The effect of Baduanjin exercise for functional ankle instability rehabilitation: study protocol for a randomized controlled pilot trial

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Study protocol

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Abstract

Background Patients with functional ankle instability (FAI) have problems with joint control, balance, gait, and postural symmetry. Baduanjin is a type of traditional Chinese exercise, which has been shown to be effective for treating many diseases and symptoms. However, the effect of Baduanjin in patients with FAI has not been proved. This trial is an assessor-blinded randomized controlled trial (RCT), its objective is to study the efficacy and safety of Baduanjin on the rehabilitation of patients with FAI. Methods Seventy-two participants, who are eligible according to the inclusion and exclusion criteria, will be randomized (in a 1:1 ratio) using a random numbers table into two groups: a Baduanjin group and a control group (subjected to conventional physical therapy). The Baduanjin group will be subjected to Baduanjin exercise in addition to the conventional physical therapy. The participants' exercise will be implemented for 4 weeks (5 days a week). All the participants will be assessed at baseline, after 2 weeks' treatment, and after 4 weeks' treatment (after the intervention). The efficacy of Baduanjin will be assessed based on three types of outcome: (1) surface electromyography (sEMG) results of the bilateral erector spinae, tibialis anterior, and peroneus longus; (2) balance function under different conditions; and (3) the severity of ankle instability in daily life, using the Cumberland Ankle Instability Tool (CAIT). Discussion The aim of the trial is to study the effect and safety of Baduanjin in patients with FAI. The study findings may show whether Baduanjin could be used to complement medical FAI rehabilitation methods. The study findings could also highlight the importance of Baduanjin in promoting the bilateral symmetry of motor function.

Background

Ankle sprains occur frequently in daily life and during physical exercise. There are 23000 cases of ankle sprains per day in the USA [(1)] and about 1.5 million ankle sprains in UK emergency departments each year [(2)]. A study has shown that about 20%–40% of people develop chronic ankle instability (CAI) after an acute ankle sprain [(3)]. Generally, CAI is divided into FAI and mechanical ankle instability (MAI) . The doctors generally certify the FAI by the history of the rates of recurrent ankle sprains, and the "giving-way" feel happening while physical movement, with or without mechanical instability[(4-6)]. Four-fifths of ankle osteoarthritis cases are reported to be caused by previous musculoskeletal injuries, and these patients are on average 10 years younger than those with primary ankle osteoarthritis [(7)]. Thus, FAI can develop into MAI [(8)]. If treatment is not timely, an ankle injury can lead to joint inflammation, degeneration, and other cartilage symptoms.

In patients with severe cases of FAI, there may be permanent inability to move the joint. Patients with FAI have problems with joint control, balance, and gait due to the handicap in neuromuscular control and sensorimotor problems. The functional changes mainly include decreased muscle strength, decreased ankle joint proprioception, and prolonged muscle response time. Furthermore, FAI can result in recurrent ankle sprains and chronic ankle joint pain. Patients with FAI often feel unable to risk relying on the affected joint, so they can have asymmetry of posture (which can include asymmetry related to sitting and standing) and asymmetry of motor function (which can include balancing and coordinating

functions and can occur in both the limbs and the trunk) [9]. Asymmetry of posture and motor function can lead to problems with the lumbar spine, spinal muscles, and the knee joint that bears the increased bodyweight. These disorders can seriously affect the patients' abilities and quality of life.

Non-surgical treatment is ordinarily the primal method in most patients, the earlier surgical treatment is generally used in patients with MAI, and in high-level athletes [10], [11]. Rehabilitation exercise plays a definitive role in conservative treatment (non-surgical treatment), which includes strength training of the muscles around the ankle, standing stability training, proprioceptive training under different conditions, and the use of external support methods including bandages and Kinesio taping. Previous studies have shown that conservative treatment affects FAI [12-14].

Using PubMed, China National Knowledge Infrastructure (CNKI), the Wan Fang and Wei Pu databases, our literature search on ankle sprains in both the sports field and medical field (in China and internationally) indicated that ankle sprains and CAI have been attracting increased attention in recent years. More than 100 articles are published in English every year, which cover the diagnosis, biomechanical characteristics, and treatment of acute ankle sprains [9] and CAI [15]. The high rate of ankle sprains and sequelea impact the patients' health, which lead to the increase of the studies on ankle sprains, CAI, and other relating problems in the past twenty years.

Baduanjin exercise is a widely practiced form of exercise in China. Its history can be traced back to ancient times. In recent years, many studies[16], [17]on the efficacy of Baduanjin exercise on psychosomatic function in different groups of patients have been or will be conducted. Baduanjin is effective in improving the adults' physical flexibility, increasing mind-body coordination [18], and modulating blood lipid metabolism[19]. Baduanjin improves pulmonary function in patients with chronic obstructive pulmonary disease [20]and increases the self-efficacy in patients with cardiovascular diseases [21]. Baduanjin can ameliorate the symptoms of depression effectively and safely in patients with depression, it also can reduce these patients' blood glucose levels [22]. Baduanjin is also a safe adjunctive rehabilitation method for patients with stroke, as it has been shown to have benefits regarding lower extremity sensorimotor function, depression, and activities of daily living [23]. Researchers have also identified the positive effects of Baduanjin on balance [23, 24] and have shown that it can improve gait performance and functional mobility in patients with Parkinson's disease [25].

The assessment and treatment of patients with CAI, in China and internationally, still needs further study[26]. At present, rehabilitation exercise for patients with FAI generally focuses on a single joint or limb, and many of the exercises require supervision or direct help from therapists or other individuals. To our knowledge, there is no effective or convenient methods exist for the other associated challenges, such as those related to weight-bearing on both lower limbs, symmetry of bilateral limb movements, and postural symmetry.

All Baduanjin movements are bilateral. Bilateral limb movement is conducive to the improvement of bilateral limb coordination, balance function, and symmetry of the body. Considering all the benefits of Baduanjin, we aim to explore the efficacy and safety of Baduanjin in individuals with FAI by a randomized controlled trial (RCT). Our hypothesis is that patients in the Baduanjin group would show better outcomes compared with control group. (Spirit Checklist 6a,6b,7)

Methods/design

Overview

An assessor-blinded, parallel-controlled RCT will be implemented to observe the efficacy and safety of Baduanjin in patients with FAI, which will be carried out in Dongzhimen Hospital, the First Affiliated Hospital of Beijing University of Chinese Medicine. A total of 72 patients with FAI who are eligible according to the inclusion and exclusion criteria will be recruited and randomly assigned (in a 1:1 ratio) to Baduanjin or control group. Outcomes will be evaluated at three timepoints: at baseline, 2 weeks, and 4 weeks.(Fig. 1) (Spirit Checklist 8,9)

Fig. 1 Flow Chart of the Study

Ethics

The trial has been approved by the Research Ethical Committee of Dongzhimen Hospital, the First Affiliated Hospital of Beijing University of Chinese Medicine (no. DZMEC-KY-2019-18) and it will follow the principles of the Consolidated Standards of Reporting Trials (CONSORT) statements as well as the Declaration of Helsinki. The trial is registered with the Chinese Clinical Trial Registry (ChiCTR1900021939). Any changes of the protocol will be reported to the Research Ethical Committee. They will determine whether the change of the protocol is necessary. The members of the study team will supervise the safety of participants during the trial. (Spirit Checklist 5d,24,25)

Participants and recruitment

The participant recruitment has been conducted in the outpatient clinics of the Rehabilitation Department and Orthopedics Department of Dongzhimen Hospital, the First Affiliated Hospital of Beijing University of Chinese Medicine. An advertisement has also been posted on the hospital's bulletin board. The adverts provided the contact information of the eligibility screener (who doesn't involve in other study tasks). (Spirit Checklist 15)

Inclusion criteria

The inclusion criteria are as follows, it was proposed by the International Ankle Consortium in 2014[27]:

Aged 15–50 years.

A history of at least 1 significant ankle sprain.

The initial sprain must have occurred at least 12 months prior to study enrollment.

Was associated with inflammatory symptoms (pain, swelling, etc.).

Led to at least 1 interrupted day of desired physical activity.

The most recent injury must have occurred more than 3 months prior to study enrollment.

We define an ankle sprain as “An acute traumatic injury to the lateral ligament complex of the ankle joint as a result of excessive inversion of the rear foot or a combined plantar flexion and adduction of the foot. This usually results in some initial deficits of function and disability [28].”

A history of the previously injured ankle joint “giving-way” (with at least two episodes of “giving-way” in the 6 months prior to study enrollment) and/or “recurrent sprain” and/or “feelings of instability.”

We define “giving-way” as “The regular occurrence of uncontrolled and unpredictable episodes of excessive inversion of the rear foot (usually experienced during initial contact while walking or running), which do not result in an acute lateral ankle sprain.”[27]

We define “recurrent sprain” as two or more sprains to the same ankle [28].

We define “feeling of ankle joint instability” as “The situation whereby during activities of daily living (ADL) and sporting activities, the participant feels that the ankle joint is unstable, and is usually associated with the fear of sustaining an acute ligament sprain [28].”

Cumberland Ankle Instability Tool (CAIT) [29] score < 24.

Written informed consent.

Exclusion criteria

The exclusion criteria are as follows, it was proposed by the International Ankle Consortium in 2014(27):

A history of previous surgeries to the musculoskeletal structures (i.e., bones, joint structures, and nerves) in either lower limb extremity.

It is understood and accepted in clinical and research practice that surgery to repair insufficient joint structures is designed to restore structural integrity but creates residual changes in the central and

peripheral portions of the nervous system. Even with appropriate rehabilitation and follow-up management, there are concomitant neuromuscular and structural alterations after surgery that would confound the ability to isolate the effects of CAI.

A history of a fracture in either lower limb extremity requiring realignment.

Similar to the first exclusion criterion, significant compromise to skeletal tissue threatens the internal validity of the selection of participants with isolated CAI.

Acute injury (i.e., sprains or fractures) to musculoskeletal structures of other lower extremity joints in the previous 3 months, which affected joint integrity and function resulting in at least 1 interrupted day of desired physical activity.

Central nervous system disease, ear disease history, cognitive dysfunction, or other diseases which make the participants unable to cooperate with the rehabilitation treatment and assessment. (Spirit Checklist 10)

Informed consent

The patients will be notified about the study method and processes, and they will be informed of their rights, the benefits of taking part in the trial, and the things they will do if they consent to take part. The participants are voluntary to participate in the trial and they will be able to withdraw from the trial at any point for any reason. If there are any adverse events (including any accidents), the participants will be asked if they want to withdraw. When the participants withdrew from the trial, their data will be saved to analyze in the end of trial. The participants will sign the informed consent when they agree to participate in the trial.

Sample size

The trial will entail a preliminary pilot study (based on the availability of resources); therefore, the sample size will be small. After several rounds of discussion and demonstration, the experts of the study group decided to include patients with the minimal clinical effective sample size of 30 patients in each group. Considering a 20% loss rate, 36 patients should be included in each group. The random envelope method was used for grouping concealment. (Spirit Checklist 14)

Randomization and allocation concealment

A random number list has been generated through the computer by the study statistician. The random envelope method was used for grouping concealment. Patients who are eligible according to the inclusion and exclusion criteria and consent to take part in the trial will be assigned to the Baduanjin or

control groups. The group allocation outcome will be sealed in opaque envelopes. The group allocation manager will open the envelope and inform the eligible participants their group assignment. (Spirit Checklist 16a,16b,16c)

Blinding

The eligibility screener, outcome assessor, data analysts and data collectors will be blinded to each participant's group allocation. The eligibility screener will be responsible to collect the baseline data. The group allocation manager will inform the Chinese medicine rehabilitation specialist about the participants' information in the Baduanjin group. However, during the trial, it would be impossible to blind participants regarding group allocation. Before the trial, we will explain the differences between the two study groups to the participants. We will make clear to the participants that they must do the exercise in accordance with the trial plan if they consent to participate. The eligibility screener, group allocation manager, and outcome assessors will not be responsible for patient treatment or data analysis. The rehabilitation specialists and Chinese medicine rehabilitation specialist will not be responsible for data analysis or any other study work. Before the data analysis, all the data will be saved by the researcher who is responsible to the data analysis, the unblinding will last until the data analysis ends. All the researchers have been trained about the trial plan and schedule. They will not violate the trial schedule to communicate the contents regarding as group allocation and data analysis privately. (Spirit Checklist 17a,17b)

Interventions

Control group

Participants allocated to the control group will receive conventional physical therapy[30-32] including muscle strengthening, balance function training, gait training, etc. The rehabilitation specialists will arrange suitable therapy for the participants. All patients will undergo 30 min of conventional physical therapy every day, once a day, 5 days per week (followed by 2 days of rest) over 4 weeks, leading to a total of 20 sessions. (Spirit Checklist 11a)

Baduanjin group

Participants allocated to the Baduanjin group will be trained Baduanjin exercise by a Chinese medicine rehabilitation specialist in addition to the control therapy. The Chinese medicine rehabilitation specialist is qualified and experienced in teaching Baduanjin. The Baduanjin group will be subjected to additional Baduanjin exercise after conventional physical therapy, the Baduanjin training would be consistently

performed for 30 min every time. The Baduanjin group participants will grasp the Baduanjin exercise before the trial. The Chinese medicine rehabilitation specialist will teach participants the Baduanjin and protect them. (Spirit Checklist 11a)

Outcome measures

In this study, we selected several objective evaluation parameters to observe and investigate the outcome. Outcome measures will include the surface electromyography (sEMG) results of the bilateral erector spinae, tibialis anterior, and peroneus longus muscles extracted from graphic information by FlexComp Infiniti System (Canada), balance function outcome by NeuroCom Balance Manager system(46mm*46mm,Basic Balance Master, USA), and CAIT score. All primary and secondary outcome measures will be assessed at baseline, 2 weeks, and 4 weeks by experienced and qualified outcome assessor.

The outcome assessor who has been trained the schedule of trial assessment will be blinded to each participant's group allocation until the end of trial. (Spirit Checklist 18a)

Basic characteristic variables

The two groups participants' demographic information including gender, age, ethnicity, occupation, medical history and other detailed information will be recorded and collected at baseline to compare their statuses and features. The rehabilitation specialists will monitor the participants' status and measure the participants' vital signs, such as the blood pressure, respiration rate, and pulse.

Primary outcome measures

1) sEMG results: The fibula muscle plays an important role in supporting the ankle joint, so we regard its strength as one of the primary outcome measures. The sEMG oscillations of the erector spinae, tibialis anterior, and peroneus longus muscles will be compared among each pair of bilateral muscles at the three timepoints (at baseline, 2 weeks, and 4 weeks). The sEMG oscillations in bilateral muscle function before and after treatment will also be recorded and assessed, as will the change over time, from week 2 to week 4. The differences in all these bilateral muscle function results will be compared between the Baduanjin and control groups.

2)Balance function: The evaluation equipment of Neurocom Balance Manager system includes a 46mm*46mm fixed force plate, a 46mm*46mm foam surface, two data processors, and a screen. The evaluation outcomes are showed in chart, the (center of gravity) COG track presented in each evaluation condition, a comprehensive score that showed patients' COG control ability also in the chart. The evaluation items include Modified Clinical Test of Sensory Interaction on Balance(mCTSIB), Weight

Bearing Squat (WBS), Limits of Stability (LOS), Unilateral Stance (US), and Rhythmic Weight Shift (RWS). The characteristics of balance function will change under different conditions. The differences in balance function between the groups, and the trend in balance function over time in the two groups, will be assessed.

Secondary outcome measures

The CAIT questionnaire[33] will be used as the secondary outcome measures. The questionnaire includes 9 self-reported questions that the participants should answer. The contents involve to the pain around of ankle joint, balance function, ankle sensorimotor function, the condition of ankle sprains and the severity of ankle instability. The higher the questionnaire score, the better the ankle function. (Spirit Checklist 12)

Adverse Events

If there are any adverse events during the trial, the researcher will report it to the Research Ethical Committee, and record it on the case report form(CRF). Furthermore, the researchers will protect the participants and arrange adaptive exercise for the participants according to the study schedule. If the participants have any adverse events (recurrent ankle sprain, fatigue, and other adverse events), the researchers will take emergency treatment and the expert in the study group will come to participate in the treatment. The participants can withdraw from the trial if there is the need to suspend the exercise. (Spirit Checklist 11b,22,30)

This protocol has been planned according to relating items from the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist (Additional file 1) and the SPIRIT figure (Fig. 2).

Fig. 2 Schedule of enrollment, interventions, and assessments(Spirit Checklist 13)

Data management and monitoring

When the assessor completes the CRF, the data collectors will save the contents of CRF which include the baseline data and outcome measurements data in the computer. The two data collectors will check the contents each other to make sure their data is correct. All the materials and data including the electronic data and paper forms will be saved in the database in the Clinical Research Center of Dongzhimen Hospital. Only the members of the trial group have the right to check the data. The participants' personal information will not be revealed. (Spirit Checklist 5d,18a,19,27,29)

Statistical analysis

The researchers blinded to group allocation will analyze the data using Statistical Product and Service Solutions (SPSS) software version 20.0. We will compare the data between the Baduanjin and control groups. We will also assess the change in the results (including the sEMG bilateral muscle data) of the Baduanjin and control groups over time at three timepoints (at baseline, 2 weeks, and 4 weeks) to further explore the functional recovery over time and the mechanism of action of Baduanjin in patients with FAI. For normally distributed continuous variables, we will use the *t*-test, and for non-normally distributed continuous variables, we will use the Mann–Whitney U test. The continuous variables are showed with mean, standard deviation and 95% confidential interval (CI). Count data will be described using frequencies (with percentages), and compared using the chi-squared test. The intention-to-treat analysis will be conducted if there are participants who suspended the test. $P \leq 0.05$ will define statistical significance. (Spirit Checklist 18b,20a,20b,20c,21a)

Discussion

Baduanjin involves safe and easy to learn bilateral movements that patients with unstable ankle joints can perform by themselves. Bilateral limb movements are helpful for improving coordination, postural symmetry, and balance function. In addition, during the practice of Baduanjin, the knee joints are slightly bent, which helps to increase lower limb strength. Closed-chain motion (where the distal segment, e.g., the foot, is fixed against resistance) is a safer weight-bearing motion than open-chain motion (where the distal segment is not fixed). Thus, Baduanjin is suitable for patients with an unstable ankle joint, and a technique they can practice by themselves. Baduanjin movements are simple to learn and can be easily adhered to. While practicing Baduanjin, respiratory movements and respiratory rhythm promote the contraction and stability of the core muscles, which improves trunk stability, postural control, and postural symmetry. The requirements regarding limb movement coordination can also promote the contraction and stability of core muscles, which is conducive to trunk stability and the improvement of postural control and symmetry. The practice of Baduanjin requires stable posture and focus on the exercise, and individuals must control their body as much as possible, so they can mobilize more muscles and use more strength. In this trial, we intend to study our hypothesis and our deduction on the efficacy of Baduanjin more deeply.

This trial will be the first to study the effects of Baduanjin on patients with FAI. The results will provide data about the effects of Baduanjin on patients with FAI, in terms of whether it can provide easy, safe, and effective relief for these patients, and would include its effects on postural symmetry and erector spinae functional status. The outcome assessor will test the bilateral erector spinae, tibialis anterior, and peroneus longus muscles to observe whether the bilateral muscles become more symmetrical after Baduanjin. If Baduanjin can play an important role in improving balance and postural symmetry, patients with FAI could routinely practice the exercise by themselves, which would reduce medical costs. The study findings could highlight the importance of Baduanjin in promoting the bilateral symmetry of motor function. This study may lead to the growth of more effective methods to reduce the rates of acute and chronic ankle injury, particularly in the more active crowd. The effect of Baduanjin on ankle injuries has not been previously studied. The result of this study will provide clinical data on the problem whether the

Baduanjin has effect on the bilateral symmetry of motor function and balance function in individuals with FAI.

Trial status

The trial is currently in the recruitment phase. This trial started on 1 April 2019 and will end on 31 December 2020.

List of abbreviations

CAI: chronic ankle instability

CAIT: Cumberland Ankle Instability Tool

CI : confidential interval

COG：center of gravity

CRF: case report form

FAI: functional ankle instability

LOS: Limits of Stability

MAI: mechanical ankle instability

mCTSIB: Modified Clinical Test of Sensory Interaction on Balance

RCT: randomized controlled trial

RWS: Rhythmic Weight Shift

sEMG: surface electromyography

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

US: Unilateral Stance

WBS: Weight Bearing Squat

Declarations

Ethics approval and consent to participate

This trial has been approved by the Research Ethical Committee of Dongzhimen Hospital, the First Affiliated Hospital of Beijing University of Chinese Medicine (no. DZMEC-KY-2019-18). Each participant will sign the informed consent before he or she enters into the trial and the consent form will be saved in the CRF. (Spirit Checklist 26a,32)

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests. (Spirit Checklist 28)

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Authors’ contributions

LZ registered the trial and contributed to the design of the study and writing the trial protocol. ZHL contributed to the design of the study, the content of the Baduanjin exercise training program. JJA contributed to the design of the study and translate the trial protocol. KSL, YTS, RYY and DYL made considerable contributions to the manuscript by providing important suggestions, they also took part in translating the protocol. All authors read and approved the final manuscript.

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Figures

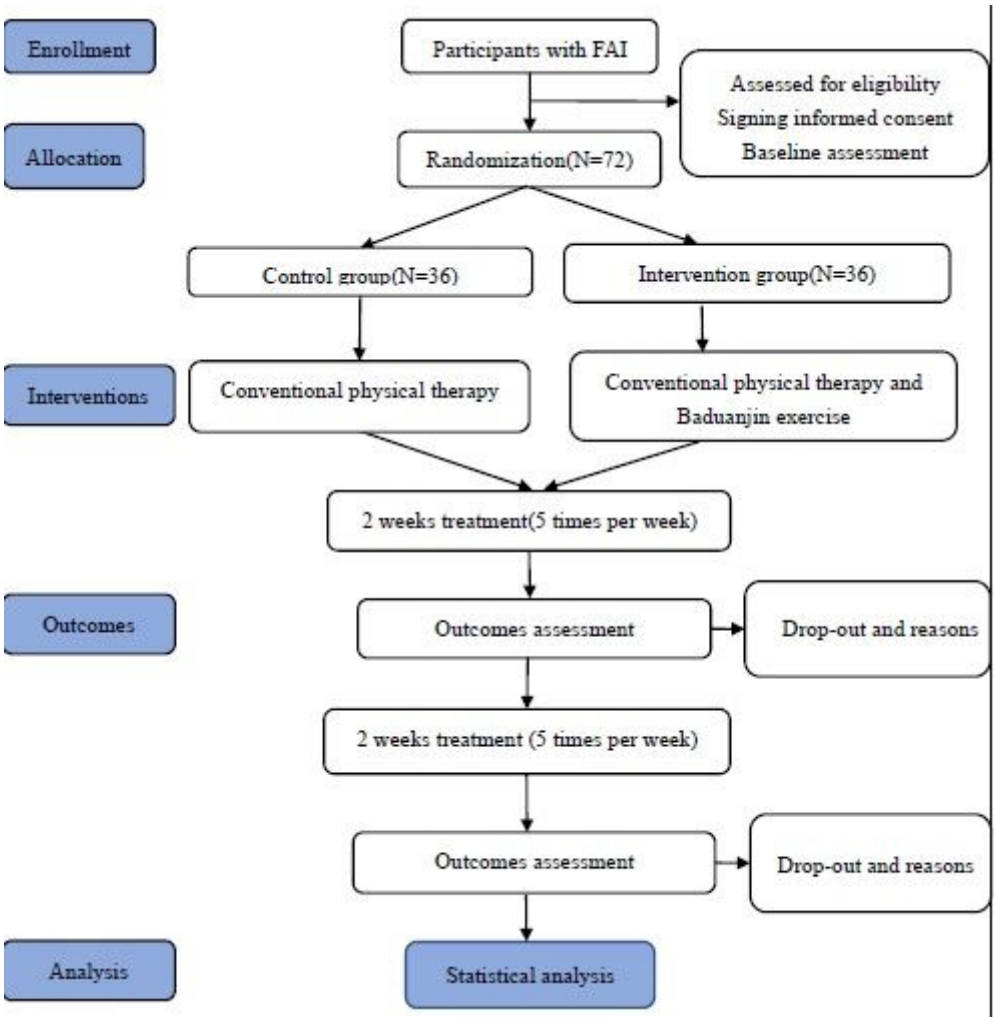

Figure 1

Flow Chart of the Study

TIMEPOINT	Enrollment	Allocation	Treatment phase (5 days' treatment per week followed by 2 days of rest)			
			1st week	2nd week	3rd week	4th week
ENROLMENT:						
Eligibility screening	√					
Informed consent	√					
Randomization		√				
Baseline data collection		√				
INTERVENTIONS:						
Baduanjin group			√	√	√	√
Control group			√	√	√	√
ASSESSMENTS:						
Balance function				√		√
sEMG				√		√
CAIT				√		√
Adverse events			√	√	√	√
CAIT Cumberland Ankle Instability Tool, sEMG Surface electromyography						

Figure 2

Schedule of enrollment, interventions, and assessments (Spirit Checklist 13)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1SPIRITchecklist.doc