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Cognitive behavioural therapy to reduce anxiety and depression in atrial fibrillation

Submission date
15/05/2017

Recruitment status
Suspended

Registration date
25/05/2017

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] 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 an abnormal heart rhythm characterised by rapid and irregular beating. Often it starts as brief periods of abnormal beating which become longer and possibly constant over time. Most episodes have no symptoms. Occasionally there may be heart palpitations, fainting, light headedness, shortness of breath, or chest pain. The disease is associated with an increased risk of heart failure, dementia, and stroke. Some of the research suggests that this can lead to anxiety and depression in some patients. This study is looking at whether or not patients with AF experience anxiety and depression after being diagnosed and if so, whether or not psychological therapy can help to improve these symptoms. There are different types of psychological therapies, one of which is cognitive behavioural therapy (CBT). CBT is type of a talking therapy that helps people to manage their problems by changing the way they think and behave. It is most commonly used to treat anxiety and depression. The aim of the study is to investigate whether or not CBT helps to reduce anxiety and/or depression among patients with AF compared to usual care.

Who can participate?
Adults with AF who are depressed and/or anxious.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive up to 16 hour-long weekly sessions of CBT. These sessions include discussion of patients' current reported difficulties, their concerns and misconceptions surrounding the disease and its' treatment. Those in the second group receive usual care, which involves being given information about self-referral to Therapy services and/or be referred by their GP. At the start of the study and after six and twelve months, participants in both groups complete a range of questionnaires to assess their mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their anxiety and/or depression symptoms because of the therapy they receive. There are unlikely to be any risks of taking part however since these the in-depth therapy sessions may cause some feelings of distress. The therapist will provide support and they will be able to discuss any concerns with them.

Where is the study run from?
Sandwell and West Birmingham Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
34498

Study information

Scientific Title
Cognitive Behavioural Therapy to reduce anxiety and depression in patients with Atrial Fibrillation

Acronym
CBT-AF

Study objectives

The aim of the study is to investigate whether or not the new cognitive behavioural therapy (CBT) intervention helps to reduce anxiety and/or depression among patients with atrial fibrillation compared to people who receive usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands- South Birmingham Research Committee, 02/02/2017, ref: 16/WM/0502

Study design
Randomised; Interventional; Design type: Treatment, Screening, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety and depression in people with atrial fibrillation

Interventions
Participants will be recruited from GP practices and specialist AF clinics. The potential participant will be screened for eligibility using the GAD-7, PHQ-9, and AFSS questionnaires. Eligible patients will be invited to participate in the trial, consented and randomised, in their GP practice.

CBT arm (intervention arm): CBT will be led by one of two trained therapists and delivered individually, in the patient's GP practice. There may be up to 16 weekly sessions, each lasting up to 60 minutes, which will include discussion of patients' current reported difficulties, their concerns and misconceptions surrounding the disease and its' treatment. Intervention will begin with development of an individualised formulation and treatment plan and goals. Interventions will be chosen in accordance with this but are likely to include CB interventions and tailored to individual needs. Worksheet-based activities with individualised homework tasks will be utilised. Patients in the CBT group can be prescribed antidepressant and/or anti-anxiolytic by their GP, as deemed appropriate. Any newly prescribed psychiatric medication will be recorded. Where patients require further cognitive behavioural therapy sessions, over the allocated 16 sessions per patient, they will be referred for continued care by their GP (with their allocated therapist if possible).

Usual care (routine arm): Those randomised to usual care will be given information about self-referral to Therapy services and/ or be referred by their GP. Patients with moderate anxiety and /or depression could be offered guided self-help talking therapies/CBT by a psychological well-being practitioner, while those with severe anxiety and/or depression would be referred for individual CBT or group therapy while waiting for individual CBT. Researchers will document how many patients were referred, whether services were accessed, what level of treatment was required and how many sessions' patients attended. This information will be gathered by the discharge letters. Usual care will allow the GP to prescribe medication as deemed appropriate.

Follow-up for participants in both groups will take place at 6 and 12 months post randomisation. If patients in either group require additional treatment relating to their AF they will be referred to Professor Lip's AF clinic based at City Hospital.

Intervention Type
Other

Primary outcome(s)
1. Anxiety is measured by using the Generalised Anxiety Disorder -7 Questionnaire (GAD -7) at screening, beginning of each therapy session (CBT arm only) 6 and 12 month follow up
2. Depression is measured by using the Patient Health Questionnaire –9 (PHQ–9) at screening, beginning of each therapy session (CBT arm only) 6 and 12 month follow up

Key secondary outcome(s))
1. Subjective ratings of AF-related symptoms and AF disease burden will be captured using the Atrial Fibrillation Severity Scale (AFSS) at screening, baseline, beginning of each therapy session (CBT arm only) 6 and 12 month follow up
2. Health outcome is measured by using the EuroQoL-5D-5L Questionnaire (EQ-5D-5L) at baseline, 6 and 12 month follow-up
3. Patient satisfaction will be measured using the Patient satisfaction Survey at 6 and 12 months
4. Health-related quality of life (HRQoL) will be measured using one disease specific, the Atrial Fibrillation Effects on QualiTy –of-Life (AFeQT) questionnaire at baseline, 6 and 12 month follow-up
5. The physical and mental HRQoL will be measured using the Short Form- 12 health questionnaire at baseline, 6 and 12 month follow-up
6. Functional impairment which attributes to the anxiety and/or depression will be measured using the Work and Social Adjustment Scale (WSAS) at baseline, 6 and 12 month follow-up

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Diagnosed with atrial fibrillation (AF) within the last 12 months
3. Defined as ‘case’ (score of ≥8 on the GAD-7 and ≥10 on the PHQ-9)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Diagnosed with AF for longer than 12 month
2. Terminal illness
3. Cognitive impairment which prevents them from being able to give informed consent
4. Unable to speak and/or read English.

Date of first enrolment
01/09/2017

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
Dudley Road
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from CBT-AF@contacts.bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

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