The Effects of Tai Chi on Grade 1 Hypertension: A Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background Medication is generally recommended to reduce the morbidity and mortality caused by cardiovascular disease in hypertensive patients. However, considering the difficulties and economic factors associated with long-term medication, interest in tai chi as an exercise treatment method has been recently increasing in Korean medical practice. Numerous studies have suggested that tai chi can be used to treat various diseases and affect psychosomatic factors such as anxiety. This study aims to evaluate the effect of tai chi in reducing blood pressure among grade 1 hypertensive patients.

Methods In this randomized, active-controlled, assessor-blinded, two parallel-armed trial, 80 grade 1 hypertension patients will be recruited and randomly assigned to the usual care group or to the tai chi group (n = 40 in each group). Subjects who voluntarily signed a study agreement will be educated to manage their own blood pressure by restricting salt intake, losing weight, moderating alcohol consumption, performing exercise, and regulating dietary intake at their first visit. In addition to self-management, the tai chi group will perform two 60-minute tai chi sessions per week for a total of 8 weeks. Blood pressure will be measured as the primary outcome. In addition, body composition, heart rate, and the perceived strength and difficulty of the exercise will be measured as secondary outcomes.

Discussion This study intends to conduct a randomized controlled trial of tai chi, which is not widely practiced in Korea. This study will provide valuable data on the effects of tai chi on hypertension, to inform non-pharmaceutical treatment options for this disorder.

Background

According to the Korea National Health and Nutrition Examination Survey (2015), the prevalence of hypertension is 27.9% in Korea, and 36.8% of Korean adults belong to the pre-hypertension category [(1)]. The prevalence of age-related hypertension was 52.1% in males and 51.5% in females aged 60-69 years, and 61.7% in males and 71.3% in females aged 70 years or older [(1)]. The higher prevalence in older patients is because age-related reductions in blood vessel elasticity increase the systolic blood pressure (SBP) and decrease the diastolic blood pressure (DBP) [(2)]. If blood pressure is not controlled, blood vessel damage will occur and lead to complications of hypertension [(2)]. If hypertension is not detected early and treated properly, it can lead to complications such as myocardial infarction, stroke, and kidney failure [(3)].

The goal of controlling hypertension is to reduce the morbidity and mortality caused by cardiovascular disease by maintaining normal blood pressure [(4, 5)]. Medication for hypertension is generally recommended for SBP greater than 140 mmHg in patients younger than 60 years of age or DBP greater than 90 mmHg regardless of age [(6)]. However, considering the side effects and economic factors associated with long-term medication, non-medication therapy such as healthy eating habits, exercise, smoking cessation, and moderation of alcohol consumption are widely used to treat and manage hypertension along with pharmacotherapy [(7)]. In particular, Emily et al. [(8)] reported that physical activity,

including moderate-intensity exercises such as walking or home exercise, reduced the blood pressure in incident hypertension after 15 years of follow-up.

In recent years, there has been an increasing interest in tai chi as an exercise treatment method for treating various diseases [9-15]. According to a study conducted by Kim [16], tai chi may lower sympathetic tone and increase parasympathetic tone, which may affect autonomic nervous system changes. In addition, a randomized controlled study conducted by Tsai. et al. [17] suggested that a 12-week period of tai chi exercise reduces blood pressure as well as lipid levels, and improves patient anxiety.

In this study, we will analyze the blood pressure, heart rate, and body composition of grade 1 hypertension patients who were diagnosed during a medical examination in a hospital or had SBP of 140~159 mmHg or DBP of 90~99 mmHg in a screening test. Using the obtained data, we will evaluate the effectiveness of tai chi by comparing hypertension control in a group practicing usual care with that in an experimental group practicing usual care with tai chi exercise. The effectiveness of tai chi for hypertension will thus be assessed in this randomized, active-controlled, assessor-blinded, two parallel-armed trial.

Methods And Analysis

Study design

The proposed study is a randomized, active-controlled, assessor-blinded, two parallel-armed trial. The trial will be conducted at Pusan National University Korean Medicine Hospital (PNUKH) in Yangsan, Korea. The study protocol was approved by the Institutional Review Board (IRB) of PNUKH on 16 January 2019 (IRB approval number 2018014) and was also registered in the Clinical Research Information Service (Identifier: KCT0003632, 18-March-2019).

Participants

Inclusion Criteria

◦ Grade 1 hypertension patients who were diagnosed during a health checkup or at the hospital or were screened for an SBP of 140 to 159 mmHg or DBP of 90 to 99 mmHg

◦ Persons who can communicate normally

◦ Participants who signed the study agreement and voluntarily agreed to participate in the study

Exclusion Criteria

◦ Individuals who participated in another trial within a month before this study

◦ Patients whose high blood pressure is deemed by a doctor as difficult to treat with exercise, because of conditions such as severe pain or joint deformation

◦ Persons who are unable to communicate properly due to dementia or mild cognitive impairment

◦ Pregnant patients

◦ Individuals who cannot be included in this study in accordance with the investigator's judgment

Discontinuation/Dropout Criteria

◦ Identification of previously undiagnosed severe diseases after the enrollment and before the start of the clinical trial.

◦ Presence of other diseases (except hypertension) that can influence the results of the trial

◦ Participants' absence at the time of filling the case report form (CRF) at two consecutive instances.

◦ Participant's demand for discontinuation of the trial.

◦ Failure to follow-up.

Recruitment

Patients will be recruited using advertisements on the Pusan National University Yangsan Hospital (PNUYH) and PNUKH bulletin boards, local public health centers, and other local government offices. Patients who are interested in participating will first answer screening questions to determine their eligibility. Eligible patients will receive an explanation of the study and voluntarily decide whether they wish to participate in the clinical trial. After the patient has consented to the study agreement terms, a clinical research coordinator (CRC) will check whether the patient is suitable in accordance with the inclusion and exclusion criteria. Then, the patient will be assigned randomly to the tai chi group or usual care group. After allocation, the CRC will schedule the treatment procedure for the study. The first participant was enrolled on April 17, 2019.

Randomization

A statistician who is not involved in conducting and assessing the clinical trial will generate a randomization allocation sequence using the statistical program SAS® Version 9.4 (SAS institute. Inc., Cary, NC). By using this program, the statistician will assign all 80 participants to each group while applying the blocked randomization assignment method, with the same probability that each participant will be selected. Then he/she will prepare sealed envelopes and pass them to the CRC. The CRC will open a sealed envelope with codes (A or B) written for the trial in sequence and inform the practitioner of the

result. Depending on the result, the practitioner will assign the participant to the experimental group or the usual care group (Figure 1).

Blinding

Since blinding of the intervention in the experimental group will be impossible, allocation concealment and blinding of participants will not be performed. Instead, outcome assessor and data analyst blinding will be performed, and they will not participate in the procedure. A co-researcher blinded to group assignments will assess the results in a separate room after the end of the procedure. A data analyst who is also blinded to study assignments will analyze the statistical data to prevent selective reporting of outcome variables. This method of maintaining blinding involves assigning the same number of patients to each group and not notifying the person who performs the patient recruitment and group assignment. Unblinding will be permitted only when it is necessary to reveal the participant's allocated intervention, such as in cases of severe side effects, at the discretion of the assessor.

Education levels of the practitioners

All Korean medical doctors (KMDs) participating in this study as practitioners or researchers are licensed by the Ministry of Health and Welfare of Korea and have at least one year of clinical experience. These practitioners will be adequately trained to closely adhere to research protocols and to familiarize themselves with research treatment methods. All tai chi educators are trained Korean rehabilitation medical trainees or specialists in tai chi exercise practice, with at least one year of tai chi experience. Among them, the research director of this study has more than ten years of tai chi experience.

Intervention

At their first visit, patients in both groups will be educated to manage their own blood pressure by restricting salt intake, losing weight, moderating alcohol consumption, and performing exercise and dietary regulation. Additionally, patients in both groups will be asked to not perform any intense exercise that could influence the results of the trial. After education, the usual care group will self-manage their own blood pressure for 8 weeks.

In addition to self-management, the experimental group will perform tai chi as the study intervention. The tai chi used in this study is Chen style 18-form tai chi which will be conducted over two 60-minute sessions per week for a total of 8 weeks (80 percent compliance and more than 13 sessions in total). In each session, patients will perform 10 minutes of warm-up exercises, 40 minutes of tai chi, and 10 minutes of cool-down exercises. To maximize adherence to the study protocol, the intervention will mostly be performed at the PNUKH 6^{th} floor ward, and if group education is needed, practitioners can visit external locations. The patients in the experimental group will receive a reference book that will promote their retention and complete follow-up, and a daily log will be recorded after exercise to check the number of exercises the patient conducted. At weeks 4 and 8, both groups will visit the hospital and fill the CRF. After treatment, both groups will be monitored for an additional four weeks.

Outcome Assessment

At the initial screening visit, the CRC will explain the study protocol to the patient. Then, the participants will be asked about their sociodemographic characteristics, including age, gender, occupation, past history, present illness, and medications, at an isolated room for allocation concealment. All adverse events will be recorded, and the practitioners will check the severity of the events and decide the continuance of the trial. Follow-up assessments will be performed once at 12 weeks after the initial screening visit (Table 1, Figure 1).

Primary outcome measurements

Blood pressure will be the primary outcome of this trial. The CRC will assess the participant's blood pressure in a stable state using an automatic electronic blood pressure monitor (HBP-1300, OMRON DALIAN Co., Ltd., China). To obtain accurate data, the measurements will be conducted three times and their mean value will be used as the outcome. Blood pressure will be measured at baseline (assessment 1), prior to each of the visits (assessments 2 and 3), and during the follow-up visit (assessment 4). The primary endpoint is week 8 (assessment 3).

Secondary outcome measurements

Body composition is one of the secondary outcomes of this trial. The body composition test assesses the participant's weight, body fat mass, body mass index, percentage of body fat, and weight-hip ratio. The participant will stand barefoot in the Inbody machine (Inbody 770; INBODY Co., Ltd., South Korea). After weight measurement, the participant will grasp the handles and the machine will pass multifrequency signals through the body to obtain the impedance value corresponding to each frequency. Using the measured impedance values, the machine will show the outcomes. The test will be conducted at baseline (assessment 1), week 8 (assessment 3), and at the follow-up visit (assessment 4).

Heart rate is the other secondary outcome of this trial. Participants will assess their heart rate in a stable state. Heart rate will be measured simultaneously with blood pressure; thus, measurements will be conducted at baseline (assessment 1), prior to each of the visits (assessments 2 and 3), and during the follow-up visit (assessment 4).

The strength and difficulty of the exercise is the other secondary outcome. The purpose of this survey is to compare the subjective strength of the exercise with absolute strength. The experimental group will be asked four questions. Was this exercise easy to follow? Was tai chi useful for improving your health? Was the time at which tai chi was conducted appropriate? Was the provided reference helpful for tai chi exercise? Participants will answer each question using a 0 to 10 category scale. They will rate the difficulty of tai chi exercise using the 0 to 10 visual analog scale (VAS) scale, on which VAS 0 indicates no difficulty, whereas VAS 10 indicates the maximum possible difficulty the person can imagine. Both surveys will be conducted once at the end of the exercise training; thus, the measurement point will be week 8 (assessment 3).

Sample size

This study referred to the results of a previous study [18] that used tai chi as the main evaluation index. The calculated sample size necessary for the t-test was 36 subjects in each group. The sample size calculation was conducted by G power analysis with an effect size of 0.67, test power of 0.80, and significance level of 0.05. Considering a dropout rate of 10%, we aim to recruit a total of 40 subjects in each group.

Statistical analysis plan

Continuous variables will be expressed as mean ± SD (standard deviation), and categorical variables will be expressed as n (%). The demographic baseline information will be tested using the Chi-squared test and independent t-test for age, gender, occupation, past history, present illness, and medications.

For primary outcome statistical analysis, the effectiveness of tai chi will be tested by calculating the differences in the degree of change in the maximum SBP and minimum DBP before (baseline) and after (week 8) treatment for each test subject. Comparisons of the differences before (baseline) and after (week 8) tai chi in the same group will be performed using the paired t-test, and differences between the experimental and control groups will be compared using an independent t-test. If the test results of the samples do not satisfy the normal criteria, they will be tested using a nonparametric test (a Wilcoxon signed-rank test or Wilcoxon rank-sum test) corresponding to the statistical technique.

Among the secondary evaluation variables, the heart rate and the results of the body composition analysis will be tested to verify the effectiveness of tai chi by calculating the difference between before (baseline) and after (week 8) the tai chi exercise in the same manner as described above. Another secondary measurement variable, the strength and difficulty of the exercise, will be evaluated through the researchers' observations, and the numerical value will be analyzed by a simple descriptive statistical method. We will perform a simple correlation analysis or simple regression analysis to determine whether there is a correlation between the differences in blood pressure changes and the strength and difficulty of the exercise perceived by the experimental group.

Information regarding adverse events will be collected through patient reports and researchers' observations, and the frequency of adverse events will be determined by the Chi-squared test or Fisher's Exact test. All statistical analyses will be conducted in a two-sided manner, with a significance level of 5%. In addition, when missing data are generated, we will use the principle of intention-to-treat (ITT) analysis for the primary and secondary analyses. In the case of ITT analysis, last-observation-carried-forward (LOCF) and multiple imputation methods, which are widely used in clinical research, will be applied to process missing data and additional multiple imputation or regression analysis will be used to check the differences in results.

Safety

Because this is a simple exercise intervention study rather than a clinical study that applies untested drugs or medical devices, there is no possibility of adverse events caused by general Korean medical treatment. However, the investigators will explain all possible adverse events that may occur after tai chi to the participants and educate them to report all adverse events after the procedure. All adverse events recorded during the research period will be analyzed and reported. In general, due to the interventional characteristic of exercise, simple muscular pain of the exercise site may occur. We will provide beverages such as bottled water or green tea during the exercise so that the subject can obtain water if necessary. In order to prevent falls and severe muscle aches, we will prepare a chair during exercise and provide a space to sit and relax according to the patient's physical strength. If a direct injury has occurred in connection with this study, appropriate medical action may be taken, as determined by the investigator of the clinical trial.

Data monitoring staff members of the clinical research service institution (Woosuk University) will periodically monitor the study by telephone, e-mail, or visits, if necessary. The monitoring staffs will be composed of one statistician and one clinical research methodology specialist. The monitoring staffs shall review the progress of the study and check all records of CRF. In addition, they will oversee whether the study is following the protocol finalized before the trial. In case a problem is identified, they will communicate with each other and modify the plan to solve the problem. If modifications of the protocol are required during the study, we will submit the modified protocol to the IRB. In case approval of a clinical trial or an alternation of the approved clinical trial is needed, the new plan or the changed plan with each clinical trial stage shall be submitted for approval by the clinical trial review committee. However, auditing and interim-analysis are not planned in our trial.

Additionally, as we will not collect any biological samples and do not intend to use the participants' data in future studies, we do not need any additional consent provisions for collection and use of participant data and biological specimens in ancillary studies. In accordance with government regulations and standards, all documents related to the conduct of clinical research must be kept by the director of clinical research, or the director of the institution and the clinical research manager, for three years after the completion of the clinical trial. However, the director of clinical research can change the preservation period and storage place in consultation with the clinical research manager.

Ethics and dissemination

As this clinical study was prepared with patient rights and well-being in mind based on the Helsinki Declaration, clinical research supervisors and staffs will analyze and understand the research plan accurately and actively respond to the problems of research participants.

Before participating in the clinical study, the researchers will explain all the details of the research, after which the research participants will be required to voluntarily agree to participate in the research. English initials of the names of participants in the trial will be recorded, and identifying information will be thoroughly managed through the Subject Identification Code List (SICD) to prevent personal information such as social security number from being leaked. Researchers and research organizations will be able to

view the clinical research data at the time of reviews of the monitoring staff, inspections and IRB assessments, and government surveys. After completion of the research, the researcher will consult with the clinical research service institution (Woosuk University) to prepare a report of this study. The study findings will be disseminated in peer-reviewed journals and presented at national and international conferences. Additionally, we will share the deidentified individual patient data (IPD) and the datasets used or analyzed during the study can be requested from the corresponding author.

Discussion

When searching the research trends of the effects of tai chi on blood pressure in Korea, we found studies that assessed the effect of tai chi on waist circumference and blood pressure of the elderly [18] and the effect of tai chi on the cardiac autonomous nervous system and blood pressure of elderly women [16]. These studies show that tai chi was conducted mainly in the elderly. In addition, in the systematic review by Hwang et al. [19], only randomized controlled trials (RCTs) from China, Italy, United Kingdom, USA, Hong Kong, and Taiwan were reported, and RCTs from Korea were not reported.

The limitation of this study is that participant blinding cannot be achieved due to the nature of the intervention. Because the experimental group has to perform tai chi, participants will know whether they belong to the experimental group or the comparator group. This knowledge may affect the results of the study by influencing other behaviors, that may thus differ between the groups.

The strength of this study is that we will conduct this evaluation in ordinary adults aged 19 to 70 years instead of limiting it to the elderly. In addition, this study will perform an RCT of tai chi, which is not widely practiced in Korea. Tai chi is easy to perform and not strenuous, so it can easily be implemented at home and can be easily followed by anyone. As a result, this study will provide valuable data on the effects of tai chi on hypertension.

Trial Status

Protocol version: 1.6.

Protocol date: 24-April-2019.

Recruitment began on 17-April-2019.

Approximate completion date of recruitment: December-2019.

This trial was prospectively registered before the recruitment.

Abbreviations

IRB: Institutional Review Board, PNUKH: Pusan National University Korean Medicine Hospital, CRF: case report form. PNUYH: Pusan National University Yangsan Hospital, CRC: clinical research coordinator,

KMD: Korean medical doctors. SBP: systolic blood pressure, DBP: diastolic blood pressure, VAS: visual analog scale. ITT: intention-to-treat. LOCF: last-observation-carried-forward, SICD: Subject Identification Code List, IPD: individual patient data

Declarations

Ethics approval and consent to participate

This study was approved by the Pusan National University Korean Medicine Hospital IRB (IRB approval number: 2018014). All participants will sign the latest version of the informed consent form approved by the IRB. This trial was registered at the Clinical Research Information Service (CRIS identifier: KCT0003632), which is one of the World Health Organization's International Clinical Trials Registry Platforms. If protocol modifications are necessary, it will be reported to the IRB. The personal information of subjects will be kept secret and will be processed anonymously.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used or analyzed during the study can be requested from the corresponding author.

Competing interests

The authors declare no competing interests.

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Authors' contributions

SHL designed the study and drafted the manuscript. ISJ planned the statistical strategy, and EJP was actively involved in the sample size calculation and random allocation. EHH is the principal investigator

at the hospital and will educate tai chi to patients along with BJK. As investigators at the hospital, IHP, BJK, and MSH were involved in the study design and IRB approval. ISJ and MSH are the principal investigators of the research project and have the final responsibility for publication. All authors have read, revised, and approved the final version of the manuscript.

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References

1. Ministry of Health & Welfare DoHP. Korea National Health and Nutrition Examination Survey. 2016. p. 50.
2. Mosley II WJ, Lloyd-Jones DM. Epidemiology of Hypertension in the Elderly. Clin Geriatr Med. 2009;25(2):179-89.
3. Turgut F, Yesil Y, Balogun RA, Abdel-Rahman EM. Hypertension in the elderly: unique challenges and management. Clin Geriatr Med. 2013;29(3):593-609.
4. Carlberg B, Nilsson PM. Hypertension in the Elderly: What Is the Goal Blood Pressure Target and How Can This Be Attained? Curr Hypertens Rep. 2010;12(5):331-4.
5. Hartley L, Flowers N, Lee MS, Ernst E, Rees K. Tai chi for primary prevention of cardiovascular disease. The Cochrane database of systematic reviews. 2014(4): Cd010366.
6. Nilsson PM. Blood pressure strategies and goals in elderly patients with hypertension. Exp Gerontol. 2017;87:151-0.
7. Mahmood S, Shah KU, Khan TM, Nawaz S, Rashid H, Baqar SWA, et al. Non-pharmacological management of hypertension: in the light of current research. Ir J Med Sci (1971 -). 2019;188(2):437-52.
8. Parker ED, Schmitz KH, Jacobs DR, Jr., Dengel DR, Schreiner PJ. Physical activity in young adults and incident hypertension over 15 years of follow-up: the CARDIA study. Am J Public Health. 2007;97(4):703-9.
9. Ahn Y-J, Jo S-H, Lee S-H, Lim J-H. The review study on Yoga, Qigong, and Taichi interventions for anxiety: Based on Korean journal articles from 2009 to 2015. J Oriental Neuropsych. 2016;27(1):23-31.
10. Ji HQ. The Effect of Tai Chi Exercise on Attention Concentration and Dynamic Balance in Children with ADHD [master's thesis]. Pusan: Pusan National University; 2015.
11. Kim KL, Bae SJ, Seo HK. The Effect of Tai Chi on Health Related Fitness and Cognitive Function in Elderly Women with Dementia. J Kor Soc Rhythmic Exercises. 2018;11(2):51-8.
12. Kim Y-S, Park M-S, Kwak Y-S. 12-Week Tai Chi Exercise on Physical Fitness, Blood Pressure, and Cholesterol in Elderly Women. J Kor Soc Wellness. 2012;7(1):119-28.

13. Lee HY. The Effect of Tai Chi for Patients with Type 2 Diabetes - Analysis According to the Styles of Tai Chi Considering the Intensity: Systematic Review [master's thesis]. Pusan: Pusan National University School of Korean Medicine; 2015.
14. Li F, Harmer P, Fitzgerald K, Eckstrom E, Stock R, Galver J, et al. Tai chi and postural stability in patients with Parkinson's disease. N Engl J Med. 2012;366(6):511-9.
15. Son JT, Hwang H. Comparison of Subjective Symptoms, Physical Fitness, Depression and Self-efficacy before and after Tai Chi in Patients with Rheumatoid Arthritis: Based on 3 Years Data. J Muscle Joint Health. 2018;25(3):230-9.
16. Kim J-H. The Effect of Tai Chi Chuan Training on the Automatic Cardiac Nerve Activity and Blood Pressure in Elderly Women with Hypertension. J Kor Soc Dance Sci. 2014;31(1):157-68.
17. Tsai JC, Wang WH, Chan P, Lin LJ, Wang CH, Tomlinson B, et al. The beneficial effects of Tai Chi Chuan on blood pressure and lipid profile and anxiety status in a randomized controlled trial. J Altern Complement Med. 2003;9(5):747-54.
18. Lee YM. The effects of Tai Chi on waist circumference and blood pressure in the elderly. J Physical Therapy Sci. 2017;29(1):172-5.
19. Hwang E-H, Heo K-H, Lee G-S. Effect of Tai Chi as Therapeutic Exercise on Blood Pressure Rapid Systematic Review. J Oriental Rehab Med. 2013;23(1):101-13.

Table

Table 1. Schedule of data collection and measurement

Measures	Screening (week 0)	Active treatment								Follow-Up
		Week 1	Week 2	Week 3	Week 4(visit 1)†	Week 5	Week 6	Week 7	Week 8(visit 2)†	f/u 1† (12 weeks after screening)
Study agreement	●									
Check for participation in other clinical trials	●									
Sociodemographic characteristics[1]	●									
Tai chi exercise		Two sessions per week								
Body composition test	●								●	●
Measurement of vital signs[2]	●				●				●	●
Strength and difficulty of exercise									●	
Number of tai chi sessions attended										●
Adverse events					●				●	●

† window of visiting: ±3 days. f/u, follow-up.

1. age, gender, occupation, past history, present illness, and medications

2. blood pressure (SBP, DBP), heart rate, body temperature

Figures

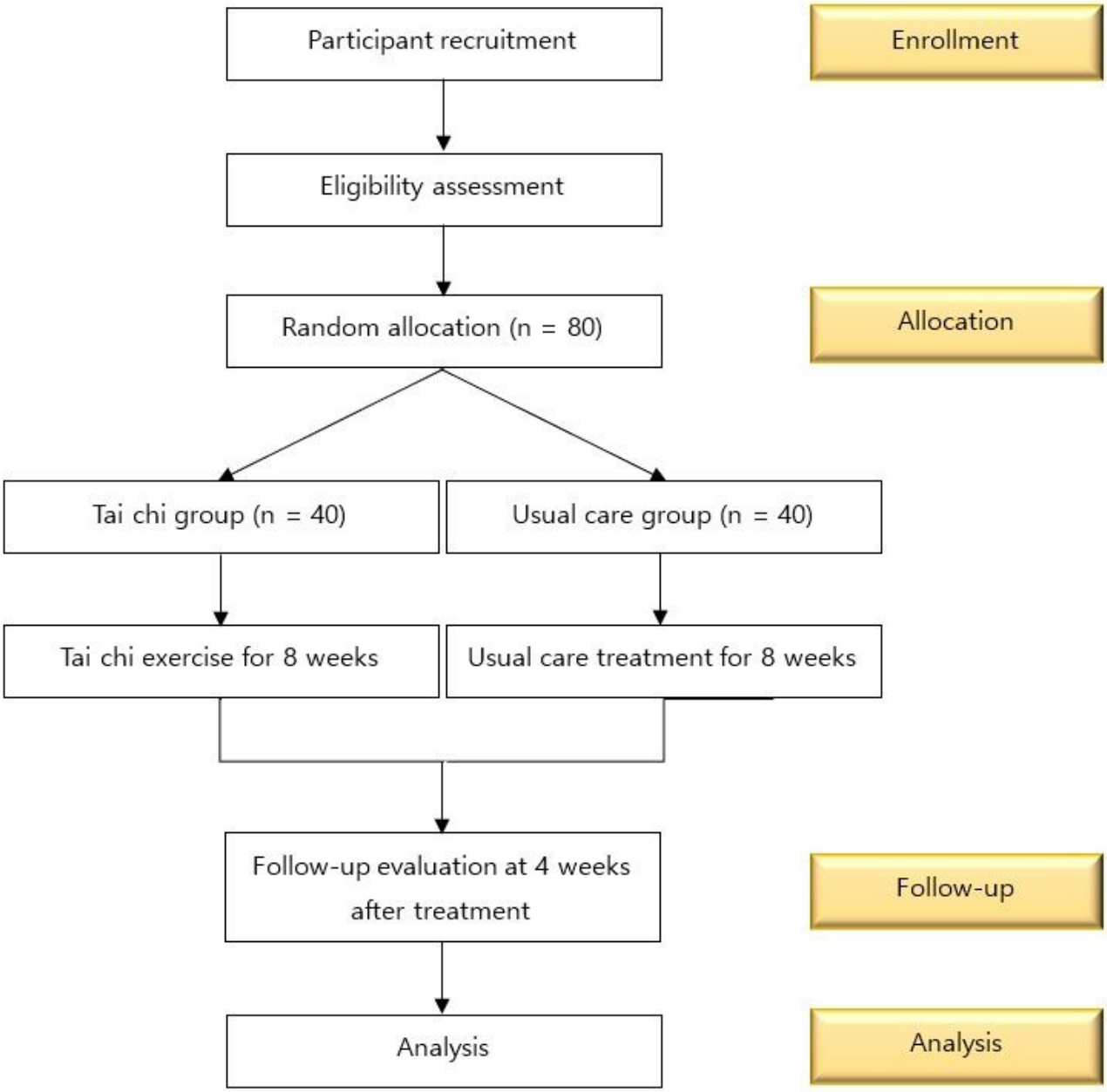

Figure 1

Flowchart outlining the study timeline, including enrollment, allocation, follow-up, and analysis

Supplementary Files

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- SPIRITChecklist.doc
- Appendix.docx