Intervention Study
Protocol

A Mind-Body Intervention to reduce symptoms among people aging with HIV (NCT03840525)

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Tool Revision History

Version Number:3.0
Version Date: June 25, 2019
Summary of Revisions Made: Added more details for recruitment and screening, and all assessment interviews

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Summary of Revisions Made: Added new compensation for group attendance as well as transportation (Uber Health); as well as personnel changes.

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Summary of Revisions Made: Removed Draft watermark; updated sample size from 72 to 48 (as approved by NIH); updated study design flowchart to reflect final sample; updated inclusion criteria to include reliable internet access; and procedures updated to reflect remote delivery changes due to covid-19.

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Summary of Revisions Made: updated the list of investigators by adding Dr Hu; added a note regarding the remote delivery of the intervention due to covid-19 in the Precis section.**;** removed duplicate objectives.

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STUDY TEAM ROSTER

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PRÉCIS

This study aims to test the acceptability and feasibility of a remotely delivered tai chi/qigong intervention (TCQ) adapted to an ethnically diverse sample of older people living with HIV (PWH) in Miami, Florida. Note: the intervention was adapted to a remotely delivery due to Covid-19.

1. STUDY OBJECTIVES

The **specific aims** for the proposed study are as follows:

Aim 1: Refine and culturally adapt a TCQ intervention protocol for a diverse sample of older PWH by conducting an expert panel (n=3), key informant interviews (n=10), a 'dry run' intervention (n=10), and 2 focus groups (n=10).

Hypothesis 1: The TCQ intervention content, recruitment process, and adherence strategies will be determined to be culturally appropriate for a diverse sample of older PWH.

Aim 2: Evaluate the acceptability of the TCQ intervention protocol for older PWH every week, 2-week post-intervention, and 3 months follow up (n = 48).

Hypothesis 2a: TCQ intervention sessions, home practice sessions, control condition, and adherence strategies (weekly phone call, newsletter, buddy system) will be rated acceptable among older PWH (> 80%).

Hypothesis 2b: TCQ intervention and control conditions will have high acceptability (% recruited who enroll; % who attend all sessions; % who regularly do home practice sessions; % complete follow up) among older PWH.

Aim 3: Evaluate the feasibility of the TCQ intervention protocol for older PWH every week, 2-week post-intervention, and 3 month follow up (n = 48).

Hypothesis 3a: Participants in the TCQ intervention will report use of the TCQ practice at 3 months follow up (>80%).

Hypothesis 3b: Trainers will report high feasibility of the TCQ intervention with clinic infrastructure and participant abilities (>80%).

Hypothesis 3c: Trainers will show high intervention fidelity (>90%) as measured by the Intervention Fidelity Checklist.

The clinical trial will aim to address AIM 2 and 3.

Design and Outcomes

This is an exploratory clinical trial in which participants will be randomized into 3 conditions: a tai chi/qigong intervention condition, a 'sham' qigong attention-control condition, and a standard of care group. The trial is to test the acceptability and feasibility of both the intervention and the appropriateness of the control condition (primary outcomes). Assessments will be conducted at baseline, 2-week post intervention, and 3 months follow up. Measures include demographics, psychological and physical symptoms, acceptability, feasibility, and intervention fidelity measures. Psychological and physical health are secondary outcomes.

Interventions and Duration

Both the intervention (qigong) condition and the sham qigong control condition will last 12 weeks in duration. The third arm will be a standard of care wait-list control condition which receives nothing. In addition, participants will be asked to do a follow up assessment within 2 weeks of completing the intervention; and again 3-month post intervention. In total, study participation should be approximately 6 months.

Sample Size and Population

The target population will be individuals living with HIV who are 50 years of age or older. The trial will enroll and randomize 48 participants into either the intervention or control conditions. Randomization procedures were determined by our data analyst and biostatistician; and is described in further detail below.

2. BACKGROUND AND RATIONALE

2.1. Background on Condition, Disease, or Other Primary Study Focus

Half of those infected with HIV in the United States are over 50[1], and this will increase to 70% by 2020[2]. Although death rates have decreased for all age groups, it has increased for older adults aged 60 and older. Over 60% of those HIV+ and over 50 are racial/ethnic minorities[1]. Older people living with HIV/AIDS (PWH) report a myriad of psychological and physical symptoms, more than do their younger HIV+ counterparts[3]. More symptoms lead to poorer medication adherence[4] and higher viral load. Few interventions exist for older PWH[5]; only 2 interventions on reducing depression and increasing coping symptoms[6,7]. None addressed physical symptoms.

Mind-body interventions, like Tai chi and Qigong (TCQ) improves both physical and psychological health and might promote immune functioning[8]. TCQ is a series of slow, low-impact meditative movements that integrates breath work, meditation, and stances. Using the National Center on Complementary and Integrative Health (NCCIH) *Framework for Developing and Testing Mind and Body Interventions*, we propose the refinement, acceptability and feasibility testing of a standardized mind body intervention – Tai Chi/Qigong Easy – shown efficacious with cancer patients, with an ethnically diverse population of older PWH (50 years of age or older). Participants will be recruited from Borinquen Health Clinic, a federally qualified health center in Miami, Florida. The intervention will be adapted to fit the cultural and HIV context; then participants will be randomly assigned to either a TCQ intervention, a sham Qigong (SQG) control condition, or a standard of care group.

2.2. Study Rationale

Co-investigator, Dr. Larkey, has conducted extensive research on qi gong interventions trying to alleviate fatigue and other symptoms among breast cancer survivors. In an NCCAM funded pilot study (U01 AT002706-03: PI Larkey), 101 breast cancer survivors (BCSs) were randomized to a 12-week Qigong/Tai Chi Easy (TCQ) intervention or sham Qigong (SQG) using similar, gentle movements without meditative state/breath focus) (publication accepted to Annals of Behavioral Medicine). Pre- and post-intervention data were collected for 87 women, mean age, 58.8,

completing the intervention (15% attrition) on the primary outcome, *fatigue*, and several other symptom and mood related factors. Fatigue was significantly decreased for TCQ compared to SQG ($p = 0.013$). The estimated effect size (Cohen's D) was 0.56, suggesting a "medium" effect, which is remarkable when one considers that the comparison group was confirmed to have the *same level of exertion and was perceived as equally beneficial*. Other symptoms/mood factors (depression, sleep quality, cognitive function) significantly improved from pre-to-post TCQ intervention (with higher values but not significantly more than the SQG intervention) indicating small effect sizes for these symptoms ranging from .19-.31. In another study, dissemination of TCQ through community sites[93] was demonstrated through a successful **"practice leader" training** model where the **Tai Chi Easy form was formalized, manualized, and standardized** for implementation across the US (18 sites). A significant decrease in stress was found pre- to post-intervention using the Perceived Stress Scale (PSS)[94]: PSS scores (10 items, alpha = .88) decreased from 1.28 to 1.20 with 4 indicating higher stress on a scale of 0-4, ($t = 3.03$, df 299, $p = .03$).

Individuals living with HIV suffer from multiple psychological and physical symptoms. Dr. Ibañez is currently collecting data on a cohort of HIV+ individuals at multiple sites in Florida. Preliminary data analysis shows that the older PWH in this cohort is experiencing both physical and psychological symptoms: 26% severe anxiety; 29% severe depression; and 22% had physical health problems. However, 45% of those over 50 reported that physical health problems did not limit their physical activities, which suggest that a mind body intervention is feasible physically.

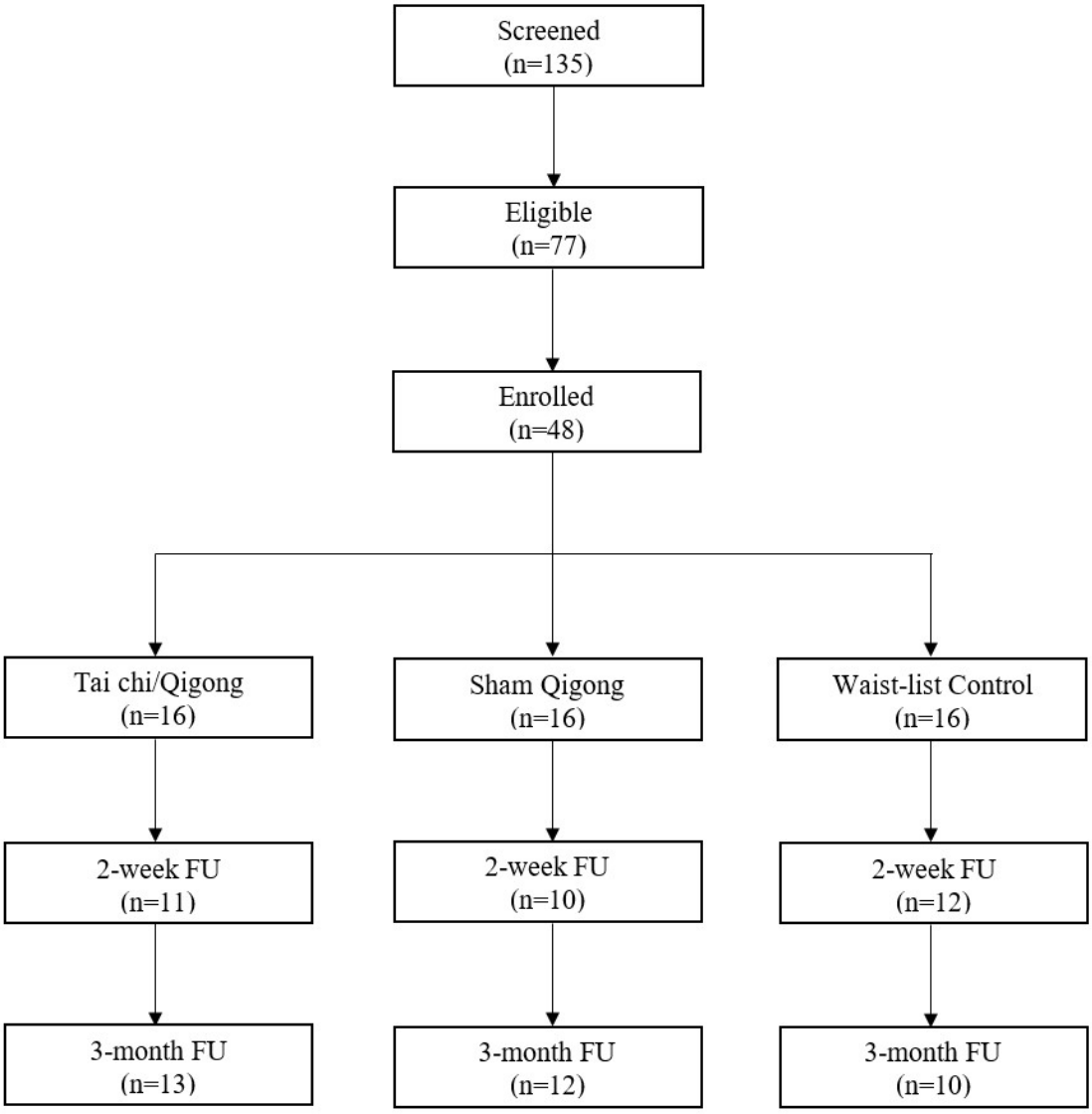
3. STUDY DESIGN

This is a 3-arm randomized clinical trial with a tai chi/qigong intervention, a 'sham' qigong control, and a standard of care wait list control condition. Both the intervention and control groups will be conducted online via Zoom videoconferencing (note: the in-person intervention was adapted to a virtual delivery due to Covid). The primary outcomes are the acceptability and the feasibility of the tai chi/qigong intervention for an older population living with HIV. The secondary outcomes are the reduction of psychological and physical symptoms. Participants (n=48) will be consented and baselined and randomized into either the qigong or the 'control groups. The intervention duration is 12-weeks, 2x/week for the first 2 weeks, followed by 1 session per week. See below for a flowchart of the study design. Table 1 describes the tai chi/qigong intervention and the sham qigong control conditions.

Table 1. Descriptive characteristics of the TCQ Intervention and Control Conditions

	Qigong/Tai Chi Easy	Sham Qigong	Standard of Care
Intervention Features	Low impact physical activity Focus on breath Meditative State Incidental Social Support	Low impact physical activity with same/similar movements as TCQ intervention Incidental Social Support	No Exercise/Activity Program
Dose/Frequency	12-weeks, 1/week 60 min class (2x per week in first 2 weeks) Approx. 2 ½ hours home practice/week	12-weeks, 1/week 60 min class (2x per week in first 2 weeks) Approx. 2 ½ hours home practice/week	n/a
Controls for	Unique focus; breath and meditative state	Low impact physical activity	n/a

Figure 1. Flowchart depicting Study Design.



4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1. Inclusion Criteria

- 50 years of age or older
- Must be HIV positive
- Able to provide consent
- Willing to participate the length of the study
- Have reliable internet access

4.2. Exclusion Criteria

- Regular involvement with mind-body interventions (yoga, tai chi, qigong) in the last 12 months (i.e., weekly practice for 3 months within the last 12 months)
- Not being able to stand for 10 minutes

4.3. Study Enrollment Procedures

Participants will be recruited either via Borinquen staff and recruitment flyers posted throughout the clinics as well as other partnering agencies and by using a professional recruiting service (Trialfacts) to conduct online recruiting.

Screening. Potential participants will be screened for eligibility using the IRB approved screener form and script (see Appendix). If potential participant is recruited via online, Trialfacts will provide the contact information and set up a time for research staff to call the participant. If determined eligible, the research interviewer will explain the study further and will fill out the Appointment and Scheduling Form. This form will be used to schedule the baseline assessment and will be placed in the participant study folder. Either the research coordinator or person screening will add the baseline appointment in the shared Qigong study google calendar. As part of the scheduling for baseline assessments, the interviewer will ask the participant to send a picture of their latest lab results for two reasons: 1) to confirm HIV status; and 2) to collect viral load data. The research coordinator should discuss with the PI when it was not possible to confirm HIV status. If found ineligible, the screener form will be kept in a separate folder, which will hold all ineligible screeners.

5. STUDY INTERVENTIONS

5.1. Interventions, Administration, and Duration

The Tai Chi/Qi gong Made Easy Intervention (TCQ). The TCQ intervention is standardized, manualized, and has a formal training program for instructors form the Institute of Integral Qigong and Tai Chi (IIQTC). We will follow a 'train the trainers' model, in which Dr. Larkey, who is an IIQTC Senior Trainer, will train 3-4 instructors on the intervention. The intervention content includes a series of repeated and easy to learn movements that are also the forms known to be linked to health benefits (Jahnke, et al., 2010). A DVD and manual demonstrating a core set of 10 exercises have been professionally produced and will be given to participants to help promote their practice at home. As part of the proposed study, we will translate and professionally produce a video (for home practice) in Spanish for Spanish speaking participants. This video will be in either a DVD format or streaming via YouTube.

The Sham Qigong is a physical activity- and attention-control group that uses similar types of movements that are part of the TCQ intervention, but without the meditative state and breath focus that is present in the TCQ group. It also has a video, participant manual, and instructor guidelines for teaching. Dr. Larkey has been fully trained and experienced in this

protocol and will teach the research coordinator and 1-2 facilitators on how to use the video, manual, and practice. Dr. Larkey will observe their practice via the video-recordings of the sessions and will oversee the respective fidelity checks. Both the TCQ intervention and the Sham qigong control group, will be revised based on the qualitative work done in the intervention refinement phase. Dr. Larkey will review at least 10% of all sessions and hold monthly phone or video calls with trainers to review feedback.

Adherence/Incentive Strategies: Based on some of the elements of social cognitive theory (SCT), we will use role-modeling and social support, and intrinsic reward to help participants adhere to the intervention. These strategies are the following: 1) the instructor will communicate with each participant when they come to the session to reinforce self-efficacy; and 2) a monthly 1 page newsletter will be emailed to all participants (or handed out at classes) with success stories, participant adherence to intervention, and positive health outcomes of participants. In addition, the research coordinator will make 2 weekly phone calls as a reminder of upcoming sessions and to assess the participant's at-home practice. In addition, there will be monetary incentives for participating in each of the assessments and the intervention. We will provide a $30 in cash for the baseline and 2 weeks follow up assessments each; and $50 for the 3 months follow up assessment. If participants attend at least 75% of the sessions, the 2 weeks follow up assessment incentive will go up to a $50.

5.2 Handling of Study Interventions

The TCQ intervention and SQG intervention has been used previously and is a standardized tai chi/qigong intervention including a manual of operations. This manual describes detailed instructions on how to deliver the TCQ and sham qigong intervention. The standard of care group will simply be no exercise or activity. Previous studies using the TCQ and sham qigong conditions show that *blinding* of the intervention was successful. Participants in both control conditions will be offered the TCQ class after their 3 months follow up assessment.

5.3 Concomitant Interventions

Not Applicable.

5.4 Adherence Assessment

Satisfaction surveys will be administered to each participant in the TCQ and in the SQG groups to assess adherence to the intervention (or control) group. Surveys will ask about their satisfaction with the groups, trainer, intervention content, home practice, video, the in-class 'buddy', and newsletter. Surveys will be administered before and after each session. The survey before each session will ask about the previous group they attended, and the survey administered after each session will assess satisfaction about that class.

Because acceptability and feasibility are the primary outcomes of the study, specific benchmarks were identified and approved by NCCIH to determine acceptability and feasibility. These are listed in the table below.

Table 2. Acceptability and Feasibility Benchmarks and Assessments

Aspects of Acceptability being Measured (adapted from Sekhon, et al (2017)[49]	Definition	Benchmark
Burden	Discontinuation/non-attendance	< 20% of TCQ and the sham qigong condition will drop out at 3 months follow up
Ethical Consequences	Any side effects with intervention	< 10% of participants will report any physical soreness or difficulties in doing qigong
Experience	Participant's experience and satisfaction	>80% qigong participants will perceive intervention positively >80% qigong participants will rate it very satisfactory or satisfactory
Affective Attitudes	Participants attitudes toward the intervention	>80% of participant in qigong condition will report positive attitudes about it (very good/good)
Opportunity Costs	Adherence and participation	Participants in both qigong and sham conditions will attend at least 75% of all sessions. Participants in the qigong condition will adhere to home practice at least 75% of the time expected (i.e., 112 out of 150 minutes/week)
Intentions	Willingness to participate	>80% qigong participants would be willing to participate again >80% qigong participants intend to continue qigong practice
Aspects of Feasibility being Measured (adapted from Bowen, et al., 2009 [50]	Definition	Benchmark
Demand	Likelihood that intervention will be used	>80% of qigong participants will report any qigong practice in the past week
Implementation	Can the intervention be implemented in a setting, often a real-world setting	Trainers will execute intervention >80% of the time >80% of trainers will rate resources needed to implement as very good/good

		>80% of trainers will report positive effects on population
Practicality	Extent to which an intervention can be delivered given the limited resources	>80% of trainers will report participant's ability to do the intervention as very good/good
Integration	Extent to which the intervention fits the system	>80% of trainers will perceive intervention fits the clinic infrastructure as very good/good >80% of trainers perceive the sustainability of the intervention as very good/good

6. STUDY PROCEDURES

Table 2. Measures and time of administration

Assessments	# of items/alpha	Screen	Baseline	Weekly/During Intervention	Post Intervention	3 month Follow up
Eligibility						
Age, HIV status (self-report/lab test)		X				
Any mind-body practice in past 12 months		X				
GAIN Cognitive Impairment	6-items	X				
Can stand up for 10 min		X				
Demographics and Covariates[85,86]			X			
HIV related stigma	6-items/ α= .75					
Social Support Scale						
DAST			X		X	X
AUDIT			X		X	X
Psychological Symptoms[87,88]						
Depression Anxiety & Stress Scale (DASS-21)	21 items/		X		X	X
Physical Symptoms[89,90]						
The Revised Sign & Symptom Check-List for HIV (Holzemer)	45 items; α=.71- .91		X		X	X
HIV-related Fatigue Scale (MAF)			X		X	X
Adherence[91]						
5-item Adherence questions MMAS-8			X		X	X
Viral load (from participants)			X		X	X
Feasibility						
# approached (if face-to-face)		X			X	
# screened		X			X	
# eligible		X			X	
# consented and enrolled		X			X	

# refused to participate Reasons for refusal # randomized into study % attended TCQ and control sessions % completed home practice % completed FU assessments		X X X		 X X	X X X X	 X
Acceptability Satisfaction surveys per session Satisfaction with adherence strategies (weekly calls, buddy system, etc)				X	X	
Feasibility of implementation in clinic setting (trainers)					X	
Intervention Fidelity Meditative Movement Inventory (participants) Intervention Fidelity Checklist	9 items; α = .86-.90			 X	X	

6.2 Description of Evaluations

6.2.1 Screening Evaluation and Process

These evaluations occur to determine if the candidate is eligible for the study.

Screening

A brief screening tool will be used to determine eligibility. It will include the following items:

- How old are you? (*must be 50 or over)*
- Are you HIV positive? (*must be positive)*
- Have you regularly participated (weekly for 3 months in the last 12 months) in any mind-body or alternative forms of exercise such as yoga, tai chi, qigong, or meditation in the last 12 months? *(must answer no)*
- They must pass the GAIN Cognitive Impairment Scale (based on scoring instructions) to determine if they are able to go through the consenting process and trial
- Can you stand for more than 10 minutes at a time? (answer must be yes)
- Do you have reliable internet access?

Research staff will be screening persons over the phone. During the screening process, all persons screened will not provide their names. They will be given a screening ID number and, if found eligible, the interviewer will ask for a first name only, phone number, and will schedule the person for a baseline assessment during which they will be consented and enrolled into the study. People screened and found eligible will be scheduled for a baseline assessment within 2 weeks of the screening. Appointments will be entered into the study google calendar. No names will be used to set the appointments in the calendar. Only screening ID numbers will used to hold appointment times. If found ineligible, their screener form will be kept in a folder in a locked filing cabinet (see Appendix for the Screener form and script).

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

The enrollment date is the date of the baseline assessment. At this assessment, the participant will be consented, complete all baseline assessments, and then randomized into one of three conditions. Assessments will be administered using RedCAP.

Baseline Assessment

Research staff will call all participants scheduled for a baseline assessment the day before the assessment to confirm attendance. All assessments are done via phone due to Covid restrictions. Assessors should have:

- Participant study folder labeled with assigned PID number
- Baseline checklist
- Informed Consent Form
- Monetary incentive with log form (if paying participants at the time of interview)
- List of computer-generated randomized group assignments (Only Research coordinator will provide to assessors)

The participant study folder should also include the adverse event form, follow up visit checklist, and study completion forms for future use as applicable.

Consenting Procedure. The baseline assessment begins with the consenting process. The research interviewer will be well-trained on the consenting process as well as the baseline measures. The interviewer will provide the participant with the informed consent form to read, but the interviewer will also explain the purpose of the study and will summarize the main points (e.g., procedures to expect; confidentiality will be maintained; they can stop participation at any time; participation will not affect treatment at Borinquen or Pridelines (if recruited from clinics); incentives will be provided, and any risks and benefits to participation). Consent forms will be available in English or Spanish. The Spanish consent forms will be back translated. At the end of the consenting process, the interviewers will ask participants if they have any questions. All consents will be verbal consent and done via the phone. Forms must be signed by the interviewer (as a witness) and will be stored separate from any other data or identifying information in a locked file cabinet in the FIU midtown research office which is locked nightly.

Once the participant signs the consent form, the research assistant sends participant a Qualtrics link to attach a photo of their most recent lab report or medication bottle (this is to confirm status), completes the locator form with the participant, and then begins the interviewer-administered RedCAP survey. The photos will be stored in Qualtrics secure server.

The Locator Form is used to help remind participants about upcoming groups, to assess acceptability via phone calls, and schedule participants for their follow up appointments. The locator form will be part of the baseline assessment and administered using RedCAP.

Baseline Measures. The following are all the baseline measures by domains that will be administered via RedCAP (see the Appendix for detailed scale items):

- Demographics
- Covariates (HIV stigma, social support, alcohol use, drug use)
- Psychological symptoms (depression, anxiety, general distress)
- Physical symptoms (HIV symptoms scale, HIV fatigue scale)

Randomization

Once the baseline assessment is complete, each participant will be assigned by the research coordinator to one of three conditions. A randomization scheme will be developed in SAS, generating group assignments. Randomized group assignments will then be in the format of a list kept by the research coordinator. After each baseline assessment, the research coordinator will look at the randomization list and assign the participant to the next group assignment on the list. Only the research coordinator will know the group assignment. Randomization will be tested after baseline assessments are all complete by comparing demographics across conditions.

6.2.3 Blinding

The participants will be blind to their condition, except for the group that receives the standard of care (which is no group). The study will be promoted as a "Gentle Empowering Movement" program about wellness, or The G.E.M. Study. Those in the sham qigong intervention will not be able to tell if they are in the intervention or in the control group. The research interviewer will also be blind to group assignment.

6.2.4 Follow-up Visits

There will be 2 follow-up visits: at 2 weeks post intervention and at 3-month post intervention. One week after a cohort has ended, research staff will begin to schedule the 2 week FU assessments. These assessments are on RedCAP and will also include some acceptability measures. Interviewers should begin the 2 week follow up by going over the locator form and confirm if information is still accurate. Then, interviewer should administer the RedCAP survey via phone. At the end of the interview, each participant will set up a time to come to the office to pick up their incentive (NOTE: Prior to the 2 week follow up assessments, the research coordinator confirms whether participant attended more than 75% of the group sessions or not in order to determine the incentive level).

For the **2-week post intervention**, the following will be assessed:

- Covariates (HIV stigma, social support, alcohol use, drug use)
- Psychological symptoms (depression, anxiety, general distress)
- Physical symptoms (HIV symptoms scale, HIV fatigue scale)
- Acceptability Measures
- Feasibility Measures

6.2.5 Completion/Final Evaluation

- For the **3 months follow up** assessment:
- Covariates (HIV stigma, social support, alcohol use, drug use)
- Psychological symptoms (depression, anxiety, general distress)
- Physical symptoms (HIV symptoms scale, HIV fatigue scale)
- Acceptability Measures
- Feasibility Measures

At the 3 month follow up, interviewers will administer the survey questions on RedCAP. Once the appropriate level of incentives is provided to participant, the interviewer will complete the Study Completion Form. This form will be placed in the participant study folder. If the participant completing the study is from either of the control conditions, they will be offered the TCQ intervention.

Weekly assessments

In addition, acceptability and feasibility will be assessed every week either in person regarding each session or via the weekly calls. Weekly calls will ask about adherence to home practice; and acceptability of home practice, and satisfaction with the intervention. A brief satisfaction survey will be administered to each participant after each group session.

7. SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

See below

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

All safety parameters will be assessed, recorded, and analyzed by the research team through weekly meetings between the PI and staff; monthly investigator meetings; and the DSMB meetings every 6 months. Safety issues will be part of every DSMB agenda. There will be a protocol in place for addressing safety issues (See DSMB Plan).

7.3 Adverse Events and Serious Adverse Events

Serious Adverse Events (SAE): An experience occurring during study participation that may involve imminent danger to the participant or others. For this study, SAEs include the following events that occur after entrance into the study:

- Death, serious injury, a life-threatening experience, drug overdose, or suicide attempt
- Hospitalization or prolongation of hospitalization (including medical or psychiatric hospitalization)
- Persistent or significant disability or incapacity
- An unanticipated event that, in the PI's judgement, represents a significant hazard or potentially serious harm to research participants or others.

Adverse Events (AE): An untoward experience occurring during study participation that does not rise to the level of an SAE. For this study, specific AEs include the following events that occur after entrance into the study:

- Increased substance use, medical problems, emotional problems, or victimization

- Significant physical or emotional pain, homicidal thoughts, or suicidal thoughts
- Breach of confidentiality
- An unanticipated event that, in the PI's judgement, represents a non-serious adverse event that nonetheless resulted in increased risk to research participants or others

7.4 Reporting Procedures

See below

7.5 Follow-up for Adverse Events and Safety Monitoring

All research and intervention staff will be trained on the definitions of SAEs and AEs and its reporting procedures. Staff will notify the PI immediately after the occurrence of an SAE or AE. Weekly meetings between staff and investigators will have SAEs and AEs as an agenda item. All SAEs and AEs will be reviewed by the PI for severity and whether it is attributed to the intervention. SAEs will be reported to NCCIH and to the FIU IRB within 24 hours, with a written report within 48 hours. For all SAE's, the Event Report Form will be completed by the PI. The research coordinator will keep a log of all adverse events, unanticipated problems, and protocol deviations on the Adverse Event Log Form. All AEs that occur during the study will be documented and reported by the investigators to NCCIH and the FIU IRB at the time of their continuing annual reviews. Participants that suffer an SAE or AE due to the study and still want to continue participating in the study, may do so if the PI agrees that continued participation is safe.

8. INTERVENTION DISCONTINUATION

If a review of adverse events shows significant harms or if there is any breach of confidentiality, the study will be stopped, and a review of existing procedures will be conducted.

9. STATISTICAL CONSIDERATIONS

9.1. Data Analysis Plan

Randomization. 48 participants will be randomized into one of three treatment groups each with 24 participants. A stratified block randomization scheme will be used. Stratification by language preference will ensure even distribution across groups, if needed. Four blocks of 18 will facilitate timing of 'cohorts' to enhance logistics of treatment implementation. Randomization will be done through the Plan Procedure in SAS®, using a random seed. Upon enrollment, the recruiter will assign the participant to the treatment group according to the sheet.

Blinding. For logistical reasons the study will be partially single blinded. Those randomized to the TCQ and sham conditions will be blinded to which group they were assigned, whereas the standard of care control group will know they are assigned to the control condition based on format and content of the condition. Data collectors will also be blinded to group assignment at baseline. Only the PI and the research coordinator will know group assignment.

Data Analysis of Aims 2 and 3. Data obtained through RedCAP software will be imported into SAS® version 9.4. Instruments will be coded according to their respective scoring

instructions. Unless specified by the instrument, missing items will be imputed based on averaging values within the instrument for a given individual, if no more than 15% of items are missing. If more than 15% of items for an individual are missing, that instrument will be set to missing for the individual.

This is a pilot study to assess feasibility and acceptability of an intervention adapted to a different population. As such, analyses will be primarily descriptive; hypotheses will not be assessed through statistical significance, in accordance with recommendations for analysis of pilot studies[99]. Feasibility, acceptability, and clinical (physical and psychological) outcomes will be described through proportions, means, and changes over time. 95% Confidence Intervals (CI) will be calculated to estimate precision. Regarding clinical outcomes, we will focus on estimating treatment effect sizes and respective 95%CI, which will help to determine the sample size needed for a larger scale RCT. Baseline demographic and clinical characteristics, including stigma, social support, and depressive symptoms, will be summarized by treatment condition, and compared for even distribution of characteristics to assess effectiveness of the randomization.

Aim 2: Evaluate the acceptability of the TCQ intervention protocol for older PWH every week, 2-week post-intervention, and 3 months follow up (n = 48).

Aim 3: Evaluate the feasibility of the TCQ intervention protocol for older PWH every week, 2-week post-intervention, and 3 month follow up (n = 48).

Similar data analysis will be conducted for both acceptability and feasibility. To address acceptability among participants, we will use data from the satisfaction survey which will be administered weekly during the intervention and at post-intervention. Individual items from the survey such as percent sessions attended, frequency of home practice sessions, average length of home practice sessions, and questions on opinion of the intervention sessions, home practice sessions, and video, will be plotted over time to examine variability of acceptability measures over time. Next, participant's average score over the intervention period will be averaged. These averages, as well as the items from the post-intervention satisfaction survey will be categorized into acceptable, borderline acceptable, or not acceptable. Cutoffs will be based on the approved benchmarks. From these data we will determine the proportion of participants who rate the intervention as acceptable. To estimate precision, 95%CI will be calculated using Wilson's score method, which uses asymptotic variance and is appropriate for small sample sizes[100.] If the proportion of participants who rate the intervention as acceptable is 80% or greater, we will consider the intervention acceptable. If it is not, we will evaluate the width of the confidence interval to determine variability, as well as look specifically at each item to determine what aspects are deemed unacceptable. Feasibility will be measured by assessing the study retention rate, whether it is feasible for participants to do the movements, and whether it is feasible to deliver the intervention remotely.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Research staff (research coordinator, graduate assistants) will conduct interviews using REDCap software and computer-assisted personal interviewing (CAPI) techniques via phone. All measures are in the Appendix.

10.2 Data Management

Any data that needs to be entered or downloaded, acceptability measures and session attendance information will be done at the FIU research offices and under the supervision of Dr. Ibañez and the research coordinator. Data collected at the three main assessment timepoints (baseline, 2-week post intervention, 3-month follow up) does not require data entry since it is collected via laptops using RedCap software. The staff handling project data will also be fully trained in confidentiality procedures and safeguards. All staff will be required to complete CITI Human Subjects, and Good Clinical Practice training. Interview data will be stored on encrypted drives, password protected computers. Weekly, all data will be downloaded onto the FIU Sharepoint drive for added protection and deleted from the individual laptop, if applicable. Quantitative data will be stored in REDCap and in the study's FIU Sharepoint folder.

10.3 Quality Assurance

10.3.1 Training

The staff handling project data will be fully trained in confidentiality procedures and safeguards. All staff will be required to complete CITI Human Subjects and Good Clinical Practice training.

10.3.3 Metrics

n/a

10.3.4 Protocol Deviations

The PI will meet with the research coordinator weekly to discuss any issues and/or potential protocol deviations. In addition, the PI or the research coordinator will randomly select participant files to review consent forms and relevant data for deviations. Any deviations will be immediately reported to the research team, IRB, and NCCIH.

10.3.5 Monitoring

Consent forms and other data reviews will be done by the PI at least once a week, or as needed. Intervention fidelity assessment will also be done by Dr. Larkey at least once a month, or as needed.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent documents and any subsequent modifications will be reviewed and approved by the FIU IRB.

11.2 Informed Consent Forms

A verbal consent will be obtained from each participant. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. Participants who are not able to provide their consent will be excluded from the study. Consenting will occur at the baseline assessment time point but before initiating the assessment.

11.3 Participant Confidentiality

Any data, forms, reports, video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB or NCCIH. All data will be stored in the FIU research office or on FIU SharePoint drive. Consent forms will be stored in a locked filing cabinet in the FIU research office space which is locked nightly but separate from the data. Data collected via laptops will be encrypted and stored on a cloud server (i.e., SharePoint at FIU).

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, or the NCCIH as part of their duties to ensure that research participants are protected.

12. COMMITTEES

There is a Data Safety Monitoring Board (DSMB) established for this clinical trial. It will meet every 6 months to review the progress of the clinical trial; and determine if discontinuation or continuation is justified.

13. PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will be made available for review by all investigators, and with NCCIH as needed or requested.