Rage Against the Pain: An Alternative Yoga Program to Address Chronic Low Back Pain Among Veterans (PPO 19-362; NCT05103475)

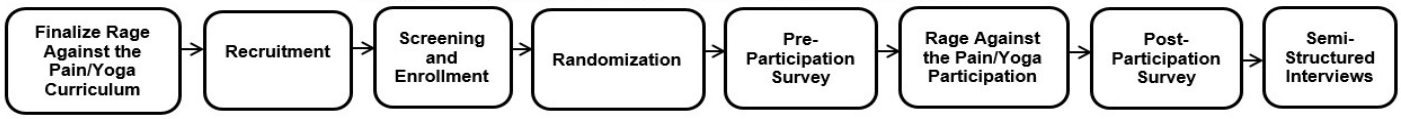
PROTOCOL

12/15/2022

RESEARCH DESIGN/METHODS

Design Overview. This mixed-methods pilot intervention study will employ pre-and- post-intervention data collection (*see Figure 2 below*).

Figure 2. Main Study Activities and Flow of Data Collection



***Design/Setting*.** All research activities will take place at the Hines VA Hospital located in the Chicagoland area. Yoga classes will be offered through the Recreation Therapy Service at Hines, in the dedicated space where currently offered yoga classes are held. Survey data collection activities will be completed via mail/phone or in person (per the Veterans' preference), and semi-structured interviews will be completed via phone.

***Sample*.** Our sample will be comprised of Veterans who receive primary care services at Hines and experience chronic low back pain. We will identify Veterans who, in the prior 3 months, received a diagnosis associated with chronic low back pain (e.g., ICD10 codes associated with back pain and low back pain extracted from VA administrative records (the CDW)). As needed, we may also identify eligible individuals via provider referral and/or snowball sampling (i.e., peer referral), as described below.

***Recruitment*.** We will mail recruitment materials to individuals identified as eligible based on ICD10 codes inviting them to participate in a VA research study aimed at helping Veterans who experience chronic low back pain. We will require real SSN access to pull Veteran demographic, health and contact information for recruitment efforts. Patients will receive a recruitment letter and flier in the mail and will be asked to contact our study team if they are interested in participating. As needed, we may also place follow-up telephone calls to Veterans who do not contact us. If needed, we will also employ the following recruitment strategies: we will post fliers in primary care and pain clinic waiting areas; we will ask providers working in primary care and pain clinics to refer eligible Veterans to the study; we will have our project coordinator recruit in person in pain clinic waiting areas; we will ask Veterans who enrolled and participated in early classes to refer their peers to the study (i.e., snowball sampling). Veterans who are interested will contact our project manager, who will screen them for eligibility based on the inclusion criteria detailed below using a screening form. If we receive responses from primarily women Veterans early in our recruitment efforts, we will target later recruitment efforts to male Veterans to ensure that both male and female Veterans are represented in the study.

***Randomization*.** Eligible patients will be randomly assigned to RAP or treatment as usual (regular yoga routinely offered at the hospital, which at our facility is Hatha yoga) using a random number generator.

***Intervention Details*.** Both the RAP and Hatha yoga classes will be offered once a week for 12 weeks; this 'dose' of yoga has been found to be effective in a previous randomized controlled trial (RCT) focused on yoga participation among individuals with back pain.[1] Classes will be about 60 minutes long. To accommodate targeted class sizes, we will run two cohorts, either concurrently (on different days of the week) or in waves (one session held after the first is completed) if needed. Yoga mats, straps and sets of blocks will be available for participants to use.

During the beginning months of the study we will hold a series of meetings with our yoga teachers, research team and advisory panel members, to finalize the curriculum, music play-lists and scheduling (day of the week and time of the day) of the classes; however, yoga poses that are known to benefit individuals who experience chronic low back pain will comprise the poses used in each program. These poses already comprise much of Hatha yoga classes, and we do not anticipate that finalizing the curriculum for either program will be significantly time-intensive.

Participating in the Rage Against the Pain and treatment as usual (Hatha yoga) interventions will entail following along with the yoga poses and corresponding breath work (e.g., suggestions for when to inhale and exhale commensurate with the movement) being cued by the instructor. Veterans will be clearly cued about options for modification for every pose, including options to modify poses using a chair or the wall; Veterans who are unable to engage in a modified version of any pose will be instructed to take child's pose or rest in a chair, against the wall or on the floor during that pose. When the set of movements for each class has been run through, the class will engage in a culminating activity (meditation referred to savasana or

or cool down, see below) wherein Veterans will be instructed to sit in chairs or lay on the floor with their eyes closed to relax. Veterans will be asked to complete practice logs in class.

We will also share a training manual with our Veteran participants (along with a yoga mat, strap and set of blocks) and encourage them to engage in home practice (ideally, about half an hour three times per week in addition to the weekly group classes).[2]

Treatment as Usual. The 'treatment as usual' class will be conducted in the style of the yoga classes currently being offered to Veterans at the Hines VA Hospital, which is a program akin to Hatha yoga with chair modifications available to all Veterans who choose/need to use them (described above).

Rage Against the Pain. The RAP program curriculum will mirror that of the Hatha Yoga classes, but will differ from this traditional yoga practice in a number of ways: (1) the classes will be set to rock/heavy metal music; (2) meditation will not be incorporated; (3) yoga terms will not be used to describe the poses/movements (rather, poses will be cued in plain descriptive English terms); (4) the culminating activity for the class will be called a 'cool down' (rather than the typical relaxation/meditation exercise used in yoga, referred to as savasana).

Possible Risks or Discomforts. Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the following risks or side effects: participating in the Rage Against the Pain High Intensity Stretching or Hatha Yoga classes may cause muscle soreness, pain, fatigue, injury, and/or emotional discomfort; participating surveys/semi-structured interviews may lead to discomfort with answering certain questions (Veterans will be informed that they do not have to answer any question(s) that make them feel uncomfortable). The recreation therapists running the intervention classes are trained and will make sure the class activities can be modified to make sure everyone can participate safely. Participants will be encouraged to participate at their own ability and not push past their limits. Our instructors are seasoned VA recreation therapists and have experience with working with Veterans who experience pain.

There is also a small risk of breach of confidentiality. We will take every possible step to protect the privacy of the study information, such as using a study ID rather than participant names for all data collection (surveys and interviews) and making sure research data are secure and computer files are password protected.

Risks of the usual care are not risks of the research. Those risks are not detailed in this protocol. During the consenting process, participants will be asked to talk with their health care providers if they have any questions about the risks of usual care. Participation in research may involve a loss of privacy. All research records will be kept as confidential as possible.

To mitigate any potential risks or discomforts, we have developed a comprehensive safety plan (please see below).

Safety Considerations. We recognize that safety must be an utmost concern in developing and testing the RAP program. As such, we consulted with others in VA on how best to design the safety plan for this proposal, to ensure that no relevant facets were overlooked. We have incorporated safety considerations into every aspect of the program to ensure the well-being of those Veterans who choose to adopt/participate. This comprehensive strategy is based on established best practices from other recent studies examining the impact of yoga on pain in Veterans with low back pain.[3] We will also work with our yoga teachers and advisory panel members (including a physical therapist (PT)) to ensure that program curriculum is well-designed and focused on safety considerations. Our safety plan is described in detail below.

Inclusion Criteria. Veterans will be eligible to participate in the study if they: (1) currently receive primary care services at the Hines VA, and (2) received a diagnosis associated with chronic low back pain in the previous 3 months as identified through the CDW using relevant ICD-10 codes and a screening questionnaire, as appropriate

Exclusion Criteria. Veterans will be ineligible to participate in the study if any of the following are true for them: (1) they currently regularly participate in yoga; (2) they regularly participated in yoga in the previous 6 months; (3) their back pain is a symptom of a specific treatable or underlying disease/condition(s) (e.g., ankylosing spondylitis, active or recent malignancy, fracture/spinal cord injury, spinal infection); (4) they are experiencing progressive neurological deficits; (5) they have any other condition which results in severe disability (e.g., non-ambulatory, hemiparesis, severe cognitive deficits); (6) they have a diagnosis associated with psychosis; (7) they are currently experiencing issues around substance abuse (not including prescription opioids), as identified through ICD-10 codes associated with 'mental and behavioral disorders due to

psychoactive substance use' recorded in the patient's medical record in the previous 3 months (which will be extracted from the CDW); (8) they do not plan to be living in the Chicagoland area for the duration of the study. These exclusion criteria are based on the criteria used by Saper et al.[4] in their RCT of yoga for Veterans with chronic low back pain. In addition, women Veterans who are pregnant at the time of screening will not be enrolled in the study.

Pre-Enrollment Screening. Currently, the yoga programs offered at the Hines VA do not require that Veterans are cleared by their health care providers before they participate. Rather, the yoga instructor reviews the medical record of each Veteran before they can enroll in the yoga class to make sure that individual is not contraindicated from participating. However, other programs that might be considered more 'risky' (e.g., therapeutic horseback riding) do require that the patient receives medical clearance before they are able to enroll/participate. Because this is a research study, out of an abundance of caution, we will require that all Veterans are cleared by their Hines primary care provider before we allow them to enroll in the study. That is, when a Veteran contacts our research project manager and expresses interest in participating, our project manager will contact their primary care provider at Hines, explain what participation would entail and what are our inclusion and exclusion criteria are, and ask the provider to endorse that patient's participation or let us know that they do not believe the Veteran to be a candidate for participation. In addition, as she is available, the PT on our advisory panel will complete in-person PT balance screens (as needed) with Veterans who are interested. The instructors will conduct chart reviews for any concerns or contraindications to participating in weekly classes.

Class Size. We will run two 12-week sessions of each respective yoga program. We will enroll 8-10 Veterans in each to ensure the yoga instructor can pay adequate attention to each participant and assist with modifications/pose adjustments as needed and appropriate.

Multiple Clinicians in the Room. As scheduling allows, the PT on our team will attend yoga classes. This will allow for extra clinical coverage to help Veteran participants modify poses as needed and monitor participants to ensure they are participating safely.

Pose Modifications. Yoga instructors will cue options for modification of each pose. Veterans will be encouraged to participate at their own ability and not push past their limits. Our yoga instructors are seasoned VA recreation therapists, and have experience working with Veterans who experience pain.

Monitoring Adverse Events. We will meticulously monitor adverse events. Adverse events will be tracked in a number of ways: (1) all participants will be encouraged to discuss any impacts they believe program participation may be having on their health with the yoga instructors either before or after class each week – we will ask both the participants and yoga instructors to report this information to the study project manager, (2) we will include a question on the post-program follow-up survey to assess any perceived impacts of participation on Veterans' health, and (3) among Veterans who do not complete the follow-up survey or leave this question blank, the study project manager and/or PI will conduct a thorough chart review to rule out notation of possible study-related adverse events in the patient's medical record.

Right of the Investigator to Terminate Participation. We have the right to terminate a Veteran's participation, without regard to their wishes, in the research study if any of the following occur: (1) they become uncooperative or unwilling to complete study-related tasks; (2) they are experiencing undue stress from the study procedures; (3) they are experiencing undue physical strain from the study procedures (e.g., the exertion required is too great for them, participation is causing them excessive pain, etc.); (4) they have a substance abuse, mental health, and/or medical problem that interferes with completion of the study-related tasks; (5) they behave inappropriately in a session or while completing a study-related task; (6) the study is stopped by the sponsor, which is the VA Office of Research Development.

Follow-Up Care. If a Veteran experience injuries from their participation in this research project, we will either (1) get their permission to contact your Hines primary care provider and suggest that they follow up with the Veteran, or (2) escort the Veteran to the Hines Emergency Department, contact the Hines rapid response team (if you are within the area of their purview), or call 911. We will not be doing follow-up care with individuals who choose to withdraw from the study.

Enrollment and Sample Size. As mentioned above, we will aim to enroll 16-20 Veterans in RAP and another 16-20 Veterans in the Hatha yoga program, for a total recruitment target of 32-40 Veterans. Looking back 3 months, we estimate that there are approximately 1,500 Veterans at Hines who meet our study eligibility criteria. Accordingly, we do not anticipate having any difficulties identifying and enrolling enough patients to meet this target. However, if needed we will expand our time-frame to include Veterans who received the

relevant diagnoses in the previous 6, 9 or 12 months. Of note, goals for aims 2 and 3 include determining feasibility numbers for recruitment and estimates of effect sizes to inform power considerations for the next step, the larger trial.

***Data Collection*.** Our data collection instruments reflect the factors that influence behavior as outlined in our conceptual framework; the relevant factors are noted in italics next to relevant questions in the appendices. Outcomes and strategies for measuring each are described below and summarized in Table 1.

Pre- and Post- Program Participation Surveys. All Veterans who are enrolled into the study will receive a pre-participation survey (Appendix D) approximately 1 week before the RAP/Hatha yoga classes begin, and a post-participation survey approximately 1 week after the 12-week programs are finished (Appendix E). Surveys will be mailed to Veterans so that persons who do not attend the first class of the program they are randomized to or do not complete the program still have the opportunity to fill out a survey. This will allow us to also compare outcomes between individuals who did and did not complete the programs. Veterans will also be given the option to complete the surveys over the phone with the study project manager, and we will follow up with Veterans who do not return a mailed survey by phone to optimize response rates. We will also provide Veteran to complete the baseline survey in-person at the time of study enrollment. Veterans who attend the first and last yoga class of each session will also be provided an opportunity to complete the survey in person at their preference. Veterans will receive $25.00 in appreciation of their time for each returned survey (up to two total surveys). Of note, we will not provide any token incentives for completing the yoga programs because we do not want to contaminate adoption rate data such that we cannot tease out whether Veterans are participating because they like the program or because they want to complete the program so that they can earn the incentive.

Table 1. Main Outcomes and Method of Data Collection

Outcome	Pre-Participation Survey	Post-Participation Survey	Post-Participation Semi-Structured Interview	Sign-In Sheet	Targeted Chart Review
Program Initiation	X	X		X	
Program Participation	X	X		X	
Pain Intensity	X	X	X		
Pain Interference	X	X	X		
Pain Behavior	X	X	X		
Back Pain-Related Function	X	X	X		
Health-Related Quality of Life	X	X	X		
Sleep	X	X	X		
Depression	X	X	X		
Stress	X	X	X		
Pain Medication Use	X	X	X		X
Use of Other Pain Management Programs	X	X	X		X
Perceptions of the Program	X	X	X		
Experienced with Program Participation	X	X	X		

The surveys will include measures of pain intensity; pain behavior; function; quality of life (QOL); sleep; depression; stress; medication (and other pain reduction strategy) use, and; patient perceptions of and experiences with the program.

Pain intensity will be measured using the Defense and Veterans Pain Rating Scale,[5] a valid and reliable numeric rating scale that asks individuals to report the average intensity of their low back pain on a scale of 0 (no pain) to 10 (worst pain imaginable)[6] for the previous 7 days.

Pain interference (how much the individual's pain has interfered with all aspects of their life in the prior 7 days) will be measured using the validated, reliable Patient-Reported Outcomes Measurement Information System (PROMIS) 8-item pain interference short form.[7] PROMIS scores are standardized to reflect the general adult US population, such that a mean score of 50 reflects average pain experience; higher scored indicate greater levels of pain interference.

Back pain-related function will be measured using the Roland-Morris Disability Questionnaire (RMDQ), a valid and reliable scale of physical disability resulting from chronic low back pain.[8] The RMDQ asks individuals to read 24 items noting back pain-related functional impairments and mark those that describe them. All marked items are summed for a total score ranging from 0 (no impairment) to 24 (maximum impairment). A 30% reduction in score from baseline coupled with an improved self-reported pain intensity rating is considered a clinically significant impact.[9]

Health-related QOL will be measured using the Medical Outcomes Study 12-Item Short Form Health Survey (SF-12),[10] a valid and reliable measure that produces physical and mental health sub-scale scores.

Sleep will be measured using the Insomnia Severity Index, which is a valid and reliable 7-item scale that produces a composite score of an individual's level of sleep disturbance during the past 14 days.[11] Item responses are added to obtain a total scale score; greater scores indicate more disturbed sleep and cut-points are provided by the scale developers that map to levels of clinical severity of sleep disturbance.

Depression severity will be measured using the 8-item Patient Health Questionnaire (PHQ-8), a valid and reliable measure that assesses individual's depression severity by asking them to evaluate 8 items that

reflect symptoms of depression and indicate how often they have experienced each in the prior two weeks on a scale of 0 to 3 (not at all - nearly every day).[12] Scores range from 0 (no depression symptomology) to 24 (most severe symptomology); scores can also be classified into mild, moderate, moderately severe and severe categories using cut-scores defined by the scale developers.

Stress will be measured using the Perceived Stress Scale (PSS) – 4 Item, a valid and reliable measure of individual's perceptions of how stressful their life experiences are.[13] The PSS is comprised of 4 questions and produces a composite score of perceived stress (higher scores indicate higher perceptions of stress).

We will ask participants to self-report any *pain medication use* (e.g., opiates, muscle relaxants, NSAIDs) in the pre- and post-participation surveys. Medication use will be corroborated through brief, targeted chart reviews, which reflects the process used by Groessl et al.[3] to collect information about pain medication use for their RCT of yoga for low back pain among Veterans. We will also ask participants to report *any use of other programs for pain management* (e.g., acupuncture, massage, mindfulness/meditation, cognitive-behavioral therapy) on both the pre- and post-participation surveys. This information will also be corroborated through brief, targeted chart reviews. The surveys will also include some basic questions (that map to our conceptual model) about patient's *perceptions of and experiences with the program* (extent to which they liked it, would participate again, would recommend to a peer, felt it impacted their health and how); these topics will be assessed in-depth via the post-participation semi-structured interview.

Program Initiation and Participation. The primary focus of this study is the reach and sustained engagement of the RAP program, which we hypothesize will be greater compared to traditional (Hatha) yoga. *Program initiation* (e.g., reach) will be defined as the number of individuals who start the RAP or Hatha yoga programs after being screened, deemed eligible for participation, and randomized to one or the other. *Program participation* (e.g., sustained engagement) will be defined as the average number of classes Veterans attended for each respective program, and the number of Veterans who attended the majority (9/12) of classes. These outcomes will be tracked via self-report (on the post-participation survey) and in real-time by asking Veterans to sign in before each class they participate in. In addition, we will ask any Veteran who contacts us indicating interest but ultimately chooses to not enroll in the study before they are enrolled/randomized why they are choosing not to participate.

Post-Participation Interviews with Veterans (Appendix F). To gather in-depth data about Veterans' perceptions of and experiences with the RAP and Hatha yoga programs, we will invite Veterans who completed the majority (e.g., 9 of 12) of program sessions to participate in a semi-structured interview. We will also conduct interviews with a sample of Veterans who did not complete a majority of sessions of either program, to ascertain why they stopped participating. We will conduct interviews with all Veterans who wish to complete an interview, for a total of up to 40 interviews. Interview participants will receive $30 in appreciation of their time. Our interview questions will reflect the factors detailed in our theoretical framework. Examples of questions include: did you like participating in the [RAP/Hatha yoga] program; did you talk about participating in the [RAP/Hatha yoga] program with your peers? what about your family members or significant other?; was there anything that made it difficult for you to participate?; was there anything that could have increased your interest/commitment to completing the program?; do you feel that participating in the [RAP/Hatha yoga] program impacted your back pain?; what about other things that could be related to your back pain, like your mood or sleep? A hallmark of qualitative research is its flexibility;[14] thus, further questions may arise depending on participants' responses, enabling us to probe into related domains. Interviews will last approximately 30 minutes and will be audio-recorded and transcribed verbatim for analysis. We will obtain verbal consent using a consent script before conducting the interview.

Costs to Participants and Payment.

Costs to Participants. A Veteran subject will not be required to pay for medical care and services received as a subject in an approved VA research study. Some Veterans are required to pay a co-payment for the care they receive. These requirements will continue to apply to medical care and services provided by the VA that are not part of this research study.

Summary of Payment Offered for Participation. Payments will be provided through a voucher that can be redeemed for cash at the Agent Cashier or by direct deposit. As noted above, Veterans will receive: (1) $25 for each survey that they complete and return for this study (up to $50 total if they return both surveys); (2) if they are asked participate in an interview, they will receive $30 upon completion of that interview. Therefore, if a Veteran returns both surveys and completes an interview, they may receive up to $80 total

throughout their participation in this study. These payments will not be pro-rated if a Veteran withdraws from the study or if their participation is terminated before the study is over.

***Data Analyses*.**

Quantitative Analysis of Surveys. We will use descriptive statistics (proportions, means) to assess adoption, sustained engagement, and pain and related outcomes. All outcomes will be scored based on the guidelines of each respective measure. Rates of adoption (e.g., program initiation, defined as the number of Veterans who start the RAP or Hatha yoga programs after being screened, deemed eligible for participation, and randomized to one or the other) and sustained engagement (e.g., participation, defined as the average number of classes Veterans attended for each respective program, and the number of Veterans who attended the majority (9/12) of classes), will be compared for the RAP and traditional yoga groups using bivariate analyses (t-tests, chi-square tests) , to determine if initiation and participation rates are statistically significantly higher for the RAP vs. Hatha yoga groups (Hypothesis 1) . We will use bivariate analyses (t-tests) and ANOVA to compare outcomes (pain intensity; pain behavior; function; QOL; sleep; depression; stress; medication (and other pain reduction strategy) use) (1) for each Veteran before and after program participation, and (2) between Veterans in the RAP vs. traditional yoga programs. We will also compare all outcomes by gender. We will calculate effect sized for all bivariate comparisons. As mentioned above, our goals for aims 2 and 3 include determining feasibility numbers for recruitment and estimates of effect sizes to inform power considerations for the next step, the larger trial. We will use our adoption and participation rates to base recruitment and enrollment targets for that trial, and will base power calculations off of the effect sizes on key outcomes (e.g., pain intensity, interference, back-pain related function) observed in this pilot. Survey data on patient experiences with and perceptions of the programs, assessed in part via open-ended questions on the post-program participation survey, will be content coded by Dr. Etingen and the qualitative research specialist and triangulated with interview data under the guidance of Dr. Hogan (please see below).

Qualitative Analysis of Semi-Structured Interviews. Audio-recordings of the post-participation semi-structured interviews will be transcribed verbatim. Qualitative analysis software will be used to support analyses. Our qualitative analysis approach will be both deductive and inductive.[15] We will develop an initial code list *a priori* that reflects categories of interest, based on elements of our conceptual model (e.g., Veterans' attitudes toward participating in yoga, their perceived subjective norms and behavioral control, and their behavioral intention). Within each category, we will inductively develop additional codes and analyze the text for themes and patterns. This will be an iterative process where our code list may be revised to account for novel instances in the data. We will continue until saturation[14] is reached across categories. Established qualitative analytic techniques will be used throughout this process, including the constant comparative method, which involves identifying key themes and concepts emergent from the data to generate meaningful categorization.[14]

We will leverage a team-based approach to qualitative analysis drawing on the breadth of expertise of our team. Dr. Etingen and the qualitative research specialist will first independently review and open-code 3-5 transcripts to identify prominent themes. They will then convene a series of meetings to compare their codes, develop a set of analytic categories agreed upon through discussion, and develop the initial code list. They will continue with the next set of transcripts to develop new codes and revise codes applied to all prior transcripts, until they reach saturation with codes and themes, and finalize a codebook. Dr. Etingen and the qualitative research specialist will then code un-coded transcripts until they reach inter-coder reliability greater than >0.90%.[16] The iterative, collaborative nature of this process will maximize the validity and overall soundness of our analysis.

Limitations. We recognize that because we are proposing to carry out the study activities at one VA facility, cultural idiosyncrasies may impact the generalizability of our results to other VA facilities. In addition, while we know that yoga is under-utilized, particularly by male Veterans, we do not know what proportion of Veterans that could benefit from yoga participation choose not to participate because they have a negative perception of it. Because of this, we cannot say for certain how many Veterans might benefit from the alternative program we are proposing, though we anticipate it will be a significant number based on postulations in recent literature[17] and feedback from Veterans (described above).

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