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Cognitive behaviour therapy for epilepsy: improving seizure control and quality of life

Submission date	Recruitment status	[ ] Prospectively registered
26/11/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/08/2020	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Cognitive behaviour therapy for epilepsy: improving seizure control and quality of life - a pilot randomised controlled trial

Study objectives
This is a pilot/feasibility study investigating the use of cognitive behaviour therapy (CBT) plus standard medical care vs standard medical care alone in improving seizure control and quality of life in adults with refractory epilepsy. Specifically this feasibility study will enable us to:
1. Evaluate the applicability of our CBT techniques to a broader sample of patients than in our previous work
2. Determine the acceptability of this randomisation and treatment approach in a sample of patients attending specialist epilepsy clinics, thereby informing recruitment rates when designing a later, larger randomised controlled trial (RCT)
3. Obtain information on treatment effect sizes to undertake power calculations for a larger RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint South London and Maudsley and the Institute of Psychiatry NHS Research Ethics Committee, 04/07/2008, ref: LREC 08/H0807/44

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Epilepsy

Interventions
Following baseline recording of seizure frequency participants will be randomly assigned to one of two arms:

CBT (plus standard medical care):
CBT will comprise 12 weekly/fortnightly individual therapy sessions with the CBT therapist, over 4 months. Treatment will follow our prepared treatment manual, with homework tasks and seizure recordings reviewed at each session. In addition to seizure-specific interventions (e.g. development of countermeasures), more general cognitive behavioural therapeutic techniques will be employed to address the management of times of increased vulnerability to seizures and to improve patients overall physical and emotional well-being, with a view to relapse prevention. Handouts will be given to participants.

Standard medical care:
Participants will be seen by their epilepsy specialist in their regular clinic, depending on clinical need. As with the CBT group, we will monitor the number of appointments that participants have with their epilepsy specialist over the 4-month period and whether any medication changes are implemented during that time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Monthly seizure frequency, monitored throughout the study. Total duration of follow-up: 12 weeks.

Secondary outcome measures
1. Liverpool Seizure Severity Scale at baseline, 8 and 12 weeks
2. Hospital Anxiety and Depression Scale at baseline, 8 and 12 weeks
3. Quality of Life in Epilepsy Inventory-31 (QOLIE-31) at baseline, 8 and 12 weeks
4. Health service usage for previous 8 weeks, assessed using the Client Service Receipt Inventory (CSRI) at baseline, beginning of treatment, 8-week follow-up and for previous 4 weeks at 12 week follow up
5. Health status, assessed by Euroqol EQ-5D at baseline, 8 and 12 weeks

Overall study start date
01/12/2008

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Both males and females, age 18-65 years
2. Clinical diagnosis (with supporting electroencephalography [EEG]) of epilepsy
3. A maximum of 40 seizures/month involving alteration/loss of consciousness (i.e. complex partial or generalised seizures) with no limit to simple partial seizure frequency
4. Stable medication for the month prior to recruitment
5. Able to attend weekly/fortnightly sessions
6. Willing to complete questionnaires regularly to monitor progress

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Total final enrolment
26

Key exclusion criteria
1. History of, or current actual/suspected non-epileptic seizures
2. <2 seizures per month in each of the preceding four months
3. Active major psychiatric disorder
4. Drug/alcohol dependence
5. Receiving active vagus nerve stimulation (VNS) for seizures that has been adjusted within the previous 12 months
6. Insufficiently fluent in English to be able to undertake treatment and complete questionnaires without the assistance of an interpreter
7. Established learning disability (or where this has been measured formally, IQ <70)

Date of first enrolment
01/12/2008

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Psychology
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Institute of Psychiatry, King's College London (UK)

Sponsor details
c/o Mrs G Lambert
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Sponsor type
University/education

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Epilepsy Research UK (UK) (ref: P0805)

Alternative Name(s)
ERUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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?
Basic results		07/07/2017	07/08/2020	No	No