

Seizure first aid training for people with epilepsy attending emergency departments and their significant others: the SAFE intervention and feasibility RCT

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Scientific summary

The SAFE intervention and feasibility RCT

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Scientific summary

Background

Epilepsy is one of the UK's most common serious brain disorders. Up to 20% of people with epilepsy visit hospital emergency departments each year, approximately 60% of whom do so multiple times. These visits are expensive for the NHS; half result in hospital admission.

People with epilepsy visiting emergency departments report more seizures, anxiety and stigma and are more likely to live in a socially deprived area than those in the wider epilepsy population. Identifying people with epilepsy who visit emergency departments can be challenging; most are unknown to specialist epilepsy services and are not referred on to them following emergency department visits. General practitioners are also not always informed of the contact that people with epilepsy have with emergency services.

National Audit of Seizure Management in Hospitals data and similar data indicate that many emergency department visits by people with epilepsy are clinically unnecessary. This is because most of these emergency department attendees have known, rather than new, epilepsy and have experienced uncomplicated seizures. Although frightening, such seizures can be managed by people with epilepsy and their family and friends without medical attention, as guidelines state.

Emerging evidence suggests that people with epilepsy and their significant others, to whom care decisions can be delegated, have low confidence in their own seizure management, which may explain why some people with epilepsy make clinically unnecessary visits. Offering people with epilepsy who frequently attend emergency departments, and their significant others, a self-management intervention that improves their confidence and ability to manage seizures may lead to fewer visits.

We report a project seeking to develop the first such intervention: Seizure first Aid training For Epilepsy (SAFE). To develop the intervention, an existing group-based seizure management course, which is offered by the Epilepsy Society (www.epilepsysociety.org.uk; Chalfont St Peter, UK) in the voluntary sector to a broader audience, was adapted. A pilot randomised controlled trial of SAFE was then conducted. A pilot was appropriate because the feasibility and optimal design of a definitive trial was unclear.

Aim and objectives

Part A: intervention development

- Optimise the content, delivery and behaviour change potential of the Epilepsy Society's course for people with epilepsy attending an emergency department and their significant others.

Part B: pilot randomised controlled trial

- Conduct an external pilot randomised controlled trial of SAFE plus treatment as usual versus treatment as usual only to estimate recruitment, consent and follow-up rates in a definitive trial.
- Estimate the annual rate of emergency department visits in the treatment as usual arm and the dispersion parameter to inform the sample size calculation of a definitive randomised controlled trial.

- Test the acceptability of the randomisation to participants.
- Evaluate SAFE's implementation fidelity in the pilot randomised controlled trial.
- Analyse the cost of implementing the SAFE programme.

Methods and analysis

Part A: intervention development

Design

An experience-based co-design approach comprising three iterative stages identified the changes required to the Epilepsy Society's intervention: stage 1 – leading representatives from professional groups supporting people with epilepsy reviewed the course materials and were interviewed about the changes needed; stage 2 – the Epilepsy Society's original intervention was not underpinned by a clear behaviour change mode and, therefore, the intervention's behaviour change potential was optimised; stage 3 – focus group discussions took place with service user representatives who received an initial adaptation of the intervention. Data from the different stages were captured using audio-recordings, thematically analysed and considered by a multidisciplinary intervention panel.

Recruitment

A purposive sample of representatives from neurology, emergency medicine, the ambulance service, specialist nursing, general practice, user groups and health-care commissioning was recruited with the help of professional organisations. Epilepsy user groups helped to recruit service user representatives. To be eligible, user representatives (be they a person with epilepsy or one of their significant others) needed to be aged ≥ 16 years and able to provide informed consent. User representatives who were people with epilepsy needed to have visited an emergency department in the previous 2 years for epilepsy.

Part B: pilot randomised controlled trial

Design

The design was an external pilot randomised controlled trial. Recruited people with epilepsy (and their significant other if they took part with one) were randomised to receive SAFE plus treatment as usual or treatment as usual only. The SAFE programme was delivered by an epilepsy nurse in a hospital's educational centre. Participants allocated to treatment as usual received SAFE only after the trial finished.

The proposed primary outcome measure for a definitive trial of SAFE is emergency department use in the 12 months following randomisation measured using routine hospital data. In the pilot trial this was captured by Hospital Episode Statistics. Participants provided consent for the release of these data. Proposed secondary outcomes included self-reported emergency department use, fear of seizures, knowledge and confidence managing seizures, quality of life, distress, seizures, stigma, carer burden, service use and adverse events. These were measured by a researcher, blind to treatment allocation, who completed questionnaires with participants at 3, 6 and 12 months post randomisation. At the assessment at 12 months, participants also provided feedback on trial participation.

Rates of recruitment and retention were calculated, as was the emergency department event rate in the control arm. Emergency department visits measured using routine hospital data for the 12 months prior to and 12 months following randomisation were also compared with self-reported emergency department visits for these periods. The estimates from the pilot trial were evaluated against two predetermined 'stop/go' progression criteria for a full trial: $\geq 20\%$ of eligible people with epilepsy needed to agree to take part and primary outcome data at 12 months needed to be secured for $\geq 75\%$ of people with epilepsy. Although the trial was not designed to detect a clinically important difference in emergency department use, an estimate of SAFE's effect on this measure was also calculated to help to inform the possible design of a future trial.

It was anticipated that 12 months of attendances at three NHS type 1 emergency departments would be sufficient to secure a sample of 80 people with epilepsy for the pilot trial, with 40 people with epilepsy in each treatment arm, permitting the study to estimate a drop-out rate of 25% (with a 95% confidence interval of 10%) and a consent rate of 20% (with a 95% confidence interval of 4%). Assuming data on emergency department use at 12 months were not available for 25% of people with epilepsy, outcome data from 60 people with epilepsy would still allow for robust estimation of the emergency department rate and dispersion parameter.

Measures of implementation fidelity (adherence and competence) for SAFE were developed and their inter-rater reliability assessed. Adherence was assessed by a checklist of the items constituting the intervention. Competence was measured by calculating facilitator speech during the intervention (didacticism). The measures were then used by independent raters, who listened to audio-recordings of all trial SAFE sessions.

A microcosting exercise calculated the fixed and variable costs of delivering SAFE. The process involved a health economics researcher meeting with intervention staff and mapping out the work and resources required for each of the courses run. The cost of developing SAFE was also determined.

Recruitment

Using electronic attendance records and triage cards, local principal investigators at three NHS type 1 emergency departments in north-west England retrospectively identified people with epilepsy who had visited emergency departments in the previous 12 months for epilepsy and posted an invitation letter. Inclusion criteria were an age of ≥ 16 years, an established diagnosis of epilepsy (≥ 1 year), an antiepileptic medication prescription, reported visits to an emergency department on two or more occasions in the previous 12 months, and the ability to provide informed consent, participate in SAFE and complete questionnaires in English. Those receiving an invitation letter were instructed that if they were not interested in taking part in the trial or not eligible that they should opt out of further contact within 3 weeks. A research worker telephoned those not opting out to explain the study further and verify patient eligibility and willingness to participate. The research worker met with those who wanted to take part and their significant others, and secured informed consent and completed baseline questionnaire assessments.

Results

Part A: intervention development

Over a period of 8 months, feedback from nine representatives from different professional groups, 13 people with epilepsy and 10 significant others was secured and the finalised SAFE intervention developed.

During stage 1, health-care professionals considered the Epilepsy Society's course to provide a good foundation but requested changes to its language and presentation style to make it less didactic and to emphasise the benefits to service users. They recommended the inclusion of new content to elicit and address service users' fears relating to seizures. To promote consistency and make the intervention suitable for delivery in the NHS, a trainer's manual was also developed. During stage 2, the behaviour change potential of the intervention was optimised. Specifically, the intervention development panel considered self-affirmation theory to be pertinent because the course would highlight to some participants that their past behaviour conflicted with medical guidance. To mitigate against the defensive processing of information that, according to the theory, can result, a brief kindness questionnaire was inserted at the intervention's start. During stage 3, service users reported having a positive view of the intervention, its videos and the associated educational materials. Their feedback resulted in changes to the order of the content, the addition of information relating to post-ictal states and the generation of a website that held the content of the course to mitigate the effect of memory difficulties and to allow the information to be shared with other significant others.

The finalised SAFE intervention was intended for delivery to groups of up to 10 patient–carer dyads by a single facilitator with knowledge of epilepsy and to last \approx 4 hours, including breaks. It contained six modules centred around basic epilepsy and first aid knowledge, the recovery position, informing others about epilepsy and how to help if seizures occur, medical identifications, seizure triggers and home safety. Materials included presentation slides and professionally produced videos. The total cost of developing SAFE was £9947.

Part B: pilot randomised controlled trial

Fifty-three people with epilepsy and 38 of their significant others were recruited over \approx 7.5 months. The consent rate (12.5%, 95% confidence interval 9.3% to 15.6%) and eligibility rate (10.6%, 95% confidence interval 9.6% to 11.5%) were low. Despite an amendment to extend the period within which people with epilepsy could be identified from emergency departments (i.e. the previous 18 months rather than the previous 12 months of attendances), the intended sample size could not be recruited.

A lack of granularity by which attendances were coded in the emergency departments' record systems meant that identifying people with epilepsy was resource intensive, requiring \approx 3 days of a local principal investigator's time at each site. Contacting patients by telephone was also challenging. The researcher made successful contact with only 47.8% of eligible patients.

The mean age of the people with epilepsy recruited was 39.9 years, 29 (56.9%) were female and most lived in areas of high levels of social deprivation. The median time since diagnosis was 21 years. Those recruited were similar in age and social deprivation to those declining participation. The recruited sample might not have been representative of the target population in sex. Moreover, 74.5% reported seeing an epilepsy specialist in the previous 12 months, which is higher than expected.

Of those recruited, 51 people with epilepsy (and 37 significant others) were randomised: 26 people with epilepsy (and 18 significant others) to SAFE plus treatment as usual and 25 people with epilepsy (and 19 significant others) to treatment as usual only. The demographics, disease characteristics and scores on the assessment tools at baseline were similar in each treatment arm, but there was some imbalance in prior emergency department use. Most people with epilepsy (76.9%) randomised to SAFE received the intervention and it was found to have been delivered with high fidelity. No participants allocated to treatment as usual attended a SAFE course by mistake. Delivering SAFE was estimated to cost £333 per patient (with or without a significant other) and it is plausible that it could be delivered for as little as £261 per patient.

Routine data on emergency department use at 12 months were secured for 94.1% of people with epilepsy, but obtaining it took 8.5 months and was resource intensive, and the application for these data was initially rejected by NHS Digital on the basis of what proved to be incorrect reasoning. Self-reported emergency department data at 12 months were secured for only 66.7% of people with epilepsy. It was found that participants reported more emergency department visits than were recorded in routine data. For the 12 months prior to randomisation, participants reported 3.8 more emergency department visits on average than were recorded in routine data.

Negative binomial regression estimated emergency department use at 12 months to be, according to routine data, \approx 47% lower in the SAFE plus treatment as usual arm than in the treatment as usual only arm, but not significantly so. In the SAFE plus treatment as usual arm, emergency department use reduced from 2.1 visits over a 12-month period to 1.8 visits; in contrast, the mean number of visits in the treatment as usual arm increased from 3 to 3.4.

No serious adverse events related to participation occurred, and all but one of the 32 (68.1%) people with epilepsy and the 20 (62.5%) significant others providing feedback on trial participation said that they would participate again, with SAFE participants valuing the intervention.

The estimated effect of SAFE on emergency department use and the dispersion parameter in the control arm ($k = 0.69$, range 0.17 to 1.21) indicated that a definitive trial of SAFE's efficacy would require a sample of ≈ 674 people with epilepsy. The consent rate in the pilot indicates that it would need ≈ 39 emergency department recruitment sites.

Conclusions

The co-design approach allowed for a brief, manualised intervention that was supported by stakeholders and based on an NHS-feasible delivery method to be rapidly developed.

A pilot randomised controlled trial was conducted successfully. Persons from the target population could be identified, recruited, randomised and treated as intended. Outcome data for the proposed primary outcome measure could be secured for most participants and meant that the trial satisfied the predetermined 'stop/go' criterion of $\geq 75\%$.

However, the consent rate for the pilot trial was low and meant that the second 'stop/go' criterion of $\geq 20\%$ was not met. The low consent rate raises concerns about the representativeness of the sample that would be recruited into a definitive trial and its external validity. The low consent rate also means that a definitive trial would require a larger number of recruitment sites than most definitive trials and be expensive. It may even not be possible to secure the required emergency departments to act as recruitment sites because the resources required from them to identify participants may be prohibitive.

Implications for NHS service commissioning, policy and practice

- The trial was not designed to determine SAFE's efficacy. There remains limited evidence to justify the commissioning of such a service.
- Some people with epilepsy are unknown to ambulatory care services and cannot be readily identified. Increasing the granularity with which attendances at emergency departments are coded could enable them to be readily identified, supported and involved in research.
- Using routine data on emergency department use in trials could make trials less vulnerable to losses to follow-up and mean that trials are not exposed to apparent recall bias. However, stakeholders need to be given more assurances from those holding the data that the data are likely to be provided, and provided in a timely manner.
- A case can be made for converting SAFE into a free online resource to which people could be directed in the short term, going some way to address the otherwise unmet seizure first aid training needs of people with epilepsy who visit emergency department and their significant others.

Recommendations for further research

- A full definitive trial of SAFE, with the current design, is not feasible.
- Research to determine how people from the target population can be better recruited is required.
- Converting SAFE into a free online resource could provide an opportunity for an alternative method of evaluating its effect. Via a pre-post design, persons accessing the online resource could complete brief measures to assess change in seizure first aid confidence and skills and give their consent for researchers to access routine data on their use of emergency departments before and after viewing the resource.

Trial registration

This trial is registered as ISRCTN13871327.

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