UNIVERSITY OF WASHINGTON INFORMATION STATEMENT

Digital Hypnosis Study

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this form carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

- The purpose of this pilot study is to test the feasibility, usability, and acceptability of a self-hypnosis program for chronic pain management that could then be developed into a mobile application [app].
- The hypnosis treatment involved in this pilot study has been shown to be effective for chronic pain management. However, you might not experience any benefit from being in this study.
- The information from the study may help us treat chronic pain more effectively.
- If you participate in this study, we will need about 2-3 hours of your time over a 2-3 month period. This does not include time you may spend accessing the audio recordings on your own.
- Participation in study activities includes:
    - Baseline Survey (15-20 minutes, online)
    - Use of Hypnosis Audio Recordings
        - 8 Week Group: Access to recordings for 8 weeks; may use up to 2 hours total/day
        - 4 Week Group: No access to recordings for 4 weeks, then access for 4 weeks; may use recordings up to 2 hours total/day
    - 4-Week Survey (10-15 minutes, online)
    - 8-Week Survey (10-15 minutes, online)
    - Optional online focus group at end of study participation (45-60 minutes)
- You will be able to continue to access the recordings for one year after your participation or until the study is over, whichever comes first.

PURPOSE OF THE STUDY

Chronic pain is a significant problem affecting millions of Americans. Individuals with chronic pain also experience a number of other problems, such as mood and sleep problems. All of these can have negative effects on a person's quality of life. Self-hypnosis training has been found to be effective for managing chronic pain. Unfortunately, self-hypnosis training often takes place in person, which can make it difficult for some to attend. The purpose of this pilot study is to test whether a self-hypnosis training app is feasible, useable, and acceptable to people experiencing

chronic pain. We also want to see if this type of treatment can help reduce pain and improve other areas of people's lives, including mood and sleep.

STUDY PROCEDURES

After we go over this form, and we have answered any questions you have about the study, we will ask for your verbal agreement to participate. After you provide your verbal consent to participate, we will collect your contact information, including contact information for people we may contact if we are unable to get a hold of you after multiple attempts.

Overview of Study Activities

- Informed Consent Process (20-30 minutes, telephone)
- Baseline Survey (15-20 minutes, online)
- Use of Hypnosis Mobile App
    - 8 Week Group: Access to audio recordings for 8 weeks; may use audio recordings up to 2 hours total/day
    - 4 Week Group: No access to audio recordings for 4 weeks, then access for 4 weeks; may use audio recordings up to 2 hours total/day
- 4-Week Survey (10-15 minutes, online)
- 8-Week Survey (10-15 minutes, online)
- Optional online focus group at end of study participation (45-60 minutes)

Focus Groups: Once you conclude the hypnosis program, study staff will invite you to participate in an **optional** online focus group to discuss your satisfaction with the hypnosis program. There will be up to 4 focus groups and you can choose which scheduled group fits best with your schedule (each focus group will aim to have 5-8 participants). Study staff will ask open-ended questions and write de-identified notes (notes that do not include your name or other ways to identify you). Questions would include but not be limited to:

- Overall, what was most and least satisfying about this hypnosis program?
- Were there challenges/difficulties with the program and using the audio recordings?
- We are going to develop this program into an app using your feedback. In the app, are there certain specific features you would want (e.g. choices of voices, inductions, suggestions, etc.)

These procedures are explained in more detail below. At the end of this form, there is a table that lists study procedures to help you understand the time commitment. You should only agree to participate if you think you can finish the study.

Informed Consent Process

This form and informed consent process is for all study activities that will take place with UW research staff. We will review the details of the study with you and answer any questions you may have to see if you are interested in participating. You will receive a copy of this information statement. This informed consent process should take about 30 minutes.

Baseline Survey

If you choose to participate in the study, we will first ask you to complete a Baseline Survey on a secure website. There will be some basic demographic questions about yourself (e.g., age, sex, race, gender, ethnicity, education level, employment status, income, marital status, etc.). You would also answer some questions about your pain, including its history, type, duration, average intensity, and how it has interfered with your life. There are also questions on sleep quality, mood, and opioid medication use.

We will also ask you for information about the devices (e.g. smartphone, laptop) that you use to access the audio recordings in this study. You can choose not to answer these questions. We will ask you for:
- A list of devices that you have access to, including phones, pads, laptops, and desktops.
- Type of device used when participating in study, company, operating system, and model number

The Baseline Survey should take around 15-20 minutes, and you will be paid $30 for completing it.

Hypnosis Audio Recordings

After you complete the Baseline Survey, you will be randomly assigned (by chance, like flipping a coin) to one of two groups. Both groups would be given access to audio recordings that teach you self-hypnosis techniques.

You would choose different recordings available that help you learn how to enter a state of focused attention to help you change how you experience pain. Each recording lasts about 5, 10, or 20 minutes, and is provided by a male or female voice. You may listen to the different recordings as much as you would like for up to two hours a day. You would be asked some questions before and after you listen to the recordings, including questions about your pain intensity and your experience listening to the recordings. You do not have to answer any questions that you do not wish to answer while using the audio recordings.

One group would be able to use the audio recordings for eight weeks. The other group would have no access to the audio recordings for four weeks (a waiting period), and then have access for four weeks. You would not have to pay anything to use the audio recordings. After you receive access to the audio recordings, a research staff member will call you to see how you are doing with the audio recordings, and to answer any questions or concerns you may have. You will not be paid for using the audio recordings.

At the end of your participation in the hypnosis program, you will be offered access to the audio recordings. Participants who would like access will be given continued access as long as the same version of the audio recordings are available. If access is continued, we will send you a brief, secure online survey on a monthly basis about your responses to the audio recordings, both positive and negative. You would still be considered a research participant for the duration you have access to the recordings. **However, you would not be compensated for these optional additional surveys.**

Follow-Up Surveys

About 4 weeks after randomization and again at 8 weeks after randomization, you will be asked to complete an online survey similar to the Baseline Survey above. Additionally, we will ask about your satisfaction with the audio recordings, your interest in continued access to the audio recordings, your willingness to pay for continued access if the option was given, and overall usability of the hypnosis program. Each of the two online surveys will take 10-15 minutes, and you will be paid $30 for completing each survey.

RISKS, STRESS, OR DISCOMFORT

Surveys

You may experience fatigue and/or boredom while completing the online surveys and/or while listening to the audio recordings. Some people may find some of the questions we ask during the

online surveys or focus groups to be personal or sensitive, which may cause mild stress or discomfort. You may find thinking about your pain problem and other issues surrounding pain, depression, and mood uncomfortable. In addition, focusing on your pain problem may lead to a temporary increase in pain intensity. You do not have to answer any questions that you do not wish to answer, and may stop any survey at any time.

Hypnosis Exercises

Some people may find the state of deep relaxation or hypnosis uncomfortable. Some people practicing hypnosis may remember past experiences that are uncomfortable and/or cause distress, even after the session has ended. Some people practicing hypnosis may also experience mild disorientation or grogginess during or after a session has ended. Although rare, some people may experience a temporary loss of sensation in their arms or legs while practicing hypnosis.

We expect that any uncomfortable or negative effects from the surveys or hypnosis exercises are highly unlikely. If they do happen, you can talk about these issues with the Principal Investigator, Dr. Jensen, a licensed clinical psychologist. Dr. Jensen will then give you information about people you should contact if needed. You may stop a survey, use of the audio recordings, or any other study procedure at any time.

Confidentiality

Although we make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you. Please note we cannot guarantee the confidentiality of email communication.

ALTERNATIVES TO TAKING PART IN THIS STUDY

There may be other treatments or procedures available to help you manage your pain if you choose not to participate in this study. We recommend that you speak to your doctor about the different options for pain management that may be available to you.

If you would like any additional information on national resources for disability, pain, mental health, and other resources, you may request a clinical resource list be mailed or emailed to you.

BENEFITS OF THE STUDY

If the hypnosis exercises work for you, your pain may decrease. You might not experience any benefit from being in the study. The information from the study may help us treat chronic pain better.

SOURCE OF FUNDING

We are receiving financial support from the National Institutes of Health (NIH).

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. To protect your privacy, your name and other identifying information will be linked to unique study IDs. Your study IDs will not include any information that can identify you. All of the data we collect from you will be coded with your study IDs and stored in locked filing cabinets, password-protected computer databases, and/or on secure and encrypted internet databases. The master list linking your identifying information to your study data will be kept in a separate, secure location.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the U.S. federal National Institute of Health which allows us to keep your identifiable research information confidential from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

The Certificate expires when the study ends, which will be no later than August 1, 2025. Data collected prior to expiration will continue to be protected.

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If a research staff member finds out you have plans or intent to harm yourself or others, they may refer you to or contact an appropriate individual or institution. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you are not able to fulfill the study requirements.

A description of this clinical trial will be available on https://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.

USE OF INFORMATION AND SPECIMENS

Once this study is completed, we will not use the study codes linking you to your data for any additional research. We will store the codes linking you to your data in a secure database until the UW receives authorization to destroy it in accordance with federal records regulations, which could be several years. We will keep your coded, de-identified data indefinitely.

We will use the information that we collect for this study only for research purposes. The information will also be used to help determine if the app has commercialization potential. The researchers may also use this research information in the future for the development of new ways to treat pain. Study data may be shared in de-identified form (i.e., not with your name or other identifying information) with outside researchers and collaborators as requested and deemed acceptable by study investigators without getting additional permission from you. Neither you nor your family will gain financially from discoveries made using the information that you provide.

In the future, researchers may write publications using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researchers listed on page 1 of this form.

You will not be charged for any study-related procedures. You may incur costs associated with using internet to access the audio recordings and receiving text messages with study reminders. We will not reimburse you for any messaging or data charges incurred as part of participation in this study.

We will pay you up to a total of $120 for completion of the following procedures:

- $30 for completion of the Baseline Survey
- $30 for completion of the Week 4 Survey
- $30 for completion of the Week 8 Survey
- $30 for completion of the optional Focus Group

A copy of this information statement will be emailed to you at the email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the information statement. If you do not have PDF viewer software, we may be able to provide a link to PDF viewer software (such as Adobe Acrobat Reader). If you would prefer to receive a paper copy of this information statement at no cost to you, please contact the researchers listed on page 1 of this form.

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to this study, contact Dr. Jensen at (206) 543-3185 right away. He will treat you or refer you for treatment. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by enrolling in this study.

FINANCIAL CONFLICT OF INTEREST

The principal investigator of this study, Dr. Mark Jensen, is Co-Founder and owner of stocks of the company HypnoScientific, Inc. This company is sponsoring the development of the hypnosis mobile application described in this statement that will be developed and informed using the results of this study. Dr. Jensen may benefit financially if the study results lead to a mobile application that becomes commercially available and is useful for pain management. Dr. Jensen has completed a financial conflict of interest management plan with oversight from the University of Washington to make sure this study is conducted responsibly and ethically.

Participant's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research participant, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this information statement.

Study Procedures				
Procedure	**Number of Assessments**	**How Often/When**	**Time Required for Participants**	**Payment**
Informed Consent	One process	Once, before starting any study procedures	30 minutes	$0
Baseline Survey	One online survey	Once, following informed consent process	About 15-20 minutes	$30
Use of Audio Recordings	Brief questions before and after listening to each recording	8 Week Group: Access to the audio recordings for 8 weeks 4 Week Group: No access to audio recordings for 4 weeks (a waiting period), then access for 4 weeks	May use audio recordings up to 2 hours total/day during each day of access	$0
4 Week Survey	One online survey	Once, about 4 weeks after randomization	About 10-15 minutes	$30
8 Week Survey	One online survey	Once, about 8 weeks after randomization	About 10-15 minutes	$30
Online Focus Groups	Multiple online focus groups with up to 8 participants per group	Once, about 8-10 weeks after randomization	About 45-60 minutes	$30
Total Possible Payment				**$120**