

# 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
<b>Registration date</b> 10/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/08/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Primary study design**

Interventional

## **Study design**

Randomised controlled trial

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

All

**Total final enrolment**

### **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**

United Kingdom

England

### **Study participating centre**

**Department of Psychology**

London

United Kingdom

SE5 8AF

## **Sponsor information**

### **Organisation**

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

### **ROR**

<https://ror.org/0220mzb33>

## **Funder(s)**

### **Funder type**

Charity

**Funder Name**

Epilepsy Research UK (UK) (ref: P0805)

**Alternative Name(s)**

Epilepsy Research UK, The Epilepsy Research Institute, ERUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### 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