ISRCTN96895428 https://doi.org/10.1186/ISRCTN96895428

Epilepsy nurse trial for adults with intellectual disabilities

Submission date
25/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
21/02/2018

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

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

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.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/06/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
408

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
England

United Kingdom

Study participating centre
Douglas House
Cambridge
United Kingdom
CB2 8AH

Sponsor information

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

Sponsor details
University of Cambridge Research Operations Office
16 Mill Lane
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

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?
Protocol article	protocol	24/06/2016		Yes	No
Results article	results	01/02/2018		Yes	No