until the date of your withdrawal from the study. The coded data will be stored in a separate secure password-protected database, and only available to IRB-approved study staff.

Identifiers will be removed from the information collected. Only de-identified information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject.

Your de-identified Information may be used for commercial profit and you will not share in this commercial profit.

Support Calls Emails and Text Messages:

During the first 10 weeks of this study, you will receive a weekly, or bi-weekly email, text, or call from a study staff member for reminders (if applicable) and to complete surveys. The study staff will leave a message if you don't answer a phone call. A study team member may continue to call and leave several voicemails if they do not hear back from you. If you have questions about logging into OWL, need help with any problems you may have in filling out the surveys, or support, the study team is available 9am-5pm EST Monday-Friday by email, text, or phone.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side effects associated with your participation in this study:

- Some questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions regarding the surveys, focus groups and individual interviews before you participate in the study. If you get upset or stressed, you can call the research staff. The research coordinator can call a behavioral health provider if needed.

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- Meditation practices can sometimes cause stress for those who practice. If you feel stressed at any point in the study due to the mindfulness practices, you may contact the study staff who connect you with Dr.Gardiner (primary investigator) who can provide support and guidance.
- Increased psychological discomfort, due to increased attention to unpleasant thoughts, feelings, or body sensations that can lead to an increase in undesirable feelings. If this occurs during the study please let a Study Team member know. Gemini is not the appropriate place to request immediate medical help or report suicidal ideations.
- Muscle soreness due to being asked to do optional mindful movement.
- You may spend extra time learning techniques and doing study tasks.
- You might not benefit from this program.
- Despite strong efforts to maintain your confidentiality, your protected health information (PHI) might be exposed. All digital information collection and transfer using the internet carries the risk of loss of confidentiality due to privacy breaches.
- You might experience eye strain from performing device tasks.
- Group members who are posting on the optional community board will be asked to keep all information confidential, but they may not.

- You will be invited to practice mindfulness skills and techniques at home, which may involve negotiating with those at home to create time and space for practice.

We will be happy to answer any questions you have about these risks and/or side effects. Please talk with a study team member if you have any study-related questions or concerns.

Alternatives to Participation

Participation is **voluntary.** Whether or not you enroll in this study will not affect your health care. You may choose not to participate in the study and return to standard care options that are approved by your primary care or behavioral health clinical treatment team.

Benefits (good that may come from being in this research)

- You may learn about others who have similar problems as you do, helping you feel less alone.
- You may receive access to education on self-management for chronic pain

Some of these benefits may not help you directly. However, what we learn from this research may help others in the future. There is no guarantee you will benefit from being in the study.

Costs

You will not have any additional costs from being in this study. All study-related visits and procedures will be given to you at no cost.

If you are referred to tele-visits with a behavioral health care provider, costs related to your standard care will be billed as usual to you or your insurance if you choose to have the visit.

Payment

You will be paid up to $120 (or $125 if you participate in an optional focus group):

- **$20** Consent
- **$25** Baseline Assessments

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- **$25** Week 10 Assessments
- **$25** Week 16 Assessments
- $25 Week 24 Assessments
- **$5** Optional focus group or individual interview

You will only be paid for each visit and study task that you complete. You will be given your payment at the end of each visit or study task. If you complete every visit and every task in this study, then you will be paid a total of $120 or $125 for your time and effort.

Payment comes in the form of a gift card which can be redeemed throughout the study. We will send a new gift card via email at each payment time point after the corresponding visits.

You will receive gift cards that will be sent as the study progresses. Study staff will email the gift cards with the amount of your study payment after your Consent, Baseline Assessments, Week 10, Week 16, Week 24 assessment, and Focus group(optional).

Study-Related Injury

If you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. If you have depression or mental health symptoms that worsen during the study, you will be referred to an appropriate level of mental health care at CHA. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part, you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

If you no longer want to participate, you may return to standard care options that are approved by your primary care or behavioral health clinical treatment team.

If you choose to withdraw from the study completely (“Study Withdrawal”), you will no longer be expected to complete study activities listed above and you most likely will not be able to continue in the OWL website. Any information collected from you before the date you leave the study will be used in the research study. If you wish to withdraw from the study, please notify the study staff either in writing or via email that you wish to do so.

The research team may decide that you can no longer be in the study (“Study Withdrawal”). This could be for several reasons, including:

1. You are disruptive, inappropriate, or threaten other participants or study staff.
2. You are unable to complete baseline survey sessions or are unable to participate in the programs offered on the Internet for the 24 weeks of the study.
3. You start experiencing a health condition that excludes you from participating online in the study.

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4. You start to be judged to be cognitively unable to complete study surveys.
6. You are unable to participate in community discussions or focus groups without disrupting the other participants also in the study.

Audio-Video Recording of Group Sessions

Some of the live online group sessions, that you may or may not participate in,during the course may be video recorded through Zoom. This is so that we can monitor the way the group leader leads each session. Video will NOT be linked to any personal or identifying information collected in other aspects of the study, including your name. Please indicate your agreement to be
video-recorded during group sessions.

I agree to be audio-video recorded during intervention group sessions.

☐ I agree ☐ I do not agree

Audio-Video Recording of Focus Group/Individual Interview Sessions

You may volunteer to participate in focus group/individual interview sessions at the end of the course, which may be audio-video recorded. This is so that we can collect data on how and if you liked or disliked features of OWL. Audio-video will NOT be linked to any personal or identifying information collected in other aspects of the study, including your name. Please indicate your agreement to be audio-video recorded during a focus group/individual interview session.

I agree to be audio-video recorded during focus group/individual interview sessions.

☐ I agree ☐ I do not agree

Future Contact

Sometimes the study team has information about other studies or opportunities that might interest you. Please indicate below whether you give permission for us to contact you about future studies or opportunities via email or phone. We will retain your phone number and e-mail address in a separate database from the study database.

I agree to be contacted in the future about other studies or opportunities.

☐ I agree ☐ I do not agree

Email Contact

The study team will ask you to provide your email. This is so that we can reach you regarding study surveys. We will use email and text to contact you about study assessments related to the group intervention should you miss a study assessment.

I agree to be contacted via email.

☐ I agree ☐ I do not agree

Text Contact

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The study team will ask you to provide your mobile phone number. This is so that we can reach you regarding study surveys. We will use email and text to contact you about study assessments related to the group intervention should you miss a study assessment.

I agree to be contacted via text messages.

☐ I agree ☐ I do not agree

Primary Care Provider

You may have been referred to this study by a member of your care team. By checking this, you agree that you give consent to a study team member to contact your provider via letter or EMR message to inform them of your participation. This consent item does not impact eligibility.

I agree to give the study permission to contact my PCP

☐ I agree ☐ I do not agree

Cell Phone Usage

If you do not have a cell phone, tablet, or computer that can access the online platform and attend a live-online Zoom group, a cell phone will be provided to you. By checking this, I agree to use this phone only for participation in this research study. Additionally, by checking this, I agree to return this cell phone to the study team after my period of participation is complete. Appropriate return-postage will be supplied to me by the study team.

I agree to use this phone only for this study, and will return it once my participation is complete

☐ I agree ☐ I do not agree

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law. We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is your individually identifiable health information. **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 proceeding. 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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project.

If you take part in this study, you agree to let the research team use your survey information. Do not take part in this study if you do not want the research team to access your survey information.

We will follow these guides:

- We will not include any information that could identify you in any publication.
- Anonymous data from this study may be made available on a public database – it will never be made available in a way that can identify you.

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- We will remove all of your identifiable information (name, address, telephone number, *etc*.) from the study database 7 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Additionally, the study staff may be required to disclose confidential information if it becomes clear that you risk harming yourself or others. Sometimes, we are required to share your study records with others, too, including:

- Other researchers or collaborators conducting this study
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study
- Clinical staff not involved in the study, but involved in your regular treatment
- Insurance companies

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy. You will be using an internet-based program, and the data you provide may be stored on the program's website. This kind of data may include your number of logins, progress on the site, and assessments of mental health symptoms.

- **Despite our best efforts to protect privacy and ensure confidentiality, data breaches can happen when you are using internet-based technology.**

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US 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.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study, please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call or email the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

The easiest way to reach the study team with questions is by email at geministudy@challiance.org.

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You can also call study investigators if you have an urgent question or concern.

Paula Gardiner (Principal Investigator)	617-591-6132
Tori Blot (Research Coordinator)	781-873-9782

On nights and weekends, you may contact your healthcare provider if any urgent issues arise.

If you have questions about your rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am-5:00pm:

IRB Chair:
Telephone: 617-806-8702

Patient Relations Manager:
Telephone: 617-665-1398

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Confirmation from Person Obtaining and Documenting Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

_____ _____
Signature of Researcher Obtaining Consent Date

_____
Printed Name of Researcher Obtaining Consent

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