Feasibility of at Home Telehealth Yoga for Treating Chronic Pain

Study Protocol and Statistical Analysis Plan

NCT #: 04074109

November 22, 2021

Background

Chronic pain is a debilitating condition with high societal and economic costs. Pharmacological pain management includes opioids, which can be dangerous and ineffective after long-term use. Consequently, increased efforts are being made to find nonpharmacological treatment options for the management of chronic pain. For this reason, rigorous research on complementary and integrative health (CIH) for pain is a top priority and pain is the condition for which adults in the United States most often use complementary and integrative health. Chronic pain, and especially musculoskeletal pain is even more prevalent among veterans, and yoga has emerged as a popular and effective treatment option. The use of yoga to treat chronic pain has been endorsed by many organizations including the NIH, the American College of Physicians, and the VA. However, patients, especially rural and low-income patients, can encounter many barriers to practicing yoga, including travel costs and time, health conditions, bad weather, lack of transportation, and family responsibilities. One solution to overcome these barriers is to provide yoga at home using internet-based technology ("teleyoga"). Indeed, the provision of VA care via telehealth to increase access to those living far from VA medical facilities is a VA priority. Teleyoga is an innovative, potentially effective approach for treating chronic pain in veterans. Research evaluating the acceptability or efficacy of teleyoga is very limited. Our pilot data indicate that teleyoga is safe and has similar efficacy to in-person yoga for treating several common conditions in veterans, including chronic musculoskeletal pain (Schulz Heik et al., 2017). However, our teleyoga experience is limited to group yoga instruction via an audiovisual link to one or more outpatient clinics. This clinic-based modality requires participants to travel to a clinic for yoga instruction and does not overcome the multiple barriers associated with in-person care. Attempts by other groups to deliver at-home teleyoga have not overcome all the technical barriers encountered (Donesky et al., 2017). Standard Video conferencing software offers an exciting opportunity to develop at-home teleyoga using a well-resourced, scalable, and technologically advanced system. This study will focus on the treatment of chronic musculoskeletal pain, as it is the most common type of chronic pain in veterans and nonveterans (Kerns, 2018) and responds well to yoga.

Objectives

The primary objective is to test the feasibility of treating chronic pain with yoga delivered via telehealth. We will modify an existing yoga intervention for chronic musculoskeletal pain and address the technical challenges of at-home teleyoga. Then, using the modified intervention, we will demonstrate the feasibility of conducting a randomized controlled trial involving at-home teleyoga.

Specific Aims and Hypothesis

Specific Aims:

1. Modify an existing yoga intervention for chronic musculoskeletal pain and address the technical challenges of at-home teleyoga.
2. Demonstrate the feasibility of conducting a randomized controlled trial involving at-home teleyoga.

Hypothesis 1 (primary): a) Treatment satisfaction as measured by the Multi-Dimensional Treatment Satisfaction Measure will be neutral or positive for all factors. B) Treatment satisfaction will be at least neutral for all items.
Hypothesis 2 (secondary): a) It will be feasible to recruit 30 participants over a 3-month period and deliver yoga in-person or via at-home teleyoga while maintaining a retention rate commensurate with other similar studies. b) Fidelity of treatment delivery will be acceptable as measured by scoring of taped sessions. c) We expect participants will complete the PROMIS measures with a missing data rate not to exceed 15% per participant. d) The yoga intervention will be safe with no serious adverse events in either treatment group.

Study Design

This study aims to investigate the feasibility of at-home teleyoga for veterans with chronic musculoskeletal pain. We will demonstrate the feasibility of conducting a randomized controlled trial involving at-home teleyoga. We will randomize veterans (N=30) with chronic musculoskeletal pain to at-home teleyoga or in-person yoga. Primary feasibility outcomes will include recruitment rates, retention, protocol adherence, participant satisfaction from semi-structured questionnaires, adverse events, treatment fidelity, and rates of completion of study instruments. Feasibility will be determined by comparison to benchmarks from studies that used similar interventions and populations.

We intend to recruit local (residing in the San Francisco Bay Area), outpatient adult veterans with chronic musculoskeletal pain to enroll in this clinical trial. This research proposal will use randomization after baseline assessments to assign participants (n=30) to at-home teleyoga or in-person yoga (n=15 per group). Randomization will occur by identifying group membership in 30 sealed envelopes and having each participant draw one envelope. To be representative of the veteran population at VAPAHCS Health Care System (VAPAHCS) each group will have 1-2 females.

All human subjects research will be performed at VAPAHCS in Palo Alto, California or at the homes of the veterans (residing in the San Francisco Bay Area) who receive the at-home teleyoga group. There are no other collaborating sites where human subjects research will be performed.

Month					
1	2	3	4	5	6
Recruit (n=30)			Run in-person yoga groups (n=15) Run at-home teleyoga groups (n=15)		

Table 1. Recruitment Table

Group assignment and randomization

Eligible participants will be added to a cohort list; when 30 have been identified, the study team will schedule baseline assessments. After the baseline assessments, participants will be randomized to in-person or at-home teleyoga (n=15 per group). Randomization will occur by identifying group membership in 30 sealed envelopes and having each participant draw one envelope. Each group will contain 1-2 females, to be representative of the veteran population at VAPAHCS.

Statistical Plan and Data Analysis

Fidelity and Missing Data Benchmarks

Fidelity: The instructors will review the video recorded sessions using a manual checklist for instructor adherence to the yoga manuals, which will consist of a Yes/No for each procedure or instruction.

Missing Data: Like similar behavioral outcome measures, we expect missing data in the PROMIS-PI measures not to exceed 15%.

The main analytic strategy will be descriptive statistics at pre- and post-intervention assessments in each arm. We will then preliminarily compare the two conditions in line with the intention to treat principle. The purpose of these comparisons is not to provide formal inference but provide preliminary information to guide the adequately powered future trial.

The estimated changes and their group differences in pain and depression measured by the BPI-SF and BDI-II will provide preliminary data on target engagement and therefore inform and shape the future trial in terms of elucidating the mechanism of action. We will make a rigorous effort to minimize missing data. Nonetheless, we expect some attrition by post-intervention assessment. For group comparisons, we will focus on collecting preliminary data on clinical significance (i.e. effect size), instead of making formal inference (i.e., *p*-value).

Inclusion/Exclusion Criteria

Identify inclusion criteria.

- Veteran of the United States Armed Forces ≥ 18 years old
- Diagnosis of chronic musculoskeletal pain > 6 months (Dworkin, 2012)
- Minimum pain intensity at screening visit: pain rated ≥4 on a 0-10 Numeric Rating Scale (NRS) as recommended by IMMPACT guidelines. We intend to use the NRS from the Defense and Veterans Pain Rating Scale (DVPRS).
- Has not begun new pain treatments or medications in the past month.
- If on a psychotropic medication regimen: stable regimen for at least 4 weeks prior to entry to the study; willingness to remain on a stable regimen during the 12-week acute treatment phase.
- English literacy.
- Wireless internet connection at home.

Identify exclusion criteria.

- Participation in another concurrent clinical trial.
- Back surgery within the last 12 months.
- Back pain potentially attributed to a specific underlying cause, disease, or condition.
- Baseline pain <4 or ≥9 on a 0-10 Numeric Rating Scale (NRS) as recommended by IMMPACT guidelines. We intend to use the NRS from the Defense and Veterans Pain Rating Scale (DVPRS). For ratings ≥9, we will refer the veteran to the provider for prompt care.
- Unstable, serious coexisting medical illness.
- Unstable, serious coexisting mental illness or psychiatric conditions.
- practiced yoga ≥ 1 x in the past 12 months
- Active current suicidal intent or plan.

Criteria will be applied based on the informed consent process, a review of the participant's VA electronic medical record (EMR) and a screening interview.

The study will exclude participants with back pain potentially attributed to specific underlying causes, diseases, or conditions (e.g. pregnancy, previous back surgery, fractures, dislocations); unstable, serious coexisting medical illnesses (e.g. Congestive Heart Failure, cancer, COPD, dementia); unstable, serious coexisting mental illnesses or psychiatric conditions (e.g. unmanaged psychosis, active substance abuse); or minimal or maximal pain ratings at the time of screening (<4 or ≥ 9 on a 0-10 Numeric Rating Scale (NRS) as recommended by IMMPACT guidelines). We intend to use the NRS from the Defense and Veterans Pain Rating Scale (DVPRS).

Participants on a psychotropic medication regimen will be asked to maintain a stable regimen for at least four weeks prior to entry to the study and remain on a stable regimen during the 12-week acute treatment phase, under the patient's medical care team. Excluded participants will be reconsidered for eligibility after stability on medication is achieved. Involvement in medical treatments will be tracked closely through self-report and clinician interviews, and we will use this information when analyzing the results. Participants with active current suicidal intent or plan will be excluded. Participants at risk for suicide will be required to establish a written safety plan involving their primary psychiatrist and the treatment team, prior to entering the clinical trial.

All participants will be able to read, verbalize understanding, and voluntarily sign the Informed Consent and Health Insurance Portability & Accountability Act (HIPAA) prior to the performance of any study-specific procedures or assessments.

Since we seek to assess the feasibility of providing at-home teleyoga via VA Video Connect, all participants will need access to
wireless internet connection at home.

Informed Consent Process

Veterans will be recruited from three sources: the VAPAHCS Pain Clinic, local advertising, and web-based advertising. These sources will result in either 1) the potential participant calling the study team or 2) with the participant's consent, the study staff contacting them directly. Study candidates will be invited to the VAPAHCS for a screening visit, during which the Project Manager will obtain informed consent and review the Health Insurance Portability & Accountability Act (HIPAA) document.

The informed consent process, including the HIPAA document, is estimated to take about 30-60 minutes. It will take place in a quiet office or interview room, or via video link.

1. The Project Manager will explain the information contained in the written informed consent (purpose, procedures, risks, benefits, alternatives to participation, etc.) and HIPAA documents to the study candidate verbally, in lay language.

a. The Project Manager will check for comprehension, allow the study candidate ample opportunity to ask questions throughout the process, and repeat the information, as necessary.
b. Care will be taken to inform the study candidate that his/her participation is entirely voluntary, and they may withdraw at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.
c. Study candidates will then be asked to carefully read the informed consent form to consider whether or not to participate in the research and to ask questions.
d. To ensure that the study candidate understands the research, they will next be asked to summarize the consent form and HIPAA addendum, with a special focus on the discomforts, risks, benefits, and confidentiality sections.

2. If the study candidate demonstrates (by stating in his/her own words) an understanding of the purpose, risks, and benefits of the study and agrees to participate in the study, he/she will be asked to initial each page, in addition to sign and date the last page of the consent form and the HIPAA document.
3. The Project Manager who oriented and obtained informed consent will sign and date the informed consent form.
4. The Project Manager will provide the enrolled participant with a photocopy of the original signed copy and keep the original signed copy in a binder in a locked cabinet.

The emphasis on the voluntary nature of participation is designed to minimize the possibility of coercion or undue influence on participation. The study candidate will be given time to understand the written informed consent form and make an informed decision. All treatments for this study will be provided in group formats, so potential participants will be reminded that full anonymity cannot be maintained.

Following the informed consent process, the enrolled participant will complete other measures.

Screening Procedures

Potential participants (n=30) will be invited to the VAPAHCS for a screening visit. The Project Manager will obtain informed consent and review the Health Insurance Portability & Accountability Act (HIPAA) document. After obtaining informed consent, a trained researcher will collect demographic information (Demographic Questionnaire). Screening for protocol eligibility will include the Clinical Questionnaire and DVPRS.

Study Assessments

Demographics Questionnaire: Documents age, gender, education, and race/ethnicity.
Clinical Questionnaire: Self-report document focusing on the existence of 78 health symptoms taken from a list of ICD-9 codes that are highly likely to represent chronic pain.
Medication Use: Self-report of all current pharmacological and non-pharmacological treatments.
Yoga Home Practice Log: Log for participant to document their yoga home practice on non-treatment days.
BDI-II Beck Depression Inventory-II (BDI-II): Contains 21 self-report questions, scored on a 0-3 scale, related over the past two weeks to sleep, appetite, punishment, suicide, and interest in sex.

Brief Pain Inventory-Short Form (BPI-SF): Assesses intensity and impact of pain on functioning on a 0-10 rating scale. Interference is assessed on daily life (general, walking, work, mood, enjoyment, relationships, sleep). The BPI is recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group for inclusion in clinical trials evaluating pain.
Defense and Veterans Pain Rating Scale (DVPRS): A five-item scale: one 0-10 pain intensity numeric rating scale and four supplemental items measuring functional outcomes (general activity, sleep, mood, level of stress). The pain intensity scale is designed to improve upon existing scales by using visual cues and word descriptors to anchor pain ratings with perceptual experiences and limitations imposed by pain.
PEG: A 3-item pain measure derived from the Brief Pain Inventory and validated in ambulatory care settings. It includes 1 severity item (average pain) and 2 interference items (enjoyment of life and general activity).
Patient-Reported Outcomes Measurement Information System-Pain Interference (PROMIS-PI) (108): Examines the extent to which pain hinders engagement over the past seven days with social, cognitive, emotional, physical, recreational activities, and physical functioning through Likert-type 1-5 scales.
Treatment Satisfaction: Assessed using the Multi-Dimensional Treatment Satisfaction Measure (MDTSM). The measure consists of 11 subscales assessing treatment process and outcome attributes. Each subscale has 1-8 items (see Table 5). Each question except the Discomfort subscale is rated on a five-point scale ranging from "not at all (0)" to "very much (4)". Thus, a score of 2 represents a rating of neutral satisfaction. The instrument was developed for behavioral interventions and is designed to provide a comprehensive set of treatment attributes to consider when evaluating treatments in the context of pilot studies. It is designed to be completed after exposure to an intervention, to point to aspects of treatments that are viewed favorably or unfavorably. The MDTSM is relevant to many types of behavioral interventions and can be tailored to our yoga intervention. The MDTSM subscales demonstrates good internal consistency, reliability, and validity.

	Data Collection			
	Screening	Baseline	Yoga (wks 1-12)	Post-treatment
Background				
Consent Form	×			
Demographic Questionnaire	×			
Clinical Questionnaire	×			
Yoga Medical Clearance Form	×			
Medical Use		×		×
Yoga Home Practice Log			×	
Mental Health				
BDI-II		×		×
Pain/QOL/Physical				
BPI-SF		×		×
DVPRS	×			
PEG	×	×		×
PROMIS-PI		×		×
Behavioral				

Treatment Satisfaction				×
Provider Suggestions				×
Patient Safety			×	×
Treatment Fidelity			×	

Table 2. Study Measures and Timetable of Data Collection

Yoga Treatment

Participants will be randomized to in-person yoga (n=15) or online yoga (n=15). Yoga classes will be 75-minutes and will be delivered by a yoga instructor once a week over a course of 12 weeks in-person or online.

Yoga (in-person): Veterans in the in-person yoga group will attend yoga classes at VAPAHCS. The yoga instructor will provide weekly instruction at the VAPAHCS in a telehealth-equipped conference room.

Yoga (online): The yoga instructor will provide weekly instruction using approved teleconferencing software either from an offsite location or from the VAPAHCS in a telehealth-equipped conference room.

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IRB Approval Date: November 3, 2021
Expiration: Does not Expire

RESEARCH CONSENT FORM

Title of Study: Feasibility of At Home Telehealth Yoga for Treating Chronic Pain	
Title of Consent (if different from Study Title):	
Principal Investigator: Peter J. Bayley, Ph.D.	VAMC: VA Palo Alto HCS

What is this research about?

You are invited to participate in a research study to test whether it is feasible to use telehealth to deliver yoga as a treatment for chronic pain. Our goal is to modify an existing yoga protocol for musculoskeletal pain and to address the technical challenges of at-home teleyoga. You were selected as a possible participant in this study because you have indicated that you have been suffering from chronic pain. This research study is looking for 30 Veterans who exhibit symptoms of chronic pain and want to use yoga via telehealth to treat their pain.

This study is being done by researchers at VA Palo Alto Health Care System and Stanford University, and is sponsored by the National Center for Complementary and Integrative Health.

What is expected of me? (Procedures)

Baseline and Randomization (2-3 hours): You will be asked to complete self-report questionnaires about your medication use and experience of chronic pain online through Qualtrics or RedCap. If you are randomized to the at-home program, during this session we will record your phone number, physical location for at-home teleyoga and an emergency contact. This information will be used if the video conferencing session disconnects or an unforeseen emergency arises during at-home teleyoga.

Treatment (12 weeks):

At-Home Teleyoga: In the first week, you will be given a yoga mat, yoga strap, and yoga blocks for use during yoga class. You will then be assigned an iPad and given instructions on how to use the video conferencing app to participate in the yoga classes at home. You will determine the part of your home that is most comfortable and appropriate for a yoga class. You will participate in 1 yoga class per week for 12 consecutive weeks, 75 minutes per class, at a time that is convenient for the entire group and the instructor. A member of the study staff will call you the business day before class to remind you of the class appointment and remind you to charge the iPad for class. The yoga instructor will be based at the VA Palo Alto, and you will participate at home using the video conferencing app on the provided iPad.

In-Person Yoga: In the first week, you will be given a yoga mat, yoga strap, and yoga blocks for use during yoga class. You will be assigned an iPad but will not need it to participate in yoga classes. You will participate in 1 yoga class per week at VA Palo

Alto for 12 consecutive weeks, 75 minutes per class, at a time that is convenient for the entire group and the instructor.

Randomization: You will be randomized to either the in-person or at-home telehealth yoga group. Randomization is a process that is similar to flipping a coin where one side of the coin is in-person yoga and the other side is at-home teleyoga. There is a 50:50 chance of being randomized into either treatment. Both groups will receive all the same measurements and tests.

Post-Treatment (2-3 hours): You will be asked to complete self-report questionnaires about your medication use and experience of chronic pain, as well as provide feedback about the program, including any technical issues you encountered. This will be done either in-person at the VA Palo Alto, or online using RedCap or Qualtrics. You will return the iPad to study staff in-person at the VA or mail the iPad back to study staff via USPS.

Video Recording: The in-person and at-home yoga classes will be video recorded to monitor instructor fidelity to the yoga intervention manual. Video recording will be used to monitor fidelity of treatment delivery. Recordings will be made of treatment providers, not the participants. Recordings will be stored on a secure server in accordance with VA guidelines. VA record retention polices require records, including videos, created during a research project to be maintained for 6 years after study closure, wherein they will be destroyed.

What are the possible risks or discomforts?

The risks associated with this study are minimal. The yoga protocol is developed for participants with chronic pain, and you will be encouraged to move safely and modify postures as necessary. If there is an unforeseen emergency during your at-home teleyoga session or in-person yoga class, we will take the necessary steps to ensure medical help arrives to the address you provided at the start of the study.

Will I benefit from the study?

The benefits which may reasonably be expected to result from this study are relief from chronic pain.

What are my alternatives to being in this study?

You may choose not to participate in this study. If this is your decision, there are other choices including the standard treatments provided by a local clinic. Your study investigator

will discuss any alternatives with you before you agree to participate in this study. Alternative treatments include medication and behavioral therapy.

Will I get paid?

You will receive $200 as payment for your participation. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Will I have to pay anything?

You will not have to pay anything to be in this study.

Do I have to be in this study?

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care.

Can I change my mind later and stop being in this study?

You can decide to participate now, but you may withdraw your consent later and stop being in the study without any loss of benefits or medical care you are entitled to.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Will my information be protected from the public?

We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of

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Research Oversight and the VA Office of the Inspector General may have access to your 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 civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. 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 (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including research information in the medical record.

What happens if I think I've been hurt by being in this study? Who can I talk to about a Research Related Injury?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence. For further information, you may call the Human Protections Administrator at (650) 493-5000, ext. 67593 or the V.A. Regional Counsel at (415) 750-2288.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Dr. Peter Bayley (650) 493-5000 ext. 68653. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Please print or save a copy of this page for your records.

If you agree to participate in this research, please indicate this to the researchers and complete the following survey.