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Seizure first Aid training For Epilepsy: intervention development and pilot RCT

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
23/04/2015

Overall study status
Completed

Last Edited
19/05/2023

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
Epilepsy is a neurological condition that results in repeated seizures, or “fits”. These seizures are caused by a sudden burst of intense electrical impulses in the brain. This can cause the brain to function in an abnormal way. Even with treatment, one third of people with epilepsy continue to have seizures. Seizures can be frightening. Most though, stop by themselves and the person recovers without medical attention. The NHS does not offer a epilepsy course that epilepsy sufferers and their informal carers can go on. Consequently, some do not know seizure first aid, are unsure about the effects of a seizure and are fearful. This leads many to visit A&E when they have a seizure. These visits are inconvenient for patients and costly to the NHS. We want to develop a short group course called ‘Seizure first Aid training For Epilepsy’. It will be based on a half-day course offered by the Epilepsy Society.

Who can participate?
Patients diagnosed with epilepsy will be recruited from three Merseyside A&Es.

What does the study involve?
The course needs to be adapted so it is relevant to patients attending A&E. To do this, patients from A&E and carers attend the existing course and asked what changes are needed. To ensure its medical content is correct, we seek advice from health professionals.Participants and their carers are then recruited into the study and asked to complete a questionnaire about how confident they are in managing seizures and use of A&E. Patients are then randomly assigned to one of two groups. Participants in both groups continue to take their medications and see their doctors as normal. One group attends a ‘Seizure first Aid training For Epilepsy’ course with their carer (the ‘intervention group’). The other (the ‘control group’) does not. We ask patients and carers to fill in the questionnaire again 6 and 12 months later. The pilot trial is a practice run and it will tell us how best to do a bigger trial in the future to test how well the ‘Seizure first Aid training For Epilepsy’ works. At the end of the trial, the control group get to go on the ‘Seizure first Aid training For Epilepsy’ programme.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2016.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Adam Noble

Contact information

Type(s)
Scientific

Contact name
Dr Adam Noble

Contact details
University of Liverpool
Institute of Psychology, Health & Society,
The Whelan Building
Liverpool
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18717

Study information

Scientific Title
‘Seizure first Aid training For Epilepsy’ (SAFE) for people with epilepsy who attend emergency departments, and their family and friends: intervention development and pilot.

Acronym
SAFE

Study objectives

The aim of this study to to develop and evaluate a short group course called ‘Seizure first Aid training For Epilepsy’.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee North West - Liverpool East , 13/04/2015, ref: 15 /NW/0225

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Neurological disorders; Subtopic: Neurological (all Subtopics); Disease: Epilepsy

Interventions
1. Seizure First Aid Training: The exact content of the 'Seizure first Aid training For Epilepsy' programme will be determined during Part A of the project. Broadly speaking, it will consist of a 3-hour course (with breaks included) run by locally based Epilepsy Society trained educational facilitators. Participants will receive the course in addition to their usual care.
2. Treatment as Usual: The active intervention will be compared to TAU alone. The appropriate control comparison for the study will be TAU by the PWE’s normal care team.

All control participants will be offered access to the 'Seizure first Aid training For Epilepsy' programme once the study has finished. These courses will be run once all retained patient and carer participants from both arms have completed their 12 month follow up assessments.
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure

1. Intervention development phase of project:
Not applicable.

2. Pilot RCT phase of project:
The pilot will not be powered to detect a clinically meaningful difference in outcome between treatment groups, summary statistics will be calculated to measure the effect of the intervention on the proposed primary and secondary outcome measures for a future definitive trial and the precision of such estimates at the post-treatment time points.

3. Proposed primary outcome measure:
The number of epilepsy-related emergency department (ED) visits made over the 12 months following randomisation by patient participant. This will be measured using routinely collected NHS data. The Hospital Episode Statistics (HES) system provides a central record of an individual' s use of all EDs in England and data will be extracted from this system (using participants' NHS numbers) to provide information on individual participants' use of ED at baseline and over the 12 months of follow-up. HES data will be requested at the start of Project Month 32 in a single tranche.

Secondary outcome measures

1. Intervention development phase of project:
Not applicable.

2. Pilot RCT phase of project:
Secondary measures will be based on participant self-report measured using standardised questionnaires. Patient participants will be requested to complete self-report measures prior to randomisation (T0) and then 3(T1), 6(T2) and 12-months (T3) post randomisation. Carer participants will be requested to complete self-report measures prior to randomisation (T0) and then 6 (T2) and 12months (T3) post randomisation. Baseline (T0) and 12 month (T3) follow-up measures will be collected in face to face
sessions by a research worker, blind to treatment allocation. Abbreviated assessments will occur at 3 months (T1) and 6 months (T2). The 3 month assessment will be conducted by telephone. For the 6month follow-up assessment (T2), participants will be posted a set of questionnaires for completion.

3. The following self-report outcomes will be collected from participants:
3.1. Self-reported epilepsy-related ED visits (Patients only; T0, T2, T3)
3.2. Quality of life (Patients only; T0, T2, T3); using Quality of Life in Epilepsy Scale-31 (QOLIE31)
3.3. Caregiver burden (Carers only; T0, T2, T3); using Zarit Caregiver Burden Inventory
3.4. Distress (Patientsand Carers; T0, T3); using Hospital Anxiety and Depression Scale
3.5. Stigma due to epilepsy (Patients only; T0, T3); using Jacoby's 3-item Stigma of Epilepsy Scale;
3.6. Fears of seizures and epilepsy (Patients and Carers; T0, T3); using 5-items from Fears subscale of the Epilepsy Knowledge and Management Questionnaire
3.7. Confidence managing seizures/ epilepsy (Patients and Carers; T0, T2, T3); Patients will complete Wagner's 6-item epilepsy specific Mastery scale, whilst carers will complete the 6-item Condition Management subscale from Austin's Parents Response to Child Illness Scale
3.8. Seizure frequency (Patients only; T0, T1, T3); At baseline (T0), patients will be asked to complete Thapar's seizure frequency scale for the prior 12 months. At 6 (T2) and 12 months (T3) follow up, PWE will be asked for the number of seizures (of any type) they have experienced since the last assessment and the date of the first and most recent seizure since last assessment. Patients will be provided with a seizure diary at T0
3.9. Knowledge of what to do when faced with a seizure (Patient and Carers; T0, T3); using Martiniuk et al.'s (2007) 'Thinking About Epilepsy Questionnaire'

3.10. Health economics (Patients only; T0, T3); using the Client Service Receipt Inventory (CSRI)
3.11. Patient Activation Measure (Patients & Carers; T0, T3); using 13-item Patient Activation Measure (PAM).
3.12. Serious Adverse Events (Patients only; T1, T2, T3); A standardised checklist will be used to ask PWE about any new symptoms or diagnoses occurring since randomisation and length of those symptoms.
3.12. Feedback on participation (Patients & Carers, T3); adaptations of questions used in Magpie Trial.

Overall study start date
01/06/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
PART A OF PROJECT, INTERVENTION DEVELOPMENT
Patients with the following characteristics will be eligible to participate in the development phase:
1. Established diagnosis of epilepsy (1+ year)
2.. All epilepsy syndromes and all types of focal and generalised seizures
3. Currently being prescribed anti-epileptic medication
4. Age 16 years or older (no upper age limit)
5. Have visited A&E in the past 2 years for epilepsy (as reported by the patient)
6. Live in the North-West area of England
7. Able to provide informed consent and participate in the course in English

Carers with the following characteristics will be eligible to participate in the development phase:
1. A significant other to the patient (e.g., family member, friend) who the patient identifies as providing informal support
2. Age 16 years or older (no upper age limit)
3. Live in the North-West area of England
4. Able to provide informed consent and participate in the course in English

PART B OF PROJECT, PILOT RCT
Patients with the following characteristics will be eligible for inclusion in the pilot trial:
1. Established diagnosis of epilepsy (1+ year)
2 All epilepsy syndromes and all types of focal and generalised seizures
3. Currently being prescribed anti-epileptic medication
4. Age 16 years or older (no upper age limit)
5. Visited an A&E for epilepsy on 2 or more occasions within the previous 12 months (as reported by patient);
6. Live in the North-West area of England (defined as having a home postcode which indicates they reside within 25 miles of ANY of the 3 ED recruitment sites);
7. Able to provide informed consent, participate in the course and independently complete questionnaires in English.

Carers with the following characteristics will be eligible for inclusion in the pilot trial:
1. A significant other to the patient (e.g., family member, friend) who the patient identifies as

providing informal support
2. Age 16 years or older (no upper age limit)
3. Live in the North-West area of England
4. Able to provide informed consent, participate in the course and independently complete questionnaires in English
Target Gender: Male & Female ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 207; UK Sample Size: 207; Description: PART A INTERVENTION DEVELOPMENT:Stage 1 Consultation with health professional representatives: n=7 participantsStage 2 Optimisation of intervention's behaviour change potential: N/AStage 3 Consultation with service user representatives: n= 20 patient participants & n=20 carer participants.PART B PILOT RCT:n=80 patient participants & n=80 carer participants.Total N: (7 + 20 + 20 + 80 + 80) = 207

Key exclusion criteria
PART A OF PROJECT, INTERVENTION DEVELOPMENT
Patients with the following characteristics will be excluded from the development phase:
1. Acute symptomatic seizures related to acute neurological illness or substance misuse (e.g., alcohol or drug-induced)
2. Severe current psychiatric disorders (e.g. acute psychosis) or life-threatening medical illness

Carers with the following characteristics will be excluded from the development phase:
a. Severe current psychiatric disorders (e.g. acute psychosis) or life-threatening medical illness;

PART B OF PROJECT, PILOT RCT
Patients with the following characteristics will be excluded from the pilot trial:
1. Actual or suspected psychogenic non-epileptic seizures alone or in combination with epilepsy
2. Acute symptomatic seizures related to acute neurological illness or substance misuse (e.g., alcohol or drug-induced)
3. Severe current psychiatric disorders (e.g. acute psychosis) or life-threatening medical illness
4. Enrolled in other epilepsy-related non-pharmacological treatment studies

Carers with the following characteristics will be excluded from the pilot trial:
1. Severe current psychiatric disorders (e.g. acute psychosis) or life-threatening medical illness
2. Enrolled in other epilepsy-related non-pharmacological treatment studies

Date of first enrolment
01/06/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Study participating centre
Aintree University Hospital
Liverpool
United Kingdom
L9 7AL

Study participating centre
Arrowe Park Hospital
Wirral
United Kingdom
CH49 5PE

Sponsor information

Organisation
University of Liverpool

Sponsor details
Health Services Research
1-3 Brownlow Street
Liverpool
England
United Kingdom
L69 3GL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Standard approaches will be used to disseminate results, including conference presentations (nationally and internationally), open access journal publications (including the trial protocol using CONSORT Guidelines), articles in user group publications (including online) and an NIHR HS&DR report will also be produced. All applicants and user representatives shall contribute. The media departments of involved institutions shall ensure optimum coverage. We intend to publish the protocol by month 12 of the project and a main journal article report on the findings from the pilot RCT will be submitted for publication at around month 38 of the project.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	24/07/2015		Yes	No
Results article	results	01/03/2017		Yes	No
Results article		01/10/2020	19/05/2023	Yes	No
Results article		16/04/2020	19/05/2023	Yes	No
HRA research summary			28/06/2023	No	No