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Trial of Sertraline versus CBT for generalised Anx

Submission date	Recruitment status	[X] Prospectively registered
04/02/2015	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/02/2015	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/07/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Everyone experiences worry and anxiety now and then, but for some people it's difficult to control these feelings. These people may develop a condition called generalized anxiety disorder (GAD). People who have GAD feel anxious most days, which can lead to a number of debilitating mental and physical symptoms. This study will compare the effectiveness of Sertraline, a drug that increases the activity and levels of certain chemicals in the brain that may help people with GAD and Cognitive Behavioural Therapy (CBT) for anxiety symptoms for people with GAD.

Who can participate?

Adults (aged 18 and over) who have failed to respond to "low intensity" psychological interventions delivered by an Increasing Access to Psychological Therapies Service (IAPT) will be invited to participate.

What does the study involve?

After an initial assessment, participants are randomly allocated into one of two groups. Those in group 1 are treated with Sertraline for a year. Those in group 2 receive 14-16 CBT sessions. All participants are assessed for GAD 12 months after starting the study.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

A number of IAPT services in the UK

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

February 2015 to January 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Marta Buszewicz

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-004077-16

IRAS number

ClinicalTrials.gov number
NCT02347033

Secondary identifying numbers
18345

Study information

Scientific Title
A Phase IV randomised controlled trial of the selective serotonin reuptake inhibitor Sertraline versus Cognitive Behavioural Therapy for anxiety symptoms in people with Generalised Anxiety Disorder (GAD) who have failed to respond to low intensity psychological interventions as defined by the NICE GAD guidelines

Acronym
ToSCA

Study objectives
A phase IV randomised controlled multi-centre trial of the selective serotonin reuptake inhibitor Sertraline versus Cognitive Behavioural Therapy for anxiety symptoms in people with Generalised Anxiety Disorder (GAD) who have failed to respond to low intensity psychological interventions delivered by an Increasing Access to Psychological Therapies Service (IAPT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/2105; First MREC approval date 03/12/2014

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Anxiety; Disease: Anxiety

Interventions
1. Cognitive Behavioural Therapy: CBT will be delivered by high intensity therapists from local IAPT services. They will provide 14 to 16 sessions of a manualised treatment developed for use in GAD and will be trained in its delivery.
2. Sertraline: The medication sertraline prescribed by their GP according to a trial protocol matching current clinical recommendations and within a dosage between 25 and 150mg daily. We will ask GPs to review patients regularly (at least 6 times in 12 months) and patients to take the medication for a year unless they have significant adverse effects. Side-effects will be regularly monitored.
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sertraline

Primary outcome measure
Current primary outcome measures as of 06/07/2016:
HADS-A measured at 12 months. This is the 7-item anxiety component of the HADS (Hospital Anxiety and Depression Scale) a very widely used 14-item scale that can be self-administered. It has a high validity and reliability and the anxiety and depression components have been assessed separately as primary outcomes.

Previous primary outcome measures:
GAD-7; Timepoint(s): A 7-item self-complete questionnaire with very good sensitivity (89%) and specificity (82%) for GAD

Secondary outcome measures
1. Employment and Social Care questionnaire (ESC)
2. Euroquol (EQ-5D)
3. Hamilton Anxiety Rating Scale (HAM-A)
4. Health Service Outcomes
5. Patient acceptability measure (CSQ)
6. Patient Health Questionnaire (PHQ-9)
7. Patient preference rating scale
8. Work and Social Adjustment Scale (WSAS)

Overall study start date
01/02/2015

Completion date
08/02/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Gender: Male or female
3. Positive score of 10+ on GAD-7
4. Primary diagnosis of GAD as diagnosed on the Mini-International Neuropsychiatric Interview (M.I.N.I.)
5. Failure to respond to NICE defined step 1 and 2 low intensity psychological interventions for GAD

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Key exclusion criteria
1. Inability to complete questionnaires due to insufficient English or cognitive impairment
2. Current major depression
3. Other comorbid anxiety disorder(s) of more severity or distress to the participant than their GAD
4. Significant dependence on alcohol or illicit drugs
5. Comorbid psychotic disorder, bipolar disorder
6. Treatment with antidepressants in past 8 weeks or any high intensity psychological therapy within past 6 months
7. Currently on contraindicated medication: monoamine oxidase Inhibitors within the past 14 days or pimozide.
8. Patients with poorly controlled epilepsy
9. Concurrent enrolment in another IMP (medication) trial
10. Women who are currently pregnant or planning pregnancy or lactating
11. Severe hepatic impairment
12. Patient on anti-coagulants
13. History of a bleeding disorder

Date of first enrolment
01/07/2015

Date of final enrolment
08/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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