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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

Submission date
28/02/2022

Recruitment status
No longer recruiting

Registration date
25/03/2022

Overall study status
Completed

Last Edited
13/12/2024

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
286914

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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.
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.

Intervention Type
Other

Primary outcome measure
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.

Secondary outcome measures
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

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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

Overall study start date

01/03/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
106

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
England

United Kingdom

Wales

Study participating centre
Edge Hill Youth and Community Centre
79 Durning Road
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United Kingdom
L7 5ND

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Libyan Embassy - Cultural Attache

Results and Publications

Publication and dissemination plan
The obtained results from this study will be published in scientific journals and reported at scientific conferences and meetings. In addition, all participants will be informed of the study results once published.

Intention to publish date
31/12/2024

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