ISRCTN13724416 https://doi.org/10.1186/ISRCTN13724416

Mobile health technology supported rehabilitation for patients with atrial fibrillation

Submission date
14/06/2022

Recruitment status
No longer recruiting

Registration date
15/06/2022

Overall study status
Completed

Last Edited
08/08/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. It is an increasing global epidemic and public health challenge. Guideline-recommended integrated care based on the ABC (atrial fibrillation better care) pathway for 'general' patients with AF improves clinical outcomes. The ABC pathway refers to the following: Avoid stroke, Better symptom control, and Cardiovascular risk and comorbidity management, and it has been recommended in updated guidelines for the management of AF. The inappropriate prescription of oral anticoagulants (OACs) is common. Many AF patients are not anticoagulated according to their CHA2DS2-VASc risk score. Mobile Health (mHealth) and other innovative technologies are proposed for arrhythmia management. Nonetheless, mHealth-supported guideline-recommended treatment adoption in routine clinical care needs to be further clarified and adapted to the patient's risk profile and specific patient groups (e.g., for patients receiving drug treatment only, AF ablation, or left atrial appendage occlusion [LAAO]). This study aims to investigate whether mHealth technology-supported structured follow-up rehabilitation packages adapted to patient risk profiles and different treatment patterns (e.g., for patients receiving drug treatment only, AF ablation, or LAAO) will improve guideline adherence and reduce the risk of adverse cardiovascular events.

Who can participate?
Patients aged 18 years and over with AF

What does the study involve?
Participants will use the mobile Atrial Fibrillation Application (mAFA III) for the management of AF. The follow-up report and recommendation based on the updated patient's profile will be generated by mAFA III and proposed for the patients at 1, 2, 3, 6, 9, and 12 months to facilitate safe drug use, predict AF recurrence, and propose lifestyle modification to decrease the risk for recurrence after ablation. The patients will be followed up for adherence to the guideline-recommended treatment and cardiovascular events at 12 months.

What are the possible benefits and risks of participating?
Possible benefits to participation may include improved disease knowledge, timely communication with doctors, and the improvement of treatment adherence. This study does not involve any known physical risks or harm.

Where is the study run from?
Sixth Medical Center, Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
July 2020 to May 2024

Who is funding the study?
National Natural Science Foundation of China

Who is the main contact?
Dr Guo Yutao, guoyutao@301hospital.com.cn

Contact information

Type(s)
Principal Investigator

Contact name
Prof Yutao Guo

ORCID ID
http://orcid.org/0000-0002-7626-7751

Contact details
28 Fuxing Road
Haidian District
Beijing
China
100853
+86 (0)61055499311
guoyutao@301hospital.com.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Structured rehabilitation for patients with atrial fibrillation based on an integrated care approach: a prospective, observational cohort study

Acronym
SRAF Registry

Study objectives
It is hypothesized that mobile health technology-supported structured follow-up rehabilitation packages adapted to patient risk profiles and different treatment patterns (e.g., for patients receiving drug treatment only, atrial fibrillation [AF] ablation, or left atrial appendage occlusion [LAAO]) will improve guideline adherence and reduce the risk of adverse cardiovascular events.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/03/2021, Beijing Central Medical Ethics Committee of Chinese PLA General Hospital (6 Fucheng Road, 100048, Beijing, China; +86(0)10 66937166; Zhangyi@hz.com), ref: HZKY-PJ-2021-13

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not applicable

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

Interventions
In this prospective, observational cohort study, patients with atrial fibrillation aged ≥18 years will be enrolled using the mobile Atrial Fibrillation Application III for self-management. Assuming an annual rate of composite outcome of “ischaemic stroke or systemic embolism, all-cause death and cardiovascular hospitalization” of 29.3% for non-ABC pathway compliance compared with 20.8% for ABC pathway compliance, at least 1475 patients would be needed to detect the

outcome of the A, B and C components of the ABC pathway, assuming a withdrawal rate of 20% in the first year. The primary endpoint is adherence to guidelines regarding the A, B and C components of the ABC pathway. Ancillary analyses will be performed to determine the impact of the ABC pathway using smart technologies on the outcomes among the 'high-risk' population (e.g., ≥75 years old, with multimorbidities, with polypharmacy) and the application of artificial intelligence machine-learning AF risk prediction management in assessing AF recurrence. Patients with an AF burden who are taking anticoagulants will be monitored by photoplethysmography (PPG) and ECG technologies. Whether patients had compatible smart devices or experienced cardiovascular events, as well as the influence of mAFA III system support in reducing the heterogeneity of guideline adherence among primary care and Class I, Class II and III hospitals, is also assessed.

Intervention Type
Other

Primary outcome measure
Adherence to guidelines based on the ABC pathway and its individual components, measured with questionnaire or telephone or clinic visit at 1 year

Secondary outcome measures
Measured with questionnaire or telephone or clinic visit at 1 year:
1. The composite of stroke/thromboembolism, allcause death and rehospitalization:
1.1. The thromboembolism endpoint includes ischaemic stroke, transient ischaemic attack (TIA), pulmonary embolism, deep vein thromboembolism (DVT), and other thromboembolisms (e.g., peripheral embolism, atrial thrombus and left atrial appendage thrombus)
1.2. Allcause death will include cardiac death, vascular death and noncardiovascular death
1.3. Cardiac death includes death caused by STsegment elevation myocardial infarction/nonST segment elevation myocardial infarction (STEMI/NSTEMI), heart failure (HF), arrhythmia, cardiac perforation/tamponade and other deaths of cardiac origin
1.4. Vascular death will include death ascribed to ischaemic stroke, haemorrhagic stroke, systemic haemorrhage, peripheral embolism and pulmonary embolism
1.5. Rehospitalization for cardiovascular events will include stroke, systemic thromboembolism, angina, STEMI/NSTEMI, HF, and arrhythmia
2. AF recurrence after 3 months following AF ablation
3. Compliance with guideline-recommended antithrombotic management for patients undergoing LAAO or ablation plus LAAO
4. Event rates: event rate for the composite of ischaemic stroke/TIA and systemic thromboembolism, HF, cardiovascular death or rehospitalization for any cardiac cause
5. Quality of life

Overall study start date
01/07/2020

Completion date
01/05/2025

Eligibility

Key inclusion criteria

1. Patients aged ≥18 years old
2. Patients had >30-s AF on a 12-lead resting electrocardiogram or Holter
3. Patient informed consent form is signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1039

Key exclusion criteria
1. No ECG of AF is recorded
2. No informed consent is provided

Date of first enrolment
01/05/2021

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
China

Study participating centre
Sixth Medical Center of Chinese PLA General Hospital
6 Fucheng Road
Haidian District
Beijing
China
100048

Sponsor information

Organisation
Sixth Medical Center, Chinese PLA General Hospital

Sponsor details
28 Fuxing Road
Haidian District
Beijing
China
100853
+86 (0)10-66939206
jfjzyyhbhk@163.com

Sponsor type
Hospital/treatment centre

Website
https://www.301hospital.com.cn/index.html

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the ethics.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/07/2023	08/08/2023	Yes	No