

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

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| <b>Submission date</b><br>22/04/2015   | <b>Recruitment status</b><br>No longer recruiting    | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>23/04/2015 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>19/05/2023       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> 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  
L69 3GL

## 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 (Patients and 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

participants Stage 2 Optimisation of intervention's behaviour change potential: N/A Stage 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? |
|-------------|---------|--------------|------------|----------------|-----------------|
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|--------------------------------------|----------|------------|------------|-----|----|
| <a href="#">Protocol article</a>     | protocol | 24/07/2015 |            | Yes | No |
| <a href="#">Results article</a>      | results  | 01/03/2017 |            | Yes | No |
| <a href="#">Results article</a>      |          | 01/10/2020 | 19/05/2023 | Yes | No |
| <a href="#">Results article</a>      |          | 16/04/2020 | 19/05/2023 | Yes | No |
| <a href="#">HRA research summary</a> |          |            | 28/06/2023 | No  | No |