

# Epilepsy nurse trial for adults with intellectual disabilities

<b>Submission date</b> 25/03/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/02/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nearly a million adults in England have an intellectual disability (ID). Epilepsy is the most common medical illness in this group, occurring in around 26%, with even higher rates in those with more severe ID. It has a worse outcome than epilepsy in the general population, with more seizures, more multiple antiepileptic drug use and side effects, higher treatment costs and higher illness and death rates. In adults with ID and epilepsy there are suggestions that improvements may follow introduction of epilepsy nurse (EN)-led epilepsy care. However, this has not been tested in a study. Results cannot be generalised from general population studies given the more severe epilepsy and additional clinical problems of adults with ID. The primary objective of this study is to establish whether nurses with expertise in epilepsy and intellectual disabilities (ID) can improve clinical and quality of life outcomes in the management of epilepsy in adults with (ID) compared to treatment as usual. The main secondary objective will be to establish whether any perceived benefits represent good value for money.

### Who can participate?

Participants will be adults (male and female), aged 18-65 years. They will all have a developmental intellectual disability associated with an IQ of 70 or less and a diagnosis of epilepsy with a history of at least one seizure in the 6 months preceding recruitment into the study.

### What does the study involve?

The new EN treatment will be individually focused active support and management by an epilepsy nurse working according to a specific set of guidelines developed by the UK Epilepsy Specialist Nurse Association in association with the UK Royal College of Nursing. This will be compared against treatment as usual, which will be the existing management approach that includes different combinations of input by ID psychiatrists, neurologists, ID and epilepsy nurses. The new treatment will take place in participants' homes and day-care facilities. Participants will belong to a group called a cluster. Each cluster will include 34 adults with ID who have had at least one seizure in the past 6 months. Six clusters will be randomly allocated to EN treatment and six clusters to 'treatment as usual' (a total of 408 participants in the study).

What are the possible benefits and risks of participating?

Those participants in the treatment as usual group will receive their usual treatment and should notice no difference in their treatment as a consequence of being in the study. Those participants allocated to the EN treatment will receive more responsive and individual treatment and the aim of the trial is to see if this different treatment approach reduces the severity of their epilepsy or the range of anti-epileptic drug-related side-effects that they may experience. We do not expect there to be any specific side-effects from the change in treatment.

Where is the study run from?

The study is being run from the University of Cambridge, UK. The study will take place in 12 clinical services from around the UK.

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

The study is planned to start around June 2013 and to run for 32 months. It will be actively recruiting participants for about 8 months. Once recruited each participant is likely to remain in the study for 7 months.

Who is funding the study?

The study is funded by a grant from the National Institute of Health Research (NIHR UK) Health Technology Assessment (HTA) programme.

Who is the main contact?

Dr Howard Ring  
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## Contact information

### Type(s)

Scientific

### Contact name

Dr Howard Ring

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## Additional identifiers

### Protocol serial number

HTA 10/104/16

## Study information

### Scientific Title

Improving outcomes in adults with epilepsy and intellectual disability: a cluster randomised controlled trial of nurse-led epilepsy management (EpAID)

**Acronym**

EpAID

**Study objectives**

Analysis will test whether there is a significant difference in reduction in seizure severity between participants in the competency framework arm and those in the treatment as usual arm. The primary treatment outcome will be the difference between baseline and 6-month ELDQoL-SSS measurement.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/1010416>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0014/81131/PRO-10-104-16.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0014/81131/PRO-10-104-16.pdf)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee London Queen Square, 10/02/2014

**Study design**

Two-arm cluster randomised prospective trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Epilepsy and intellectual disability

**Interventions**

The novel intervention to be trialled is a defined competency-based nursing intervention, based on the Epilepsy Specialist Nurse Association (ESNA) EN competency framework for adults with ID. This has been developed by a team of expert ENs for ID and is soon to be endorsed by the Royal College of Nursing and ESNA. It is modeled on the competency framework and guidance for developing paediatric epilepsy nurse specialist services available at [http://www.rcn.org.uk/\\_\\_data/assets/pdf\\_file/0004/78673/002792.pdf](http://www.rcn.org.uk/__data/assets/pdf_file/0004/78673/002792.pdf).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

The seizure severity scale from the Epilepsy in Learning Disabilities Quality of Life (ELDQOL-SSS) instrument. This is completed by carers and provides a detailed measure of the physical severity

of seizures experienced in the preceding 4 weeks, including any associated injuries and the level of distress manifest by the patient after a seizure. This will be collected after 6 months in the trial.

### **Key secondary outcome(s)**

1. Cost-utility analysis. As part of this economic evaluation clinical demands on other health agencies, including GP, community ID team, Accident and Emergency and neurology services, will be determined, with data recorded using the Client Service Receipt Inventory over the final 2 months of participation in the trial.
2. Carer Strain Index. This will measure the effect of the intervention on carers and patients after 6 months in the trial.
3. EQ-5D, collected after 6 months in the trial, will be used in conjunction with other data collected to calculate QALYs. This will permit not only a cost-utility analysis but also comparison with the primary outcome measure (ELDQOL-SSS) in terms of sensitivity to change.
4. Carer preferences identified by willingness to pay methods. Mean willingness-to-pay values for each service will provide a measure of the strength of preference across the two service options, collected after 6 months in the trial.
5. Mean number of seizures per month. This will be derived by averaging the number of seizures per month experienced by participants over the final 2 months of the trial period. It is likely that a significant proportion of participants will have more than one seizure type. Seizure frequency data will record number of types of seizures and numbers of each type of seizure. These data will be collected from seizure diaries which participants family carers or paid support workers will complete daily. (The keeping of seizure diaries is a routine part of epilepsy management and a process likely to already be familiar to those who will be asked to keep these diaries).
6. ELDQoL subscales for side-effects, mood and behaviour collected after 6 months in the trial.
7. A series of qualitative semi-structured interviews of samples of clinicians, family and paid carers which will examine how the competency framework, compared to treatment as usual, impacts on relationships between the EN and family/paid carers with respect to:
  - 7.1. Reported perceptions of patient health and quality of life
  - 7.2. The involvement of patients in treatment decisions
  - 7.3. The active engagement of carers with clinical epilepsy services

### **Completion date**

30/11/2016

## **Eligibility**

### **Key inclusion criteria**

1. Age 18 - 65 years
2. The presence of a developmental intellectual disability with IQ of 70 or less
3. A diagnosis of epilepsy with a history of at least one seizure in the 6 months preceding recruitment into the study (not considered by those managing the epilepsy to have been a non-epileptic seizure)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. The presence of a rapidly progressive physical or neurological illness
2. Alcohol or drug dependence

**Date of first enrolment**

01/06/2013

**Date of final enrolment**

31/01/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Douglas House**

Cambridge

United Kingdom

CB2 8AH

## **Sponsor information**

**Organisation**

University of Cambridge and Cambridgeshire and Peterborough NHS Foundation Trust (UK)

**ROR**

<https://ror.org/040ch0e11>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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="#">Results article</a>	results	01/02/2018		Yes	No
<a href="#">Protocol article</a>	protocol	24/06/2016		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes