

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

<b>Submission date</b> 26/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/08/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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  
Research Governance/Clinical Trials Facilitator IoP/SLaM  
R&D Office  
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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?
<a href="#">Basic results</a>		07/07/2017	07/08/2020	No	No