ISRCTN57937389 https://doi.org/10.1186/ISRCTN57937389

Self-management education for adults with poorly controlled epilepsy

Submission date
19/03/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
03/05/2018

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with epilepsy want more support in learning how to self-manage their condition. Group patient education courses are one way this is achieved for other chronic conditions and are offered as part of routine NHS care. A promising course for epilepsy called MOSES is used in Germany. When tested in German-speaking countries, it resulted in improved patient knowledge about epilepsy, better seizure control and coping and tolerance of medication. MOSES consists of patients receiving a workbook and completing a 2-day course in groups of 8 to 12 people. The developers of MOSES have translated it into English. We aim to first adapt MOSES for delivery in the NHS context (initial study called a pilot) and then test how helpful it is for people with epilepsy in the UK (larger study called a randomised controlled trial).

Who can participate?
Pilot Phase: We shall run 2 pilot MOSES courses. We will recruit about 20 participants to attend these courses. Participants will be recruited via an advertisement on the British Epilepsy Associations website and in their user magazine. To participate a person needs to have a diagnosis of epilepsy (all epilepsy syndromes and seizures types permitted); be being prescribed anti-epileptic drugs; aged 16 years or over (no upper age limit); have experienced more than 2 seizures in the past 12 months (of any type); be able to provide informed consent, participate in the workshops and complete questionnaires in English; and live in the London area. People who have a severe psychiatric disorder (e.g., psychosis) or a terminal medical condition will not be able to participate.
Randomised Controlled Trial Phase: We shall recruit 428 people with epilepsy from 16 specialist hospital clinics from South-east England. This will compare how helpful the adapted MOSES programme (plus standard medical care) is compared to standard medical care alone. To take part, a person needs to have a documented diagnosis of epilepsy (all epilepsy syndromes and seizures types are permitted); be prescribed anti-epileptic drugs, be aged 16 years or over (no upper age limit); be able to provide informed consent, participate in the workshops and complete the questionnaires in English; and have had at least 2 seizures in previous 12 months (as reported by patient). A person will not be able to take part if they have actual/suspected psychogenic non-epileptic seizures only; have acute symptomatic seizures related to acute

neurological illness or substance misuse; have a severe psychiatric disorder (e.g., psychosis) or terminal medical condition; and/ or are enrolled in another epilepsy-related non-pharmacological treatment study.

What does the study involve?
Pilot Phase: The pilot courses shall be run at our university. Ten participants will attend each course (with 2-3 carers if patients request this). A research worker will observe each course to record their impressions. Participants will feedback on the intervention, its content and cultural acceptability by means of focus groups held on the final day of the course. Participants will also be invited to return 2-3 weeks later for individual interview and to complete the questionnaires to be used in the trial. Taxis will be arranged for participants and refreshments will be provided.
Randomised Controlled Trial Phase: The duration of the trial for a participant is 12 months. Using standard self-report questionnaires, participants will be assessed at recruitment (assessment 1), and then again 6- (assessment 2) and 12-months later (assessment 3). Areas assessed by the questionnaires include Quality of life in epilepsy, seizure control, psychological distress, confidence managing epilepsy and health service use.
A computer programme will randomly allocate patients to the MOSES programme (plus standard medical care) or to the standard medical care alone (this will be done remotely after assessment 1). Patients will be instructed not to tell research workers which group they have been allocated to.
We shall run approximately 21 MOSES courses. The time between randomisation and receipt of MOSES will be less than one month. Eight to twelve participants will be invited to each course (with two or three carers if requested by the patients). Two health professionals will facilitate each course. Each will have completed an English translation of the formalised training programme used in Germany to train persons to deliver MOSES. With participants consent, MOSES sessions will be audio-recorded to allow us to assess treatment fidelity and to permit ongoing supervision.
Once all 12 month follow-up data has been collected, delayed-MOSES courses will be run for those in the standard-medical care only group.

What are the possible benefits and risks of participating?
The overall benefit of the study is the opportunity for people with epilepsy to engage in self-management education to potentially enable them to better manage their epilepsy and improve their quality of life. A potential benefit for society will be cost savings for NHS resources. There are no known disadvantages or risks of taking part. The course is routinely given to people with epilepsy in other countries. However, the course and some of the questionnaires involve participants thinking about epilepsy and feelings. For some people, this can be upsetting. They can stop taking part in the course or doing the questionnaire at any time. This would not affect their medical care. If taking part in the course or answering the questionnaires makes a participant worried about their feelings, they can talk to their GP. They can also ask the health professionals giving their MOSES course for advice.

Where is the study run from?
The study is being done by the Clinical Neuroscience Department at King's College London, UK

When is the study starting and how long is it expected to run for?
The project will start on the 1st of June 2013 and is expected to run for 35 months.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR). Additional support is being provided by Kings College Hospital NHS Foundation Trust, UK.

Who is the main contact?
1. Professor Leone Ridsdale (leone.ridsdale@kcl.ac.uk; +44 (0)20 7848 0293)
2. Professor Laura Goldstein (laura.goldstein@kcl.ac.uk; +44 (0)20 7848 0218)

Contact information

Type(s)
Scientific

Contact name
Prof Leone Ridsdale

ORCID ID
https://orcid.org/0000-0002-2234-2859

Contact details
King's College London
Institute of Psychiatry
Department of Clinical Neuroscience
Unit of Neurology and General Practice
PO 41, Denmark Hill Campus
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0293
leone.ridsdale@kcl.ac.uk

Additional identifiers

Protocol serial number
1; HTA 09/165/01

Study information

Scientific Title
Self-Management education for adults with poorly controlled epILEpsy (SMILE): a project involving a randomised controlled trial

Acronym
SMILE

Study objectives
1. Compared to treatment as usual alone (TAU), does MOSES (plus TAU) lead to improved quality of life in a UK sample of adults with poorly controlled epilepsy at 12 month follow-up? 2. Before the trial phase of the project, to complete an external pilot consisting of two practice MOSES courses, and gain qualitative feedback from volunteers on any difficulties in participating in the course. (Phase 1 of the project)
3. To ask those completing the external pilot MOSES courses to complete the outcome questionnaires to be used in the subsequent trial and feedback on their ease of completion and

suitability. (Phase 1 of the project)
4. Compared to treatment as usual alone (TAU), does MOSES (plus TAU) lead to improvements on the primary and secondary outcome measures at 6 month follow-up, and secondary outcome measures at 12month followup. (Phase 2 of the project)
5. To describe the views of trial participants on the MOSES course, including barriers to participation and the perceived benefits of the intervention, using qualitative methods. (Phase 3 of the project)

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, NRES Committee London - Fulham, REC ref: 12/LO/1962

Study design
Mixed-methods project. Following a pilot to optimise MOSES for UK delivery, a single-blind RCT of MOSES, with a nested qualitative component (plus TAU) vs TAU

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Epilepsy/Neurology

Interventions
Following optimisation for UK delivery, a single-blind RCT will compare effect of MOSES (plus treatment as usual TAU) to TAU alone.

Active treatment MOSES: We shall run ~21 MOSES courses for those randomised to the active treatment arm. The time between randomisation and receipt of MOSES will be ~≤1 month. Eight to twelve participants will be invited to each course (with 2-3 carers if requested by the patients). Two health professionals will facilitate each course. Each will have completed an English translation of the formalised training programme used in Germany to train people to deliver MOSES. At least one of the facilitators will have a medical background so as to be able to provide appropriate care should a participant have a seizure. With participants consent, MOSES sessions will be audio-recorded to allow us to assess treatment fidelity and to permit ongoing supervision.

MOSES consists of a number of components with a range of training modules. It is a complex intervention. Materials for the delivery of MOSES include a detailed workbook for participants. MOSES is subdivided into nine modules for delivery, designed to improve participants knowledge of epilepsy in terms of its diagnosis, treatment and consequences and to improve understanding of associated psychosocial and occupational difficulties16. The modules cover:
i) Living with epilepsy: Recognising, expressing emotions about and coping with epilepsy;
ii) Epidemiology: Prevalence and age-related incidence of epilepsy;
iii) Basic knowledge: Causes, pathophysiology, types of seizures;
iv) Diagnosis: Important diagnostic tools. Importance of exact descriptions and documentation of seizures for the doctor;

v) Treatment: Various treatment possibilities, guidelines and approaches with AEDs, importance of AED compliance to achieve better seizure control;
vi) Self-control: How to influence and prevent the occurrence of epileptic seizures; recognition and avoidance of provoking factors;
vii) Prognosis: possibility of seizure remission; treatment prognosis; AED withdrawal;
viii) Psychosocial aspects: The effect of epilepsy on attitudes, on everyday life and work; ways to improve self esteem and social contacts; possibilities of vocational assistance and rehabilitation; registering as disabled and driving regulations;
ix) Network epilepsy: Addresses of organisations offering assistance and information on epilepsy; self help groups and how to develop a personal support network.

MOSES emphasizes accurate self-monitoring of seizures, the potential use of self-control techniques including recognising and avoiding seizure-provoking factors and the implementation of countermeasures to interrupt auras15. Considerable weight is also placed on the consequences of epilepsy on the quality of everyday life, the impact on vocational opportunities and on improving self-esteem. A workbook provides participants with a permanent record of the material being covered and includes written exercises to promote active processing of material as well as participation.

Courses will be delivered within meeting/seminar rooms at the local hospitals from where recruitment will occur, with courses being run on week days and week-ends. Taxis will be arranged for participants attendance at the courses and refreshments will be provided.

In addition to any interventions or procedures as part of the research, participants will continue to receive their standard medical care. No restrictions shall be placed on the usual care participants can receive.

Control condition TAU: The active intervention will be compared to TAU alone. The appropriate control comparison for the study will be TAU by the PWEs neurology team. In England all people with epilepsy are expected to have a structured medical review of their epilepsy at least yearly by either a generalist or specialist. NICE guidelines for epilepsy also recommend that when seizures are not controlled or treatment fails, it is expected that a patient will be referred to tertiary services for assessment.

Once all 12 month follow-up data have been collected, the TAU group will be offered a MOSES course, but the group will only contribute outcomes to the trial data set under the TAU condition.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome measure for this project is quality of life (QOL) measured at 12 month follow-up in this project's randomised controlled trial (Phase 2 of the project). QoL will be measured using a standardised and psychometrically robust epilepsy-specific measure, called the QOLIE31 (Cramer et al., 1998). The QOLIE31 comprises seven subscales seizure worry,

emotional wellbeing, energy fatigue, cognitive functioning, medication effects, social functioning, overall QOL. This measure is to be completed at assessments 1 (baseline), 2 (6 month follow-up) and 3 (12 month follow-up).

Key secondary outcome(s))
The secondary outcome measures are the following which will be completed as part of the project's randomised controlled trial component (Phase 2 of the project):
1. Seizure control (seizure frequency over the previous 6/12 months and seizure recency through reports of time since last seizure; Thapar et al., 2009). This measure is to be completed at assessments 1, 2 and 3
2. Impact (Impact Scale measuring self-perceived impact of epilepsy on relationships, social and occupational activities, personal health and aspirations, and standard of living; Jacoby et al., 1993). This measure is to be completed at assessments 1, 2 and 3
3. Medication adherence (medication adherence subscale from the Epilepsy Self management Scale; Dilorio et al., 2009). To be completed at assessments 1 and 3 only
4. Medication adverse effects (during the past 4 weeks, how much have you been bothered by (a) physical effects of antiepileptic medication and (b) mental effects of antiepileptic medication?; Cramer et al., 1998). To be completed at assessments 1 and 3 only
5. Psychological distress (Hospital Anxiety and Depression Scale; Zigmond & Snaith, 1983). To be completed at assessments 1 and 3 only
6. Perceived stigma (Stigma of Epilepsy Scale; Jacoby, 1994). To be completed at assessments 1 and 3 only
7. Mastery/control over epilepsy(epilepsy specific scale; Wagner et al., 1995). To be completed at assessments 1 and 3 only
8. To permit an assessment of the cost effectiveness of the intervention, participants will report their use of different health services and work status over the prior 6months (Modified Client Service Receipt Inventory; Beecham over the prior 6months (Modified Client Service Receipt Inventory; Beecham & Knapp, 2001) and to complete the EuroQoL health status measure (EQ5D; The EuroQol Group, 1990). To be completed at assessments 1 and 3 only

Completion date
07/07/2016

Eligibility

Key inclusion criteria
1. Patient has a documented diagnosis of epilepsy (all epilepsy syndromes and all types of focal and generalised seizures will be permitted
2. Currently being prescribed antiepileptic drugs
3. Aged ≥16 years (no upper age limit)
4. Able to provide informed consent, participate in the workshops and complete the questionnaires in English
5. Had at least 2 seizures in previous 12 months (as reported by patient)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Have actual/suspected psychogenic nonepileptic seizures only
2. Have acute symptomatic seizures related to acute neurological illness or substance misuse
3. Has a severe psychiatric disorders (e.g., psychosis) or terminal medical condition
4. Are enrolled in other nonpharmacological epilepsy treatment studies

Date of first enrolment
28/05/2013

Date of final enrolment
06/08/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Institute of Psychiatry, Kings College London (UK)

ROR
https://ror.org/0220mzb33

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
The datasets generated during and/or analysed during the current study are be available upon request from Professor Leone Ridsdale, leone.ridsdale@kcl.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/06/2015		Yes	No
Results article	results	01/04/2018		Yes	No
HRA research summary			28/06/2023	No	No