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Design and methods of the Gentle Cardiac Rehabilitation Study – A behavioral study of tai chi exercise for patients not attending cardiac rehabilitation

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Abstract

Introduction—Cardiac rehabilitation (CR) programs reduce overall and cardiovascular mortality in patients with a history of acute coronary events or revascularization procedures, but only 30 % of patients enroll in CR and attrition rates reach up to 60 %. Tai chi, a mind-body practice based on light/moderate aerobic exercise accompanied by meditative components could be a possible exercise option for patients who do not attend CR.

Methods/Design—Sixty patients will be randomized to a “LITE ” condition (one tai chi session twice weekly for 12 weeks) or to a “PLUS” condition (one tai chi session 3 times weekly for 12 weeks, followed by maintenance classes 1–2 times weekly for an additional 12 weeks). Measurements will be conducted at baseline, 3-, 6-, and 9 months after enrollment. The primary outcome is to determine the feasibility, acceptability and safety of each dose. Secondary outcomes include estimates of effect size of each dose on accelerometry-assessed physical activity; the proportion of patients meeting current recommendations for physical activity; and measures of fitness, quality of life, body weight, and sleep. In addition, we will collect exploratory information on possible mediators (exercise self-efficacy, perceived social support, resilience, mindfulness, and depression).

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Conflicts of interest

Dr. Wayne is the founder and sole owner of the Tree of Life Tai Chi Center. Dr. Wayne’s conflict of interests were reviewed and are managed by the Brigham and Women’s Hospital and Partners Healthcare in accordance with their conflict of interest policies.

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Conclusions—Findings from this pilot study will provide preliminary indications about the usefulness of tai chi as an exercise option for patients not attending traditional CR programs. Results will also shed light on the possible mechanisms by which tai chi practice may improve overall physical activity among patients with atherosclerotic coronary heart disease.

Keywords

Tai chi; physical activity; fitness; cardiovascular prevention; mindfulness

1. INTRODUCTION

Cardiac rehabilitation (CR) programs are exercise-based secondary prevention programs designed to help patients with a history of coronary events and coronary revascularization return to normal life and stay healthy. (1, 2) In addition to reducing overall and cardiovascular mortality, (3–5) CR improves important modifiable coronary risk factors such as physical inactivity, overweight and high serum lipid levels. (6, 7) Longitudinal studies have shown that each 1-MET improvement in fitness is associated with a nearly 20 % reduction in cardiovascular mortality, thus supporting the notion that even modest increases in fitness play an important role in the secondary prevention of future cardiac events. (8, 9) Given these significant benefits, all evidence-based guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA) give a Class I recommendation for referral to CR in patients with recent coronary events or revascularization procedures. (10, 11) Furthermore, CR is now considered essential not only for patients recovering from acute events, but also for the secondary prevention of future cardiac events among all patients with coronary heart disease (CHD). (12) Unfortunately, less than 30 % of eligible patients in the United States enroll in CR (2) and attrition during CR programs may reach up to 60%. (13) Barriers to participation and completion of CR include older age, fear or dislike of exercise, lack of transportation, depression, and high co-pays. (14, 15) These figures have prompted the AHA to call for the development of alternative programs tailored to the needs of patients not attending presently available CR programs. (2)

Tai chi is a mind-body intervention integrating low-to-moderate aerobic exercise with deep breathing and relaxation exercises. Prior studies conducted by our group and others suggest that tai chi improves aerobic capacity in older sedentary adults (16) and improves exercise self-efficacy, quality of life and mood in patients with heart failure. (17)

Several characteristics of tai chi also indicate that tai chi training may overcome multiple barriers to traditional CR. (18–20) First, it can be practiced safely by elderly and deconditioned individuals. (21–23) Tai chi gentle exercise training may also be more attractive to women, who typically dislike the exercise training offered in CRs. (24) Second, since tai chi practice does not require any particular equipment, it can be practiced at any time and place, thus facilitating adherence. Third, since tai chi is usually taught in groups and is safe even in high-risk patients, (20) it can be offered in community centers, (25–27) thus reducing transportation barriers. Finally, tai chi has the potential to impact depression and lack of social support, (28) two important determinants of the overall prognosis of these patients that are often inadequately addressed in traditional CR. (24, 29–33)

The potential for tai chi to serve as an exercise option for patients who are unable or unwilling to attend traditional CRs, however, has received little attention. The primary objective of this study is to estimate the feasibility, acceptability and safety of two different doses of a tai chi intervention: a dose previously used in large studies of patients with heart failure (“LITE” group) and a dose matching the recommended frequency and duration of exercise classes in current CR (“PLUS” group). We will also obtain estimates of effect sizes of each dose on overall physical activity and on the proportion of patients achieving current recommendations for physical activity, in addition to its possible effects on cardiac fitness; quality of life; body weight; and sleep. In addition, we will collect information on the posited mediators – i.e., exercise self-efficacy, perceived social support, resilience, mindfulness and depression – of the possible effect of tai chi on overall physical activity.

2. MATERIALS AND METHODS

2.1. Study design

This is a pilot, phase 2, randomized behavioral clinical trial designed to determine the optimal dose of a tai chi exercise intervention for patients not attending traditional CR.

2.2. Setting

Study assessments will be conducted at the Centers for Behavioral and Preventive Medicine at the Miriam Hospital in Providence, RI. Ta Chi sessions will be held in a comfortable classroom at the Center for Cardiac Fitness/Cardiac Rehabilitation at the Miriam Hospital, where regular exercise programs are safely conducted for patients with cardiovascular disease.

2.3. Population

This study will enroll 60 patients. *Inclusion criteria* are as follows: 1) Previous admission for myocardial infarction, angina, or revascularization procedures (coronary bypass/coronary angioplasty); 2) Ability to understand and speak English; 3) Age ≥ 21 ; 4) Being physically inactive; 5) Ability to understand the study procedures and willingness to commit to the demands of the study protocol. *Exclusion criteria* include: 1) Inability or unwillingness to give informed consent; 2) Planning to move out of the area within the study period; 3) Unstable angina; 4) Blood pressure $>200/110$ or symptomatic orthostatic blood pressure decrease >20 mmHg; 5) Uncontrolled atrial or ventricular arrhythmias; 6) 3rd degree AV block; 7) Pericarditis or myocarditis; 8) Recent embolism/thrombophlebitis; 9) Abnormal stress test without study cardiologist’s clearance; 10) Medical conditions likely to limit lifespan; 11) New York Heart Association (NYHA) functional class IV; 12) Signs of cognitive impairment (Blessed Orientation Memory and Concentration test (BOMC) >10); 13) Orthopedic problems prohibiting tai chi practice; 14) Ongoing tai chi or other mind-body training; 15) Current enrollment in CR; 16) Severe depression (Hospital Anxiety And Depression Scale – (HADS) scores >14); and 17) Current drug or alcohol use or dependence that, in the opinion of the principal investigator, would interfere with adherence to study requirements. For safety reasons, exclusion criteria for this study include conditions that are considered a contraindication to the participation in traditional CR (i.e., unstable angina, NYHA class III, embolism, uncontrolled arrhythmias). Patients in NYHA functional

class III will be considered eligible since prior studies have shown that tai chi practice is safe in these patients. (17)

2.4. Recruitment

Since tai chi training is delivered in a class format we will have three cycles of intense recruitment efforts in order to enroll about 20 participants per recruitment cycle. Recruitment approaches will include: 1) Referrals from the CR Center at The Miriam Hospital. Personnel from the Center routinely contact all candidates to cardiac rehabilitation to assess their interest in CR. An invitation letter signed by the Principal Investigator and succinctly describing the study procedures will be sent to all patients who have declined CR participation; 2) Flyers placed in cardiology practices and in local public venues (e.g., libraries, supermarkets); 3) On-line resources (e.g., The Miriam Hospital Intranet; Craig's List).

2.5. Screening and consent procedures

Interest assessment phone call—Interested individuals will contact the study staff using a dedicated phone number that will be included in all recruitment materials. The Research Assistant (RA) will contact participants approximately 2 weeks after the invitation letter is mailed unless the participant calls the study dedicated number declining recruitment into the study. This “opt-out” procedure has been successfully used and approved by the Institutional Review Board for other studies conducted at our institution. Patients signaling interest will be invited for an in-person screening visit.

Screening visit—Once the potential participant has confirmed interest in participating, he/she will receive a consent form to read discussing the purpose of the study, its risks and benefits and clearly stating that he/she can withdraw at any time without any adverse consequences. The RA will obtain full informed consent in person in a private room at the Centers for Behavioral and Preventive Medicine after a thorough explanation of the study design, of the study intervention, and of the risks and benefits involved. Since the study requires access to protected health information, a HIPAA authorization will be required from each individual in order to access his or her medical records. Signed informed consent forms and HIPAA forms will be kept in locked filing cabinets separate from all data. Participants will receive a copy of the consent and HIPAA document for their records. Once informed consent procedures are completed, participants will undergo a battery of screening assessments (see *study assessments* for details) and enter a 2 weeks run-in period, in which subjects will wear accelerometers (one week) for the assessment of baseline level of physical activity and undergo a baseline symptom limited exercise stress test for baseline evaluation of cardiac risk as recommended by the American College of Sports Medicine (34) and for the assessment of baseline fitness as well as heart rate and rhythm, signs and symptoms, and ST-segment changes.(35) Metabolic stress tests will be conducted by trained technicians following AHA/ACC guidelines. (36, 37) The study cardiologist will review the results of the exercise stress tests as well as other eligibility criteria and give the final clearance for the participant's enrollment in the study.

2.6. Randomization

Once all screening assessments are completed and eligibility for the study is confirmed, patients ($n = 60$) will be randomly assigned to the two different doses of the intervention (1:1 ratio). The randomization schedule will be generated in “R” (cran.us.r-project.org) and is based on a permuted block randomization procedure with small, random-sized blocks. The allocation table will be uploaded to an Access database. Once all assessments are completed, the RA will assign each participant to either dose by clicking the “randomize” button.

2.7. Study interventions

This is a behavioral, dose-ranging study. Similar to phase 2 pharmacological trials, the purpose of behavioral dose-ranging studies is to determine the feasibility and safety of a certain dose of an intervention. The concept of “intervention dose” is based on the definition proposed by Manojlovich et al., (38) where an intervention “dose” includes two components: the intervention *amount* (total number of sessions multiplied by the length of each session); and the intervention *duration* (the period of time over which patients are exposed to the intervention). Participants will be randomized either to a “LITE” condition or to a “PLUS” condition (Table 1). Regardless of dose assignment, the content of the intervention will be identical in the two groups and will be manualized prior to the start of the study.

Rationale for proposed doses—The intervention dose for the “LITE” is the one used in a previous study of tai chi conducted by our group among patients with heart failure. (17) That study had excellent retention rates and the tai chi intervention improved disease-specific quality of life, exercise self-efficacy, mood and self-reported physical activity. It is unclear, however, whether its intervention duration (12 weeks) is sufficient to maintain long-term changes in physical activity over time. The intervention dose for the “PLUS” condition (3 sessions/week for 12 weeks; 2 sessions/week for another 4 weeks; 1 session/other week for another 8 weeks) is based on AHA recommendations for the duration and frequency of exercise training in CR (39) as well as on data suggesting that a longer duration of the tai chi intervention is associated with greater effect sizes on aerobic capacity (16) and on overall physical activity. (40)

Tai chi sessions will be held in one of the classrooms situated in CR building where exercise interventions are regularly conducted in similar populations as part of the regular CR program at the Miriam Hospital. For each cohort, we will offer 3 tai chi classes per week (at different times to accommodate different schedule preferences), each lasting 60 minutes, during weeks 1–12. Patients in the LITE group will be invited to come twice a week, and patients in the PLUS group will be invited to attend 3 times a week. Given that the *content* of each session is identical between the two conditions there is no danger of contamination. Participants in the PLUS group will continue with the planned schedule (Table 2) for an additional 12 weeks (week 13–24). In addition to in-class tai chi practice, participants in both groups will be encouraged to practice at home at least three times a week using a DVD containing the tai chi exercises taught in class that will be given to each patient at the beginning of the study. Individual practice will be monitored using a self-report diary.

Protocol—A group of experts in tai chi (including a senior tai chi instructor and three additional tai chi instructors), cardiac rehabilitation, cardiovascular prevention, mind-body interventions, and exercise physiology revised the protocol used by our group in previous studies conducted among patients with heart failure and chronic obstructive lung disease (17, 41). Based on the recommendations of our experts' panel, the senior tai chi instructor (with input from the tai chi instructors) revised the sequence, body position and pace of the exercises with particular attention to slowly increasing aerobic intensity over time. An outline of the tai chi intervention to be used in this study is shown in Table 2.

Tai Chi instructors—We will use three certified tai chi instructors trained with the same Yang family style and lineage, each with at minimum of 10+ years of teaching experience. Instructors' training will include a detailed review of each element of the study protocol and of standard operating procedures, a discussion of treatment fidelity procedures as well as training in Protection of Human Subjects and cardiopulmonary resuscitation.

2.9. Safety considerations

Overall, this is a low risk study. Tai chi has been shown to be safe in older and deconditioned individuals and in patients with coronary heart disease. (23, 42) No tai chi related side effects have been reported even among high-risk patients (i.e., those recovering from coronary bypass surgery (43) or with heart failure and ejection fraction <40% and NYHA class up to III). (17, 40) The most common adverse effect of tai chi practice is muscle soreness (usually mild and lasting only a few days). (23) Rare effects include dizziness, faintness, fatigue or falls. Tai chi may, as any other physical exercise, cause shortness of breath, chest pain, or cardiac arrhythmias. Such adverse effects are serious, but they are very rare. To minimize these risks we will apply rigorous eligibility criteria and screen patients carefully; we will also supervise patients during classes and instruct them to recognize untoward signs and symptoms during individual practice at home.

Besides the exclusion criteria commonly adopted for enrollment in CRs, (1) we also included the exclusion criteria used in a previous study of tai chi for patients with heart failure. (17) All patients will undergo a symptom-limited stress test prior to the start of the intervention according to current guidelines for vigorous exercise training in persons with known cardiovascular disease (even though Tai Chi does not involve vigorous exercise). (36) We will require a negative stress test and clearance from a senior cardiologist. The exercise intervention will follow nationally recognized guidelines for initiating exercise programs in sedentary populations and we will adopt all safety measures recommended for the practice of physical activity in patients with coronary heart disease. (11, 44) The Physical Activity Readiness questionnaire (45) will be used at the beginning of each class to determine whether the participant has experienced chest pain, shortness of breath or dizziness, or has suffered joint or muscle injury since the last class. (46) During classes, the instructors will actively inquire for these symptoms. Should a participant experience any of these symptoms *during class*, the activity will be immediately stopped; the participant will be referred to his/her primary care provider and will be asked to refrain from any physical activity until he/she receive a complete medical evaluation. If symptoms are severe the patient will be escorted to Emergency Department for immediate treatment and the study

cardiologist will be paged for consultation as well. Instructors will be trained in cardiopulmonary resuscitation and an automated external defibrillator will be available in the classroom in the rare case of a cardiac event. For the *individual home practice*, participants will be encouraged to increase exercise gradually. Should a participant report adverse symptoms, he/she will be referred to his/her provider and will be asked to refrain from any physical activity until he/she receives a medical evaluation. Instructors will immediately notify the RA and the Principal Investigator about any reported adverse events. In addition, patients will be instructed to notify immediately the RA if any symptom occurred during tai chi practice at home. The RA will also contact each patient weekly by phone and actively inquire about possible symptoms.

2.8. Retention plan

Participants will be asked to provide a home and a mobile phone number as well as an email address. The study tracking system will identify participants due for a visit, and mail/email reminders or phone messages will be sent to remind participants of their follow-up appointments. We will also maintain contact by sending birthday and holiday cards. Participants who wish to drop out of the study will be queried as to their reasons for doing so and every attempt will be made to address their concerns. In addition, we will provide monetary compensation for participation in this study. Participants will receive \$ 40 compensation for each completed study assessment.

2.9. Study Assessments

Assessments (Table 3) will be performed at baseline, 3-, 6- and 9 months after enrollment. Visits will last about 45 minutes and will include the completion of study questionnaires, direct measurements of weight and height, and accelerometers fitting. During a separate visit participants will undergo an exercise stress test at baseline and at the completion of the intervention for assessment of changes in fitness. Surveys will be completed via in-person interviews at each data collection point. Research Electronic Data capture (REDCAP) technology will be used to for direct data entry in electronic surveys during the interviews (thus avoiding the use of traditional paper forms); clinical information will be collected from electronic medical records.

2.10. Screening Assessments

These following assessments are needed to determine if the candidate is eligible for the study.

Physical inactivity—The 7 days Physical Activity Recall (PAR) Questionnaire (47) will be used to determine physical activity status. Patients will be considered physically inactive if they do not meet current recommendation for physical activity, (48–51) i.e. if they participate in <60 minutes of moderate or <30 minutes of vigorous physical activity per week.

Cognitive impairment—The BOMC test (52) will be used to screen patients at baseline for cognitive impairment. Patients scoring 10 will be excluded from the study.

Blood pressure—Blood pressure will be measured using a Dinamap XL automated blood pressure monitor according to current recommendations. (53) Patients with blood pressure > 200/110 or symptomatic orthostatic blood pressure decrease > 20mmHg will be excluded from the study and referred to their primary care provider for follow-up.

Depression—Depression will be assessed using the HADS, (54) a self-administered questionnaire with two sub-scales (0–21) measuring anxiety and depression, with higher scores indicating greater psychological morbidity. The HADS has been validated in cardiac patients (55, 56) and has shown a good correlation with commonly used measures of depression (57). Scores will be calculated immediately after completion. Patients with depression scores indicating severe distress (>14) will be excluded from the study and referred to their primary care provider.

Stress test—All patients will undergo a baseline symptom limited exercise stress test for baseline evaluation of cardiac risk (34) and for the assessment of baseline fitness as well as heart rate and rhythm, signs and symptoms, and ST-segment changes. (35) Stress tests will be conducted using the standard Bruce protocol (58) following current guidelines. (36, 37) The study cardiologist will review the test results and give the final clearance for the participant's enrollment in the study.

At the screening interview we will also gather information from all participants (including those not confirmed eligible) about reasons for not attending CR using a standardized questionnaire as in Dunlay et al. (59) and about barriers to participation in the study (Exercise Benefits and Barriers Scale). (60)

2.11. Primary outcomes

Feasibility—Indicators of feasibility will include retention rates, class attendance, and individual home tai chi practice. *Attendance* at classes will be recorded at each session using a tai chi attendance log. *Individual tai chi practice* at home will be recorded using a self-reported log to be kept daily. Logs will be collected weekly during classes.

Acceptability—We will use both quantitative and qualitative methods to assess acceptability. We will ask participants to rate their enjoyment of the intervention on a visual scale from 0 to 4. (17) At the completion of the intervention patients will be invited to participate in an individual phone interview and to attend one focus group. Interviews will allow us to use pre-designed forms and scales to collect semi-quantitative data; focus groups will allow us to ask open questions and learn directly from our participants' experience. Semi-structured interviews will last 30 minutes and will be conducted over the phone. We will hold 1–2 focus groups per cohort (4–6 focus groups in total). Key qualitative domains will include: a) Patients' experience in the study (i.e., what participants liked and disliked about the intervention; preference for frequency or duration of classes; reasons for attending or missing classes; instructors; barriers to individual home practice; acceptability and barriers to a longer intervention (24 weeks vs. 12 weeks)); recruitment messages/tools; strategies to increase retention and adherence; burden and usefulness of study forms; b) Whether, in the participant's opinion, the tai chi exercise intervention overcame barriers to

CR and improved physical activity as well as each of the posited mediators (i.e., exercise self-efficacy, perceived social support, and depression). One focus group will be conducted separately with CR physicians and nurses to assess the providers' perspective on the study acceptability, feasibility, and ability to overcome barriers to CR.

Safety—We will collect information about tai chi side effects (at each session, using the Physical Activity Readiness questionnaire (45) as well as about the number of unplanned clinic visits and hospital readmissions at each data collection point. Information about hospital readmissions and unplanned cardiology clinic visits will be collected from study participants and from medical records.

2.12. Secondary outcomes

Physical activity will be measured using accelerometers (Actigraph, LLC, Fort Walton Beach, FL accelerometer model 7164 WAM). The Actigraph has the least variability and the highest overall reliability (61) and counts from treadmill walking and running (62, 63) have shown a good correlation with measured oxygen uptake. Patients will receive accelerometers at baseline and each follow-up visit to wear during the next 7 days, and will be instructed to return the accelerometer by mail using pre-stamped envelopes. The 7 days Physical Activity Recall (PAR) Questionnaire (47) will be used as a backup in case of mechanical failure of the Actigraph.

Fitness [Rate of oxygen uptake (VO₂) ml/Kg/min] will be measured at peak exercise using breath-by-breath expired gas analysis. Oxygen consumption in METs will also be calculated.

Weight and height will be measured using standardized procedures.

Sleep will be assessed the Pittsburgh Sleep Quality Index, (64) a 19 item self-report instrument designed to measure sleep quality and disturbance based on recall of sleep behaviors in the past month.

Quality of life will be measured using the Health Survey Short Form (SF-36). (65)

2.13. Posited mediators

We will gather exploratory information on possible mechanisms by which tai chi training may affect physical activity. This information will help us refine the theoretical framework for a future larger study. This is particularly relevant because the literature indicates that randomized trials of behavioral interventions based on solid theoretical models are more likely to be well designed and to have larger effect sizes than intervention not based on theory (66). We will collect information on possible mediators such as exercise self-efficacy, perceived social support, resilience and depression. In addition, since Tai Chi training is associated with meditative practices aimed at increasing present-moment awareness, we will gather information on mindfulness levels. *Exercise self-efficacy* will be measured using the Cardiac Exercise Self-Efficacy questionnaire (67).

Social support will be evaluated using the Multidimensional Scale of Perceived Social Support (68, 69) a 12-item, one-dimensional tool to measure how one perceives their social support system.

Resilience will be measured using the Brief Resilience Questionnaire, an instrument validated in cardiac patients. It was negatively related to anxiety, depression, negative affect, and physical symptoms when other resilience measures and optimism, social support, and Type D personality were controlled. (70)

Depression will be assessed using the HADS, (54) a self-administered questionnaire with two sub-scales (0–21) measuring anxiety and depression, with higher scores indicating greater psychological morbidity.

Mindfulness will be assessed using the Five Facets of Mindfulness questionnaire (short form) (71, 72) a 12-item questionnaire that measures the five identified components of mindfulness meditation: observing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.

2.14. Covariates and moderators

We will collect information about socio-demographics characteristics (age, sex, race/ethnicity, education, income, insurance status) using standard validated forms; medical history (coronary risk factors; type of coronary revascularization procedure; ejection fraction; New York Heart Association class; CHD severity; co-morbidities; and medications; all abstracted from medical records using standard abstraction forms validated in previous studies). Patients' *expectations regarding the intervention* will be assessed employing the expectancy and treatment credibility assessment from Borkovec and Nau. (73). Questions address patients' expectations about the helpfulness of a certain therapy, confidence in recommending the therapy to a friend, and overall credibility of the treatment (e.g. does the intervention make sense). (74)

2.15. Quality control

Treatment fidelity will be assessed according to the guidelines developed by the Treatment Fidelity Workgroup. (75) During the start-up period, auditor's checklists will be created to monitor fidelity to the intervention. A random selection (~10 %) of all sessions will be digitally recorded and recordings will be reviewed using the checklist. Optimal treatment fidelity would be evidenced by 100% of objectives met. If less than 85% of treatment-specific objectives are met, the auditor will remediate instructor's training as needed.

2.16. Blinding

This is a behavioral RCT and participants will not be blinded. Blinded personnel will include investigators, data entry and analysis personnel, and tai chi instructors. For practical reasons the RA cannot be blinded, however this individual will not be involved in data management or analysis.

2.17. Statistical analyses

Primary outcome: feasibility and acceptability—Descriptive statistics, plots of means and proportions at each time point, as well as t-tests (continuous variables) and chi-squared tests (proportions) will be used to compare retention rates, attendance, and individual home tai chi practice between the two doses of the intervention. We will assess differences between participants who are retained in the study or attend classes vs. those who are not retained or do not attend classes: we will use t-tests, Spearman correlation, and linear regression models to identify predictors of attendance and individual tai chi home practice; t-tests, chi-square tests, and logistic regression will be used to identify predictors of retention (i.e. gender, age, cardiac diagnosis, baseline fitness) at key time points, particularly end of intervention and last study follow-up. We will consider either dose feasible under the following conditions: a) If we achieve study retention rates of at least 80 % at the end of the study; if patients attend at least 70 % of the planned classes; and if patients report to have completed at least 70 % of the assigned home tai chi practice exercises. *Acceptability*. A dose will be considered acceptable if at least 80 % of participants will indicate grade 4 enjoyment ratings. (17)

Secondary Outcomes

Physical activity: We hypothesize that the high-dose group will have larger increases in physical activity over time compared to the low-dose group. Accelerometry measures will include number of valid days, wearing time, average counts/min, average counts/day, average minutes of moderate and vigorous physical activity (MVPA)/day, and average minutes of MVPA bouts per day (all continuous measures). To estimate mean between-dose differences in physical activity, we will use a longitudinal mixed effects regression model with subject specific intercept to account for repeat measures within individual over time. The model will simultaneously regress physical activity at follow-up ((3, 6, and 9 months) on baseline, dose group (high or low), time point (3, 6, and 9 months from enrollment, treated as a categorical variable to allow for non-linear trajectories), and their interaction. A statistically significant interaction indicates that between-group differences vary across time points. Analyses will adjust for baseline physical activity to account for possible regression to the mean. (76) Baseline variables that differ between groups and are predictive of physical activity will be included as covariates in the multivariate model. (77, 78) We will use a longitudinal regression model implemented with generalized estimating equations (GEE) with robust standard errors with the same set of predictors, to compare the proportion over time meeting current recommendations for physical exercise between groups. The other secondary outcomes – body weight, cardiac fitness, and sleep – are continuous variables. We will use similar mixed effects models (as described above) to estimate mean between-doses differences in these variables.

Exploratory analyses—We will use linear mixed modeling to preliminarily examine associations between tai chi, possible mediators, and physical activity. Since a formal mediation analysis is beyond the scope of this project, we will only examine whether associations are in the hypothesized direction (i.e. for perceived social support: we expect that tai chi training will be associated with change in social support; and change in social support will in turn be associated with changes in physical activity).

2.18. Qualitative Analyses

Data from focus groups and semi-structured phone interviews will be collected using audiotapes and observer/interviewer notes. Audio recordings of the phone interviews and focus groups will be reviewed and transcribed immediately after completion and then destroyed. We will use NVivo© qualitative data analysis software, QSR International Pty Ltd. Version 9, 2010 to import transcribed data, conduct thematic analyses, identify common themes in participants' responses, sort responses according to themes and summarize findings.

2.19. Sample size considerations

Since this is a treatment development study the proposed sample size was estimated based on practical considerations (i.e. time and costs). (79) We propose to enroll 60 patients in this study (30 per dose condition). We are aware that an increase in the intervention's dose may result in retention and adherence issues and greater effect sizes for the high-dose condition will be meaningless if we do not retain patients. We propose that, for each group, an 80 % retention rate at 9 months would be acceptable, while a retention rate lower than 55 % would not be acceptable. With the proposed sample size, we will have a power of 84 % for testing the null hypothesis that the retention rate is less than 55 % versus the alternative hypothesis that the retention rate is at least 80 % at a two-sided significance level of .05.

3. DISCUSSION

Tai chi is a traditional Chinese martial art consisting of gentle, slow body movements accompanied by meditation practices, deep breathing and relaxation exercises. (80, 81) Energy expenditure associated with tai chi practice varies between 1.5 and 4.6 metabolic equivalents (82–84) – a mild to moderate intensity of physical activity. The intensity of the exercise during tai chi training (percent of aerobic power utilized during exercise), however, can be adjusted by varying tai chi style, sessions' duration, and body position during practice (i.e., low squat vs. high squat) to meet the needs of different populations at all stages of health. (85) Two meta-analyses have indicated that tai chi effectively improves aerobic capacity (16, 86) and in addition, data from a rigorous multisite RCT conducted in outpatients with systolic heart failure found that patients participating in a 12-week tai chi training program had greater improvements in self-reported physical activity compared to controls. (17) Barrow et al. reported similar results with a slightly longer intervention (16 weeks). (40) These findings from the literature as well as solid data in support of tai chi safety among patients with cardiac disease indicate that tai chi has high potential to be a safe (deleted: and effective alternative) exercise option to promote physical activity and improve cardiac fitness among cardiac patients who, despite being fully eligible, did not attend CR. Furthermore, tai chi could overcome some of the barriers to CR participation, namely dislike of traditional CR exercise and transportation barriers.

Proposing tai chi training as an exercise option for participants not attending current CR is a novel approach. The studies that have examined the role of tai chi in the context of CR have so far examined the role of tai chi in the context of traditional CR exercise training, showing that tai chi training improves exercise tolerance and quality of life compared to CR alone

(87–89), while no study has so far investigated the possible role of tai chi as an exercise option for patients not attending traditional CR.

Tai chi differs from traditional exercise training in a numbers of ways. First, during tai chi practice participants are constantly reminded to focus their attention on their breath and/or on the movements of the body, and in this tai chi training embeds concentration and attention-focusing components similar to those practiced in other traditions, such as yoga, transcendental meditation and mindfulness meditation. Second, in contrast with the individual type of exercise training provided at CR, tai chi is usually taught in classes. Both these characteristics of tai chi exercise may provide additional benefits to those of physical exercise alone, such as, for example, improve social support, quality of life, and sleep. (85)

This phase 2, dose-ranging study will allow us to determine the safety of tai chi exercise (both in class and at home) in this population, to identify the appropriate dose of tai chi exercise that will be adopted in a future larger study, and to refine the conceptual framework that will guide this future study. We hypothesize that tai chi will increase overall physical activity (primary outcome). In addition, we posit that tai chi will improve cardiac fitness (as a direct effect of tai chi practice as well as by promoting increases in overall physical activity) and decrease body weight (likely by increasing energy expenditure). We also expect to see improvements in mood, social support and quality of life. Although full mediation analyses are beyond the scope of this pilot study, we will gather exploratory information on possible mechanisms by which tai chi training may affect the primary outcome for the future large RCT (physical activity). We will examine whether changes in exercise self-efficacy, perceived social support, resilience, and depression produce positive changes in physical activity level. We are also interested to study whether tai chi training, likely via its meditative component (i.e. mindful breathing, relaxation practices) may increase mindfulness levels and whether changes in mindfulness may explain tai chi effects (if any) on promoting overall physical activity. Notably, there is preliminary evidence that increases in mindfulness levels may promote positive changes in healthy behaviors (i.e., physical activity, diet and smoking) (90–92) that are relevant for the secondary prevention of cardiovascular disease.

According to pooled data from the Framingham Heart Study and other prospective studies nearly half of all individuals from both genders will die within five years of their first heart attack. (93) Almost a third of this high-risk population misses the “window” for behavioral changes (such as increasing activity levels) that are important for the secondary prevention of CHD. Specifically, substantial epidemiological evidence indicates that physical activity delays the development of atherosclerosis and is associated with reduced risk of coronary events. (85, 94) We propose to use preliminary findings from this dose-ranging study to conduct a future large RCT assessing the efficacy of a community-delivered tai chi intervention in improving overall physical activity and the proportion of patients achieving current recommendations for physical exercise (150 minutes of moderate intensity aerobic physical activity per week) (85) in sedentary patients with coronary events or revascularizations who are unable or unwilling to attend traditional CRs. Secondary outcomes for this RCT will be fitness, quality of life, mood, body weight, and cardiovascular events at one year of follow-up.

In sum, this pilot, dose-ranging study will provide preliminary indications about the usefulness of tai chi as a potential exercise option for patients unable or unwilling to attend traditional CR programs.

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Table 1

Schema of proposed doses

	PLUS condition	LITE condition
Week 1–12	3 sessions/week (60 min)	2 sessions /week (60 min)
Week 13–16	2 sessions/week (60 min)	-
Week 17–24	1 session every other week (60 min)	-

Table 2

Tai Chi Protocol outline

Week	Activities	Approximate Duration (min)
1–2*	Check-in	2
	Tai Chi Warm-up Exercises—Standing	
	Shaking to Awaken the Body	
	Tai Chi Swinging and Drumming the Body	
	Swinging Up and Down	
	Spiraling the Waist	
	Tai Chi Warm-up Exercises—	
	Seated Mindful stretching	
	Lower Extremities (feet, ankles, knees)	38
	Upper Extremities (hands, arms, shoulders)	
	Spinal Cord Breathing	
	Washing with Qi from the Heaven	
	Tan Tien Breathing	
	Introduction to Tai Chi Movement #1:	15
	Raising the Power	
	Tai Chi Cool-Down Exercises	5
	Self-massage and meridian tapping	
	Washing with chi from heavens	
3–8	Check-in	2
	Tai Chi Warm-up Exercises	18
	Breathing Exercises	10
	Review and practice Tai Chi Movement #1	5
	Learn and practice Tai Chi Movements #2 and #3	20
	Push and Withdraw	
	Wave Hands Like Clouds	
	Tai Chi Cool-Down Exercises	5
9–12	Check-in	2
	Tai Chi Warm-up Exercises	13
	Breathing Exercises	10
	Review and practice Tai Chi Movements #1–3	10
	Learn and practice Tai Chi Movements #4–6	20
	Brush Knee Twist Step	
	Cross hands	
	Tai Chi Cool-Down Exercises	5
Plus Group only:		
13–24	Check-in	2
	Tai Chi Warm-up Exercises	13

Week	Activities	Approximate Duration (min)
	Breathing Exercises	10
	Review and practice Tai Chi Movements #1–5	30
	Tai Chi Cool-Down Exercises	5

* Note: A 10-minute introductory lecture will be given in the first class outlining the goals and structure of the intervention, as well as participant responsibilities.

Table 3**Summary of Study-Related Assessments**

	Baseline§	At each session	3 m	6 m	9 m
<i>Screening assessments</i>					
Consent form	X				
HIPAA authorization	X				
Physical activity (PAR)	X				
Cognitive impairment	X				
Depression	X				
Blood pressure	X				
Stress test & cardiologist clearance**	X		X		
Reasons for not attending CR*	X				
Reasons for refusing participation in study	X				
<i>Covariates and moderators</i>					
Demographics*	X				
Medical history	X				
Medications and other concomitant therapies	X		X	X	X
Expectations about Tai Chi program	X				
<i>Feasibility & Acceptability (primary outcome)</i>					
n of screened & eligible individuals	X				
n refusing to participate, reasons for refusal	X				
n of dropouts and lost to follow-up			X	X	X
Reason(s) for dropping out			X	X	X
Tai Chi sessions attendance		X			
Individual Tai Chi practice		X	X	X	X
Acceptability scale					X
Individual Interviews					X
Focus groups				X	
<i>Safety (primary outcome)</i>					
Physical Activity Readiness Questionnaire		X			
Tai Chi side effects		X	X	X	X

	Baseline§	At each session	3 m	6 m	9 m
Hospital readmissions, unplanned visits		X	X	X	X
<i>Secondary outcomes</i>					
Accelerometry	X		X	X	X
7 days PAR	X		X	X	X
Fitness	X		X	X	X
Weight	X		X	X	X
Sleep	X		X	X	X
<i>Mediators</i>					
Exercise Self-Efficacy	X		X	X	X
Social Support	X		X	X	X
Depression	X		X	X	X
Mindfulness	X		X	X	X
Quality of life	X		X	X	X
Resilience	X		X	X	X

* Indicates assessment required in all screened patients regardless of participation.

** A second stress test is performed at 3 months in both groups for the assessment of fitness