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Pharmacist implementation of a treatment pathway for atrial fibrillation in care home residents

Submission date
28/09/2020

Recruitment status
No longer recruiting

Registration date
02/10/2020

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A team of researchers (a cardiologist, geriatrician, health psychologist and two pharmacists) at the University of Liverpool plan to carry out a study in care homes in Liverpool and South Sefton, United Kingdom, to find out how to best use medicines to treat older, frail people with an irregular heart rhythm called atrial fibrillation.

Atrial fibrillation is a heart condition that causes an irregular heart beat and it is very common in older people. People with atrial fibrillation are at increased risk of having a stroke caused by a blood-clot blocking one of the blood vessels supplying the brain. Frailty is related to the ageing process. As we get older, we are more vulnerable to a sudden decline in health after minor events, such as a medication change.

Atrial fibrillation in older people who are frail is often under-treated because doctors are concerned about causing more harm than good with medicines. The best way to manage atrial fibrillation is using a treatment plan known as the Atrial Fibrillation Better Care (ABC) Pathway. This involves prescribing medicines to prevent stroke, to relieve the symptoms of atrial fibrillation, and to treat other conditions that can worsen atrial fibrillation, such as heart failure, high blood pressure and diabetes. Currently, we do not know how easy it is to apply the ABC pathway to older people with atrial fibrillation who are frail, or whether this will improve their health. This research project will test this.

The information gathered from this research project will help healthcare professionals make appropriate decisions about how to best manage older people with atrial fibrillation who are frail and choose the most appropriate medications for them.

Who can participate?
People who live in care homes who are aged 65+ years who have atrial fibrillation and are frail will be asked to take part in the study.

What does the study involve?
Half of the people who take part in the study will have their medication reviewed by a pharmacist who will make treatment recommendations to their GP in line with the ABC pathway, and half will not. If people experience health events such as stroke, major bleeding, a fall, are admitted to hospital or die within the next 12-months, this will be recorded. People who take part in this project will also be asked questions about their quality of life, if they have any symptoms from their atrial fibrillation, and how much help they need carrying out usual day-to-day activities. We will also test their memory to see if this changes. Importantly, we will measure how easy it has been to apply the ABC pathway.

What are the possible benefits and risks of participating?
Better management of atrial fibrillation with medicines may improve quality of life, symptoms and help to prevent a stroke. It could also help to improve the management of some other conditions, like high blood pressure, diabetes, heart failure and high cholesterol.

There could be side effects if new medicines are started or there are changes made to current medicines. New diagnoses of conditions such as high blood pressure, heart failure, high cholesterol or diabetes may also be made. These conditions may be detected by the pharmacist from the research team who is reviewing medical notes and looking at tests results. If the pharmacist suspects that someone has a condition that they are not on treatment for, they will contact the person's GP to make a formal diagnosis and to start treatment if necessary.

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

When is the study starting and how long is it expected to run for?
September 2019 to May 2022

Who is funding the study?
1. Liverpool Centre for Cardiovascular Science (UK)
2. Wellcome Trust (UK)

Who is the main contact?
Miss Leona Ritchie (Principal Investigator and Pharmacist)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273359

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45912, Wellcome Trust Grant Code: 204822/Z/16/Z, IRAS 273359

Study information

Scientific Title
Pharmacist-led intervention for atrial fibrillation in long-term care.

Acronym
PIVOTALL

Study objectives
A pharmacist-led intervention of medicines optimisation, in line with the Atrial Fibrillation Better Care (ABC) pathway, can be implemented in care homes to improve medication management and outcomes for residents with atrial fibrillation (AF) and varying degrees of frailty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2020, Wales Research Ethics Committee 4 (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC4@wales.nhs.uk), ref: 20/WA/0164

Study design
Randomized controlled pilot and feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home

Study type(s)
Treatment

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

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

Interventions
This study is a pilot and feasibility study where participants will be randomly allocated to one of two treatment groups, the intervention or control group.

In the intervention group, participants' medication will be reviewed and optimised by a pharmacist (Principal Investigator) who will implement the Atrial Fibrillation Better Care pathway. This involves:
1) A - anticoagulation: prescribing medicines which thin the blood (called anti-coagulants) to prevent strokes caused by the blockage of the blood vessels in the brain.
2) B - better symptom control: prescribing medicines which help to improve the symptoms of atrial fibrillation (for example, palpitations, shortness of breath etc.).
3) C - cardiovascular risk factors: ensuring that medicines are prescribed to treat other conditions which can affect the management of atrial fibrillation, such as high cholesterol, high blood pressure, heart failure and diabetes.

Treatment suggestions will be put forward to the participants' GP who will decide whether to implement the suggestions at their discretion. Treatment suggestions for complex patients will be discussed with the wider multi-disciplinary research team, including a consultant geriatrician

and cardiologist, in advance of contacting the GP. When treatment recommendations are made to participants' GPs but they are not implemented, the GP will be sent a questionnaire to ascertain the reason(s) why.

In the control group, participants will receive their usual care and continue on their existing treatment plan. No changes to their medicines will be made as part of the study, but changes could still be made as part of their usual care. Any changes to medication will be recorded.

All participants (including those in the control and intervention group) will be asked to complete two self-complete quality of life questionnaires (EQ-5D-5L and Atrial Fibrillation Effect on Quality of Life questionnaires). If participants lack capacity, the Atrial Fibrillation Effect on Quality of Life questionnaire will be omitted but a carer/relative/friend will be asked to complete a proxy version of the EQ-5D-5L on the participant's behalf. All participants (including those in the control and intervention group) will also be asked to complete two researcher-administered assessments to assess their level of thinking and awareness (6-item cognitive impairment test) and frailty (Edmonton Frailty Scale). These questionnaires/assessments will be carried out at the start of the study and again at 6 months.

All other activities will be carried out independently by the researcher and include assessing participants' frailty (using the Rockwood Frailty Scale and the electronic frailty index), dependence in activities of daily living (using the Barthel Index of Activities of Daily Living), symptom control (measured using the Modified European Heart Rhythm Association Symptom Scale), medicines adherence, stroke risk and bleed risk. This will be at the start of the study and at 6 months. The researcher will also record participants' medical history at the start of the study and at 6 months. Medication history will be recorded for each participant at the start of the study, at 6 months and 12 months and health-related events will be recorded at 6 months and 12 months. Throughout the study, the researcher will collect
information to help assess the feasibility of the study.

Intervention Type
Other

Primary outcome measure
1. Care home recruitment rate measured during the 6 month recruitment period from the initial study start date
2. Participant recruitment rate measured during the 6 month recruitment period from the initial study start date
3. Participant retention rate measured at 6 months and 12 months
4. Number and nature of pharmacist medication-related recommendations (classified by type and drug(s) involved) measured at baseline
5. GP implementation of pharmacist recommendations measured at 6 months
6. Completion rate of participant self-complete questionnaires to assess generic health-related quality of life (EQ-5D-5L) and disease-specific quality of life (Atrial Fibrillation Effect on Quality of Life, AFEQT) measured at baseline and 6 months
7. Completion rate of researcher administered assessments requiring participant input to assess frailty (Edmonton Frail Scale, EFS) and cognitive function (6-item Cognitive Impairment Test, 6-CIT) measured at baseline and 6 months
8. Completion rate of GP questionnaire sent to ascertain the outcome(s) of pharmacist medicines recommendation(s) measured at 6 months
9. Percentage of missing/incomplete data for all questionnaires/assessments measured at baseline and 6 months

Secondary outcome measures
1. Generic health-related quality of life (EQ-5D-5L) and disease-specific quality of life (AFEQT) measured at baseline and 6 months
2. Health-related events (stroke, major bleeding, clots in the body, falls, hospitalisation and death) measured at 6 months and 12 months
3. Frailty measured using the EFS, Rockwood Clinical Frailty Scale and the electronic Frailty Index at baseline and 6 months
4. Cognitive function measured using the 6-CIT at baseline and 6 months
5. Level of dependence in activities of daily living measured using the Barthel Index of Activities of Daily Living at baseline and 6 months

Overall study start date
09/09/2019

Completion date
06/05/2022

Eligibility

Key inclusion criteria
1. Aged ≥65 years
2. Diagnosis of AF
3. Resident in a care home in Liverpool, South Sefton, Southport or Formby

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
21

Key exclusion criteria
1. Diagnosed with aphasia
2. Short-stay care home residents (expected stay <6 months)
3. Receiving end-of-life care
4. Non-English speaking

Date of first enrolment
01/11/2020

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
William Henry Duncan Building
Liverpool
United Kingdom
L7 8TX

Study participating centre
Care homes within Liverpool, South Sefton, Southport and Formby
-
United Kingdom
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Sponsor information

Organisation
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Sponsor type
University/education

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. The anonymised, amalgamated data will be uploaded onto the University of Liverpool repository (Liverpool Data Catalogue) so that it is available for public dissemination. There will be no participant-identifiable information uploaded, or information on which care homes or GP practices were involved. The data will be stored for 10 years and then securely destroyed. Hard copy case report forms will be securely destroyed using the confidential waste disposal provided by the University of Liverpool service management. The file which contains participant-identifiable information (the list of participants and their unique ID codes) will not be stored long-term or uploaded onto the Liverpool Data Catalogue. Instead, it will be stored confidentially by the research team (on the University M-drive) and securely destroyed after all publications related to the study have been completed and published. Liverpool Clinical Trials Unit will be responsible for archiving the Redcap database and will preserve this in line with their own standard operating procedures.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No

Results article	16/01/2024	22/01/2024	Yes	No