

Adaptation and implementation of health Qigong and Tai Chi exercises on quality of life and physical functioning in patients with atrial fibrillation: a feasibility study

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| Submission date 28/02/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 25/03/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 13/12/2024 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Tai Chi and Qigong traditional Chinese exercises are thought to be beneficial in many health conditions including heart conditions, however, there is a lack of studies showing the effect of these exercises on patients with atrial fibrillation (AF; the most common irregular heart rhythm). Therefore, the aim of this research is: To assess the feasibility of a future randomised controlled trial of Tai Chi and Qigong for patients with atrial fibrillation in terms of patients' acceptability and capability to continue the programme and their satisfaction with it, in addition to evaluating health-related quality of life and physical functioning.

Who can participate?

Approximately 106 adult participants with confirmed AF diagnoses will be recruited from primary care.

What does the study involve?

The study will take place online via the virtual platform (Zoom).

The exercise group will learn a Tai Chi and Qigong routine for 12 weeks, led by a qualified instructor. All the movements will be carried out according to the participants' capability. The participants in both groups may be interviewed online for process evaluation requirements; and 10 participants from the intervention group for the embedded qualitative study.

What are the possible benefits and risks of participating?

Benefits

This study provides an opportunity for participants to learn new exercise movements which may help to improve health and well-being. The exercises will be delivered in a group format (either in person or via video-link), and participants may find some benefit from meeting up with other people.

Risks

This study will provide specially designed exercise movements suitable for older adults, which

are of low to moderate intensity. Unexpected serious adverse events may occur but most likely will not be research-related events. Participants may experience some muscle/joint ache after taking part, but this risk is low.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
March 2020 to December 2023

Who is funding the study?
The study is funded by the Libyan Embassy - Cultural Attache.

Who is the main contact?
Ms Ahlam Abu Elkhair, ahlam244@liverpool.ac.uk

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

286914

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 286914, CPMS 49781

Study information

Scientific Title

Adaptation and implementation of health Qigong and Tai Chi exercises on quality of life and physical functioning in patients with atrial fibrillation: a feasibility study

Study objectives

To assess the feasibility of a future randomised controlled trial of Tai Chi and Qigong for patients with atrial fibrillation in terms of patients' acceptability and capability to continue the programme and satisfaction with it, in addition to evaluating health-related quality of life and physical functioning.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/08/2021, North West - Liverpool Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 21/NW/0183

Study design

Interventional randomized controlled trial feasibility study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Tai Chi and Qigong for patients with atrial fibrillation.

Interventions

Current intervention as of 27/12/2023:

Approximately 106 participants will be recruited from primary care. The study took place online via the virtual platform (Zoom). The participants were randomly assigned to either the control (usual care) or intervention group (Tai Chi/Qigong). The exercise group learned a Tai Chi and Qigong routine, led by a qualified instructor. All the movements were carried out according to the participants' capabilities.

The participants in both groups may be interviewed online for process evaluation requirements; and 10 participants from the intervention group for the embedded qualitative study.

Participants in the control group will receive usual care for the management of atrial fibrillation, consisting of stroke prevention (oral anticoagulation), AF-symptom management (rate and/or rhythm control), and management of cardiovascular and other comorbidities, as appropriate.

Participants in the intervention group will practise Qigong and Tai Chi exercises for 60 minutes for up to three sessions per week (one session minimum) for 12 weeks, either in the local community centre or online via Zoom in groups.

Patients will also receive usual care for the management of atrial fibrillation.

Previous intervention:

Approximately 106 participants will be recruited from primary care. The study will take place in the community centres and/or online via the virtual platform (Zoom). The participants will be randomly assigned to either control (usual care) or intervention group (Tai Chi/Qigong). The exercise group, will learn a Tai Chi and Qigong routine, led by a qualified instructor. All the movements will be carried out according to the participants' capability.

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Participants in the intervention group will practise Qigong and Tai Chi exercises for 60 minutes for up to three sessions per week (one session minimum) for 12 weeks, either in the local community centre or online via Zoom in groups. Patients will also receive usual care for the management of atrial fibrillation.

Intervention Type

Other

Primary outcome(s)

Recruitment rate and retention rate at baseline, during 12 weeks of the intervention:

1. Recruitment rate: the number of the returned consent-to-contact forms will be calculated from the total number of invitations sent to eligible patients (response rate). The total number of those who will attend the intervention will be counted and will be divided by the number of invitations sent.
2. Retention rate: the number of sessions that participants attend over the 12 weeks will be collected and whether they complete the whole session each time or not. 100% attendance will be recorded as a minimum of one session per week for 12 weeks.

Key secondary outcome(s)

Current secondary outcome measures as of 27/12/2023:

1. Health-related quality of life and physical functioning assessed using the Short Form 12-item questionnaire (SF-12), Atrial Fibrillation Effect on Quality-of-life (AFEQT) Questionnaire, and the EuroQol questionnaire (EQ-5D) at baseline, 6 and 12 weeks
2. Patient satisfaction with the intervention was measured using a researcher-developed questionnaire at 12 weeks

Previous secondary outcome measures:

1. Health-related quality of life will be assessed using the Short Form 12-item questionnaire (SF-12), Atrial Fibrillation Effect on Quality-of-life (AFEQT) Questionnaire, and the EuroQol questionnaire (EQ-5D), at baseline, 6 and 12 weeks
2. Physical functioning will be measured by the 6-minute walk test (6MWT), at baseline, 6 and 12 weeks
3. Balance, gait and mobility will be measured by The Short Physical Performance Battery test (SPPB), at baseline, 6 and 12 weeks
4. Patient satisfaction with the intervention will be measured using a researcher-developed questionnaire, at 12 weeks

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of AF.
2. Able to understand spoken English.
3. Able to provide written informed consent.
4. Adults aged ≥ 18 years old.

5. If social distancing due to COVID-19 persists: the participants should have internet access at home and download free Zoom software onto a computer, mobile phone, or any electronic tablet or TV for delivery of the exercise intervention.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

74

Key exclusion criteria

1. Pre-existing medical condition preventing safe exercising (i.e., inability to stand unaided).

Date of first enrolment

18/01/2022

Date of final enrolment

30/04/2023

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

Edge Hill Youth and Community Centre

79 Durning Road

Liverpool

United Kingdom

L7 5ND

Sponsor information

Organisation

University of Liverpool

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Government

Funder Name

Libyan Embassy - Cultural Attache

Results and Publications

Individual participant data (IPD) sharing plan

The data will be held at the University of Liverpool. Requests for de-identified data can be made, along with details on the planned analyses. Data will not be available until 2025. All data will be de-identified. All participants will provide written informed consent.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |
| Other unpublished results | | | 13/12/2024 | No | No |