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To determine whether Ai-chi exercises (aquatic exercises) can improve balance, functional status and quality of life in patients with Parkinson's disease

Submission date
15/02/2016

Recruitment status
No longer recruiting

Registration date
19/02/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Ai Chi is an exercise program developed in Japan where a person completes low-impact exercises in warm, shallow water. The natural resistance provided by the water helps to strengthen muscles without putting pressure on the bones and joints, which is particularly beneficial for those suffering from problems with movement. The aim of this study is to investigate the effectiveness of Ai-Chi in helping to improve balance and movement in people with PD.

Who can participate?
Adults with PD who have moderate to severe disability.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group complete 25 hour-long exercise sessions over five weeks, involving Ai-Chi exercises (deep breathing combined with broad arm, leg and body movements) in a swimming pool. Participants in the second group complete 25 hour-long exercise sessions over five weeks, involving conventional exercises (on land). For both groups, the sessions consist of a 15 minute warm up, a half hour exercise session (involving Ai-Chi or conventional land-based exercises) and a 15 minute cool down. At the start of the study and then again the day after the final exercise

session after five weeks, participants in both groups complete a number of questionnaires and physical tests in order to find out if there has been any improvement to their balance, mobility and quality of life.

What are the possible benefits and risks of participating?
Participants taking part in the Ai-Chi exercises may benefit from an improvement to their balance and mobility (walking ability) which could improve their overall quality of life. There is a risk of muscle pain after the exercise sessions, however this is only temporary. Those in the land-based exercise group also have a higher risk of injuring themselves during the sessions if they fall than the Ai-Chi group.

Where is the study run from?
Ahi Evran University Medical Faculty Educational and Research Hospital (Turkey)

When is the study starting and how long is it expected to run for?
February 2015 to January 2016

Who is funding the study?
Ahi Evran University Medical Faculty Educational and Research Hospital (Turkey)

Who is the main contact?
Dr Emine Eda Kurt

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
process no: 999506699/13

Study information

Scientific Title

Effects of Ai-Chi on balance and clinical manifestations in patients with Parkinson's disease: A randomised controlled trial

Study objectives
The aim of this study is to investigate the effects of Ai-Chi on balance, functional mobility, motor impairment, and health-related quality of life in patients with Parkinson's disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Turgut Özal University Medical Faculty Clinical Trial Ethic Committee, 09/01/2015, ref: 999506699/13

Study design
Single-centre randomised open label controlled

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participants are randomised to one of two groups.

Intervention group: Participants attend hour-long sessions, five times a week for five weeks, in which they complete Ai-Chi-exercises. The Ai-Chi exercises are directed by a physiotherapist experienced in neurologic rehabilitation and Ai-Chi, and take place in a swimming pool, in which the water was 1.20 meters deep and 32 C. Each session consists of a warm-up period, a period of Ai-Chi exercises and a cool-down period. 15 minutes of warm-up consists of free extremity movements or activities with different materials such as pool noodles and kickboards. The Ai-Chi program lasts 30 minutes and consists of 16 different movements. Ai-Chi exercises, all performed in shoulder-depth water with knees slightly flexed, use a combination of deep breathing and slow, broad movements of the arms, legs, and torso to work on balance, strength, relaxation, flexibility, and breathing. The 16 movements, or postures, follow the sequence of contemplation, floating, uplifting, folding, shooting, gathering, freeing, transferring, accepting, accepting with grace, rounding, flowing, relaxing, and sustaining. 15 minutes of a cool-down program in the water (free walking and stretching) is performed after the Ai-Chi program.

Control group: Participants attend 25 hour-long sessions, five times a week for five weeks, in which they complete control land-exercises. Each session comprises of warm-up activities, arthiculer mobilization, stretching of the spine and limbs, static and dynamic balance training, gait exercises and a cool-down period.

Participants in both groups are followed up one day after the last (25th) exercise session at five weeks.

Intervention Type
Other

Primary outcome(s)
1. Balance is measured using Biodex-3,1 and Berg Balance Scores at baseline and 5 weeks
2. Mobility is assessed using the Time Up Go Test at baseline and 5 weeks
3. Motor ability and quality of life, assessed using Parkinson's disease Questionnaire-39 and the Unified Parkinson Disease Rating Scale-III (UPDS-III) at baseline and 5 weeks

Key secondary outcome(s))
Not applicable

Completion date
15/01/2016

Eligibility

Key inclusion criteria
1. Ability to follow a stable medication schedule
2. In Parkinson Disease stages 2 to 3 according to the Hoehn and Yahr Scale 1
3. Lack of dementia (Mini-Mental State Examination score ≥24)
4. All patients’ BMI were between 18 and 30

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Having participated in physical therapy in the previous six months
2. Fear of water
3. Allergy to chlorine
4. Inability to walk independently
5. Having undergone surgical treatment for Parkinson's Disease
6. History or evidence of neurological deficit other than Parkinson's Disease (stroke, neuromuskuler disease, etc.)
7. Uncontrolled hypertension
8. Diabetes
9. incontinence
10. Open wounds
11. Osteoarthritis
12. Osteoporosis at a level that impairs walking and balance

Date of first enrolment
15/02/2015

Date of final enrolment
15/01/2016

Locations

Countries of recruitment
Türkiye

Study participating centre
Ahi Evran University Medical Faculty Educational and Research Hospital
Pysical Therapy and Rehabilitation Clinic
Ankara
Türkiye
40200

Sponsor information

Organisation
Ahi Evran University Medical Faculty Educational and Research Hospital

ROR
https://ror.org/05rrfpt58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ahi Evran University Medical Faculty Educational and Research Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	24/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes