ISRCTN11721294 https://doi.org/10.1186/ISRCTN11721294

Rehabilitation for cardiac arrhythmia

Submission date	**Recruitment status**	[X] Prospectively registered
02/03/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/08/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/07/2022	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart condition that causes irregular and often fast heartbeat.
The common symptoms associated with AF are palpitations, chest pain, shortness of breath, fatigue, dizziness, sweating, sleep disturbance, exercise intolerance, anxiety and depression which affects the quality of life (QoL).
Evidence has shown that hospital-based rehabilitation programme benefits AF patient through improving their physical activities, mental health, ability to perform social activities and overall quality of life.
In this study, we aim to understand the impact of the symptoms of AF upon patients, their attitude and expectation toward rehabilitation programme in this condition. We also aim to understand the attitude and expectation of health care professionals toward delivering rehabilitation programme to patients with AF.
Recent studies reported that patients who recovered from COVID-19 may continue to experience symptoms including fatigue, shortness of breath and irregular heartbeats. But this is not true for everyone.
Evidence has shown that physical rehabilitation programmes have a positive effect in improving patients condition and reduce disease-related symptoms such as shortness of breath, cough, palpitation and severe fatigue. However, the effect of the rehabilitation programme on reversing abnormal heart rhythm in patients with COVID-19 has not yet been studied.
In this study we aim to evaluate the benefits of the programme on reversing any cardiac rhythm disturbance that we may or may not detect.

Who can participate?
Patients 18 years or older with AF.
Health care professionals involved in the care of patients with AF.
Patients who recovered from COVID-19.

What does the study involve?
The study will involve 3 stages
1. Surveys and interviews to understand patients attitude and expectation toward rehabilitation programme for AF
2. Surveys and interviews to understand health care professionals attitude and expectation toward rehabilitation programme for AF
3. Evaluation of the benefits of the programme on reversing any cardiac rhythm disturbance by

recording the heart rate, and perform exercise tests and questionnaire before and after 6 weeks of the rehabilitation programme

What are the possible benefits and risks of participating?
Participants will have the opportunity to discuss their condition with a trained professional and describe their views about rehabilitation. and it may help us understanding the effect of rehabilitation on the heart function therefore benefiting other patients.
There are no anticipated risks in taking part and the research team are happy to reimburse the travel cost.

Where is the study run from?
Glenfield Hospital, University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2023

Who is funding the study?
Saudi Arabian Cultural Bureau (SACB).

Who is the main contact?
Prof. Sally Singh, sally.singh@uhl-tr.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Sally Singh

Contact details
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
+44 (0)1162 583388
sally.singh@uhl-tr.nhs.uk

Type(s)
Public

Contact name
Miss Munyra Alhotye

Contact details
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

+44 (0)7311 661834
ma880@leicester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289997

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 289997

Study information

Scientific Title
Rehabilitation for cardiac arrhythmia in COVID-19 and non-COVID-19 patients

Study objectives
The aims of the study are:
1. To understand patients experience with AF, attitude and expectation toward rehabilitation programme, their facilitator and barriers to the programme
2. To understand the attitude of health care professionals who are involved in the care for patients with AF toward disease management, exercise for AF patients and facilitators and barriers to rehabilitation programme
3. To explore the impact of the rehabilitation programme on autonomic nervous system and cardiac functions in patients with COVID-19

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2021, Leicester South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44(0)207 104 8372; leicestersouth.rec@hra.nhs.uk), ref: 21/SC/0172

Study design
Single centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Stage 1:
Part a. eligible patients will be contacted to answer a survey by phone, they will be asked about their AF symptoms, their perception and preference to rehabilitation programme and which programme delivery method they would prefer, they also will be asked about their internet usage and their exercise habit.
Part b. the second part will be a recorded qualitative interview through the phone, they will be asked about their experience with AF, how it affected their daily life and activity, their barriers and facilitators to rehabilitation programme.

Stage 2:
Healthcare professionals will be invited for a recorded qualitative interview conducted either face to face or by phone, they will be asked about their general attitude and views toward AF management, implementation of rehabilitation programme contents, and barriers and facilitators to rehabilitation programme.

Stage 3:
Participants will attend several hospital visits. The first visit will ensure eligibility and perform some exercise tests, questionnaires and heart activity will be recorded using an ECG monitor. The second visit will be one week later after they have worn an activity monitor for 1 week. in this visit, they will start their twice-weekly rehabilitation programme which includes exercise and education sessions for 6 weeks. On week 5 an activity monitor will be worn for the final week of rehabilitation sessions. after 6 weeks, the final visit will repeat the previous measures and this will conclude the study.
The total duration of this study is 8 weeks.

Intervention Type
Behavioural

Primary outcome measure
Autonomic function measured using 12-Leads NORAV ECG Holter device to record the heart activity for 10 minutes and 24 hours at baseline and after rehabilitation programme (6 weeks)

Secondary outcome measures
1. Physical activity (using GT3x Actigraph) for seven days before starting the programme and in the last week of the programme
We will assess the following outcome measures which are routinely collected at baseline and after 6-weeks of the programme:
2. Health related quality of life by using The EuroQual 5 domain (EQ5D)
3. Exercise capacity by using incremental shuttle walking test (ISWT)

4. Disease symptoms by using COPD Assessment Test (CAT)
5. Fatigue by using Functional Assessment Chronic Illness Therapy Fatigue scale (FACIT-FS)
6. Anxiety and mental health will be measured by using the Hospital Anxiety and Depression Scale (HADS)

For stage 1&2 of the study:
1. Patients attitude and expectation toward rehabilitation programme will be assessed using surveys and qualitative interviews.
2. Health care professionals attitude and expectation toward rehabilitation programme will be assessed using surveys and qualitative interviews.

Overall study start date
01/03/2021

Completion date
31/03/2023

Eligibility

Key inclusion criteria
For stage 1:
1. 18 years or older
2. Have a clinical diagnosis of AF and awaiting ablation
4. Able to exercise and understand exercise instructions
5. Able to speak and read English
6. Willing and able to provide informed consent for participation in the study

For stage 2:
1. 18 years or older
2. Health care professionals who are involved in the care for patients with AF
3. Willing and able to provide informed consent for participation in the study

For stage 3 (the observational study):
1. 18 years or older
2. Have a clinical diagnosis of COVID-19
3. Enrolling into post COVID-19 rehabilitation programme
4. Able to speak and read English
5. Willing and able to provide informed consent for participation in the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
For stage 3:
1. Patients with known AF or any type of arrhythmia
2. Patients using beta blockers

Date of first enrolment
01/09/2021

Date of final enrolment
30/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
University Hospitals of Leicester
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Head of Research Operations
Research Office
Trust Headquarters
Leicester
England
United Kingdom
LE1 5WW
+44 (0)1162 584109
uhlsponsor@uhl-tr.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
Saudi Arabia Cultural Bureau in London

Alternative Name(s)
Royal Embassy of Saudi Arabia Cultural Bureau in London, Royal Embassy of Saudi Arabia - Cultural Bureau in London, Royal Embassy of Saudi Arabia Cultural Bureau, SACB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer review journal and disseminated at conferences. The results of the study will be shared with the patient once study has completed.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Stage 1 Patient Interview version 2	24/05/2021	10/08/2021	No	Yes
Participant information sheet	Stage 1 Patient Survey version 2	24/05/2021	10/08/2021	No	Yes
Participant information sheet	Stage 2 Staff Interview version 2	24/05/2021	10/08/2021	No	Yes
Participant information sheet	Stage 3 version 2	24/05/2021	10/08/2021	No	Yes
Protocol file	version 2.0	24/05/2021	10/08/2021	No	No
HRA research summary			28/06/2023	No	No