At-Home Telehealth Yoga for Treating Chronic Pain in People with Alzheimer's Disease and Their Caregiver's

Study Protocol and Statistical Analysis Plan

NCT #: 04512040

February 02, 2023

Background

Pain is the most common health complaint in the general population, and within primary care (14). Chronic pain is usually defined as pain persisting for at least 3 months, although many patients suffer pain for years or even decades (15). Chronic pain affects approximately 50% - 78% of veterans (1, 2) with the prevalence of pain increasing with age (12). Chronic pain is the leading cause of work disability globally (16) and costs the US more than $500 billion each year in lost productivity (17). Chronic pain is treatment-resistant, and pharmaceuticals often bring limited benefit and have significant side effects and risks. The use and abuse of opiates to treat pain has become a major public health issue (18-20). Most chronic pain is musculoskeletal, which is defined as pain from the body's joints, ligaments, muscles, nerves, tendons, and structures that support the limbs, neck, and back (21). In 2012, 54.5% of U.S. adults reported musculoskeletal pain (22). Chronic musculoskeletal pain is even more common in veterans than nonveterans, with a prevalence of 50-75% (2, 23, 24).

Increasing age is the single biggest risk factor for AD (25). AD affects nearly 5% of persons aged >65 years (26) and nearly one third of those aged ≥85 years (26). AD is characterized by neurodegeneration and is accompanied by a range of cognitive and behavioral problems (27). Like AD, the incidence of chronic pain increases with age (28). Because both chronic pain and AD are strongly linked to age, they are often comorbid, and studies have shown a high prevalence of pain in AD. A recent meta-analysis involving 50,911 AD patients estimated the prevalence of chronic pain in AD to be 46% (3). This figure may be an underestimate because AD patients may be less able to communicate their pain, and request attention less effectively than their cognitively intact peers (29). Both chronic pain and AD are associated with behavioral and psychological problems including depression (30), insomnia (31), cognitive decline (32) and greater functional dependence (32). The co-morbidity of chronic pain in AD can therefore amplify symptoms, leading to poorer outcomes (32, 33). Moreover, recent studies have suggested a biological link between the two conditions such that chronic pain and AD may involve two intertwined pathological processes that can accelerate AD pathogenesis (34).

As life expectancy increases, the increase incidence of AD has become a major concern. The VA has estimated current and future numbers of veterans with dementia (35). The mid-range estimates for the enrolled population for 2019 were 408,933 cases of dementia, and by the year 2029, 465,636 cases dementia (high range estimates for the same time periods were 571,148, and 688,342 cases, respectively). Since AD accounts for ~70% of all dementia cases (36) and chronic pain affects approximately 50% - 75% of veterans (16, 17), it is estimated that 223,277 veterans have co-morbid chronic pain and AD, which will rise to 254,237 by 2029. Since approximately 5.8 million Americans have AD (36) and the prevalence of chronic pain in AD is 55% (3) this translates to about 3.2 million patients in the US general population currently living with both AD and chronic pain.

Nonpharmacological management of chronic pain is high on the list of priorities for both NIH (37) and the VA (38). Cognitive behavior therapy (CBT) is the gold standard behavioral intervention for chronic pain (39). However, effect sizes for CBT for chronic pain are relatively small, with only 43% of CBT trials demonstrating improvements in pain (40). Furthermore, CBT dropout rates are high (41-43). For these reasons, interest is increasing in integrative approaches to health and wellness (44). A recent survey reported CIH techniques are used by ~35% of US adults (45) and CDC data shows that among the movement practices (yoga, tai chi, and qi gong), yoga has increased most over the decade 2002 – 2012 (8), accounting for ~80% of

CIH use. Two key statistics are relevant. First, a recent survey showed rates of participation in CIH practices including yoga were significantly higher among those with a musculoskeletal pain disorder (22) than among persons without such a disorder (41% vs. 24%, respectively). Second, patients with neurological conditions including AD use yoga more frequently than those without neurological conditions (~25% vs. ~17%, respectively) (10). The trend is clear: yoga is increasingly being by AD patients, and more research is needed.

No studies have examined the effects of yoga on chronic musculoskeletal pain in AD. However, multiple reviews have defined the effects of yoga on musculoskeletal pain in other populations. A 2013 metanalysis of yoga for any type of pain (e.g., back pain, rheumatoid arthritis, migraine/headache) concluded all 16 studies demonstrated positive effects for pain, with an overall moderate effect size (46). In a "review of systematic reviews," McCall et al. examined thirteen systematic reviews of yoga for treating acute and chronic conditions (47). Chronic pain was one of only three conditions that clearly benefitted from yoga (anxiety and depression also benefited). Authors concluded that yoga had a consistently positive effect on pain, with a moderate effect size (mean ± 95% CI) of 0.74 ± 0.52 - 0.97 that was slightly lower for fibromyalgia-like pain, (0.54 ± 0.11 - 0.96).

AD patients have many health problems including sleep disorders, functional impairment, depression, and cognitive decline (32). It is reasonable to ask if yoga can treat these problems. Certainly, yoga has shown clear benefits in non-AD populations, including reductions in anxiety (48) depression (49), and improvements in sleep (50). Of particular relevance is the finding that yoga improves cognition in healthy adults, including attention and processing speed, executive function, and memory (51). These findings raise the exciting possibility that yoga could have beneficial effects for cognition in AD patients. A recent review on yoga as an intervention for mild cognitive impairment, or dementia (4) suggests this was the case, especially for attention and verbal memory, and may be mediated by improved sleep and mood. The review concludes that providers should consider yoga as a safe and potentially beneficial health approach for AD.

Caregiver stress is becoming increasingly recognized. Dementia caregiving is associated with increased levels of depression, anxiety, higher use of psychoactive medications; worse physical health and immune function; and an increased mortality rate (52, 53). Thus, yoga treatment for AD patients could also prove useful for their caregivers. Indeed, the suggestion has been made that physical therapeutic recreation programs for dementia patients should be designed to serve both the patient and their caregiver (6). By performing therapy yoga could help reduce caregiver depression and anxiety and help guide and motivate AD patients to practice during non-class days.

Interventions such as yoga pose greater demands on time and travel than many conventional medical treatments, making it especially difficult for individuals who have AD, chronic pain and/or live in remote areas. As part of a VA initiative to investigate the geographic, clinical, and social barriers to accessing in-person care, detailed information was collected on barriers to accessing healthcare from 1,295 veterans (unpublished data) (54). Results show that barriers included travel time and costs, health conditions, and bad weather. As a result, many individuals may not be able to attend in-person yoga classes. Possible behavioral and social problems in AD may discourage the caregiver from bringing AD patients to group classes, thus compounding problems of access.

Home-based yoga is a very attractive solution to address problem of access. The successful implementation of teleyoga could advance and elevate the treatment of AD and

caregivers. To date, only two small studies have examined the feasibility of at-home teleyoga involving patients with COPD (55) or cancer (56). Both studies reported negative experiences with the technology, and both concluded that internet-based yoga could be feasible if the technology was simplified.

Objectives

Specific Aims and Hypothesis

Specific Aims:
1. Modify an existing teleyoga intervention to use with AD patients and their caregivers and address the technical challenges of at-home teleyoga.
2. Demonstrate the feasibility of conducting group teleyoga with AD patients and their caregivers.

Hypothesis 1 (primary): It will be feasible to maintain an a priori adherence to $\geq$ 75% classes.
Hypothesis 2 (secondary): Treatment satisfaction as measured by the Multi-Dimensional Treatment Satisfaction Measure will be neutral or positive for all factors.

Study Design

No randomization into treatment groups will be needed in this study. The study involves the development of the technical methods and yoga protocol design needed to deliver at-home yoga instruction via videoconferencing.

Recruitment: 15 dyads (pairs of Alzheimer's disease patients and their caregivers) with chronic musculoskeletal pain will be recruited through different streams such as flyers posted at Stanford Alzheimer's Disease Research Center, and VAPAHCS Pain Clinic. We may also ask VA providers to refer their patients with chronic pain, contacting organization that provide guidance and support for people with Alzheimer's disease or chronic pain, web-based advertising, local advertising, social media advertising (Facebook, Twitter and Instagram using Web Based Recruitment Text, and mass-mailings to potential participants who may meet study eligibility criteria. To recruit AD patients, we may also use Brain Health Registry, which is a web-based platform run by UCSF to match patients with AD with suitable clinical trials (https://www.brainhealthregistry.org/for-investigators). The BHR will send our study information to interested prospective participants. These materials are attached to Tab 16 and include a BHR study description, BHR initial email invitation, BHR first follow-up email, and BHR second follow-up email.

Individual sessions: Yoga will be first be provided individually. That is, yoga sessions will include the yoga therapist, one AD patient and one caregiver. We will recruit n=5 dyads (5 AD patients, 5 caregivers).

Group sessions: The study will also demonstrate the feasibility of providing group yoga. Feasibility will be measured for recruitment, retention, and adherence. We will recruit n=10 dyads (10 AD patients, 10 caregivers). When the required number of participants have been identified, the study team will schedule baseline assessments. After the baseline assessment, the cohort will receive group yoga. We currently estimate that due to technical limitations of

instructing yoga via videoconferencing, the largest group size will be 10 participants. Since this is a feasibility study, the study is not powered for efficacy.

Yoga Intervention: We will adapt the yoga protocol from the active award. The protocol is 12 weeks in duration, 1 class/week, class length of 75 minutes, with additional homework 15-20 mins on 5 non-class days/week. The protocol uses seated/standing/supine yoga postures, breathing, and meditation, and contains standard modifications in cases of limited mobility. Participants will also receive a homework manual describing simple and safe exercises to practice for homework.

The sample size (n=15) is small, but will provide the necessary information on recruitment, adherence, acceptability and self-report measures of pain and pain-related function to plan a larger fully powered efficacy study in the future. Developing a yoga intervention for groups is typical of yoga interventions, as it allows a small staff to treat many individuals simultaneously.

The main purpose of this study is to collect information on various aspects of feasibility and not efficacy of treatment, therefore we contend that a priori matching or a priori stratification is not relevant in this case. We have also considered another challenging feature of the design; caregivers and AD patients will interact. Participants may also interact with one another directly in their groups. This interaction creates the expectation that some level of intraclass correlation (ICC) will develop such that AD patient and caregiver responses to treatment will be positively correlated. The magnitude of the ICC depends on the type, duration, and intensity of these interactions, and are currently unknown. That ICC may be negligible at baseline, but it can develop over the course of the trial. We contend that with a limited number of treatment cohorts (2), and the limited number of yoga teachers (1-2) we have very limited ability to estimate the ICC, or the component of variance associated with the group or yoga teacher. Again, the main purpose of this study is to collect information on various aspects of feasibility and ICC is of negligible importance in our design, and a priori matching or a priori stratification is not necessary in this case.

<table>
<tr><td colspan="12">Month</td></tr>
<tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td></tr>
<tr><td colspan="3">Recruit AD & Caregiver (n=5 pairs)</td><td colspan="3">Treat AD & Caregivers one-on-one format</td><td colspan="3">Treat AD & Caregivers group format</td><td colspan="3">Data analysis, manuscript submission and funding application</td></tr>
<tr><td colspan="3"></td><td colspan="3">Run AD & Caregiver pairs (n=10 pairs)</td><td colspan="3"></td><td colspan="3"></td></tr>
</table>

Table 1. Recruitment Table

Statistical Plan and Data Analysis

The main analytic strategy will be descriptive statistics for pre- and post-intervention assessments for AD patients and their caregivers. For feasibility of retention and adherence, we aim to reach at least 65% retention. For feasibility of treatment fidelity, we will aim for ≥95% of treatment components. For the outcomes that will be measured repeatedly (i.e., both at baseline

and post-treatment), we will estimate how they change over time (pre to post). Note that some of the assessment measures used are used only for AD patients or caregivers. The results will be reported for both groups separately. Accordingly, in terms of AD patient outcomes, we will estimate changes in pain (DVPRS), depression (BDI-II), sleep (PSQI) and cognition (CanTab). These results will provide preliminary data on target engagement and therefore will inform and shape the future trial in terms of elucidating the mechanism of action. For the caregiver measures, we will estimate changes in caregiver burden (Revised Memory and Behavior Problems Checklist), quality of life (SF-36), depression (BDI-II), and sleep (PSQI). We will also explore the relationship between changes in patient outcomes and their caregiver outcomes. For all analyses regarding changes in outcomes, we will first employ simple paired t-test (pre vs. post) given the correlation between pre and post measures. We will also estimate changes based on longitudinal mixed effects modeling using maximum likelihood estimation. We will put in rigorous effort to minimize missing data. Nonetheless, we expect some attrition by post intervention assessment. In our mixed effects modeling, data points that are missing due to attrition or missing assessment will be handled assuming that data are missing at random conditional on observed information. In all statistical analyses, 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

Inclusion Criteria for AD patients (As determined by):

- Diagnosis of probable Alzheimer's disease- Baseline
- Mini-Mental State Examination (MMSE) score 18-25 (Mild AD) (screening interview) ≥ 18 years old
- Has a primary care provider who can provide medical clearance for participation in the study
- Diagnosis of chronic musculoskeletal pain > 6 months
- Minimum pain intensity at screening visit: pain rated ≥4 on a 0-10 Numeric Rating Scale (NRS)
- 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 (Screening interview)
- Has a caregiver who is willing to accompany AD patient for treatment, and who can receive yoga treatment at the same time as AD patient.

Exclusion Criteria for AD patients (As determined by):

- 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 (VA EMR; screening interview)
- Baseline pain <4 or ≥9 on a 0-10 Numeric Rating Scale (NRS)

Inclusion Criteria for CAREGIVERS of AD patients (As determined by):

- Are caring for a patient diagnosed with AD who will practice yoga together with them
- Has a primary care provider who can provide medical clearance for participation in the study (Yoga Medical Clearance Form)
- Exclusion Criteria for Caregiver
- Participation in another concurrent clinical trial
- Attended or practiced yoga ≥ 1 x in the past 12 months
- Attended or practiced yoga ≥ 1 x in the past 12 months

Informed Consent Process

Participants will be recruited from four sources: Brain Health Registry, 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 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 will involve the AD patient and their caregiver together. They will complete separate consent forms. As we are enrolling AD patients with impaired consent capacity, the caregiver will act as a legal authorized representative (LAR) and provide consent for the AD patient, who will be asked to provide their assent. These forms will include the HIPAA document and are estimated to take about 60-90 minutes. It will take place in a quiet office or interview room, located in the same building as the PI, who will be available to answer any of the study candidate's questions.

1. The Project Manager will explain the information contained in the written informed consent forms (purpose, procedures, risks, benefits, alternatives to participation, etc.) and HIPAA documents to the study candidates verbally, in lay language.
    a. The Project Manager will check for comprehension, allow the study candidates 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 their 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 each 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 (See Research Strategy).

Screening Procedures

Potential participants (n=15) will be screened via phone. 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 for AD participants will include the MMSE, PEG, DVPRS and Clinical 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).
Pittsburg Sleep Quality Index (PSQI) (62): Contains 10 self-report questions regarding sleep habits over the past month, including discrete responses (e.g. amount of sleep) and responses scored on a 0-3 scale ("not during the past month" to "three or more times per week"), related to sleep quality, medication use, motivation, and fatigue. A global sum score indicates level of sleep difficulties.
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.
Treatment Fidelity: Of the 12 sessions recorded, we will randomly select a session from weeks 1-4, weeks 5-8, and weeks 9-12 for a yoga instructor to review. Following standard procedures (64), they will review the sessions using a manual checklist for instructor adherence to the yoga manuals, which will consist of a Yes/No prompt for each procedure or instruction. We will set a benchmark for minimum competency at ≥95% of treatment components (64).
Cambridge Neuropsychological Test Automated Battery (CANTAB): Cognitive function was measured with the Cambridge Neuropsychological Test Automated Battery (CANTAB) at baseline and end of treatment. Three tests were administered (PAL, SWM and RVP).
Revised Memory and Behavior Problems Checklist (RMBPC) (68): Assesses behavior problems in dementia patients. Contains 24 caregiver-report questions, scored on two scales; whether the behavior was observed ("yes"/"no"), and the degree it affected the caregiver. Scales yield scores; one total score for patient problems and three subscale scores (memory-related, depression, and disruptive behaviors), and parallel scores for caregiver reaction.
SF-36: Health related quality of life-short form (69). Eight scales measuring physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health.

	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

Department of Veterans Affairs

RESEARCH CONSENT FORM

IRB Use Only
Approval Date: September 10, 2020
Expiration Date: (Does not Expire)

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 for people with Alzheimer's disease. 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 experiencing chronic pain and have a diagnosis of Alzheimer's disease OR you care for a person with Alzheimer's disease that experiences chronic pain. This research study is looking for 15 who exhibit symptoms of chronic pain and want to use yoga via telehealth to treat their pain OR caregivers who want to support the Alzheimer's patient they care for and that exhibits symptoms of chronic pain 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 (2-3 hours): You will be asked to complete self-report questionnaires about your medication use, your experience of chronic pain, your sleep and mood, on the phone or online through Qualtrics or REDCap. People with Alzheimer's disease will also be given a brief cognitive test. Caregivers will be given an additional questionnaire on their experience of caregiving. During this session we will record your phone number, the physical location for at-home teleyoga and an emergency contact. This information will be used if video disconnects or an unforeseen emergency arises during at-home teleyoga.

Treatment (12 weeks): In the first week, you will be given a yoga mat, yoga strap, and yoga blocks for use during the yoga class that you will be attending. You will be given instructions on how you can watch and participate in the yoga classes at home via video conferencing. You will determine a part of the 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 you, the teacher, or the group. A member of the study staff will call you the business day before class to remind you of the class and to charge the iPad for class. The yoga instructor will be offering a live yoga class, and you will participate at home using the provided iPad to watch the yoga class via video conferencing alongside your caregiver or the person you care for.

Post-Treatment (2-3 hours): You will be asked to complete the same self-report questionnaires you were given before treatment and asked to provide feedback about the program, including any technical issues you encountered. This will be done either in-person at the VA Palo Alto, on the phone or online through REDCap or Qualtrics. You will mail the iPad back to study staff via USPS.

Video Recording: 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 IRB guidelines. 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 people with chronic pain and those without pain. As a caregiver you will be encouraged to move safely and modify postures as necessary in a way that is most comfortable for you. If there is an unforeseen emergency during your at-home teleyoga session, we will take the necessary steps to ensure medical help arrives to the address you provided at the start of the study, for yourself or the patient.

Will I benefit from the study?

The benefits which may reasonably be expected to result from this study are relief from chronic pain if you experience it or general relaxation associated with yoga.

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 standard treatments provided by a local clinic if you experience pain. The study investigator will discuss any alternatives before you agree to participate in this study. Alternative treatments if you are experiencing pain 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.

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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 as 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 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.

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, your rights as a participant or those of the patient you care for, 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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

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