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Management and delivery of special neurological rehab

Submission date	Recruitment status	[ ] Prospectively registered
21/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/02/2015	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7101

Study information

Scientific Title
Can rehabilitation reduce attendance at Accident and Emergency (A&E) and promote wellbeing for people with severe epilepsy? A multicentre non-randomised interventional treatment trial

Study objectives
People with poorly controlled epilepsy are likely to be taken to Accident and Emergency for seizures, and nearly one half will be admitted. Our hypothesis is that nurse-led rehabilitation would be more cost-effective in meeting the needs of people with poorly controlled epilepsy than usual care. Our aim is to produce evidence comparing the extent to usual-care and enhanced service from a nurse meet different needs and produce different outcomes, enhances clinical effectiveness and cost effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East London Research Ethics Committee (REC) 4 (formerly known as The Joint South London and Maudsley And Institute of Psychiatry Research Ethics Committee), 07/11/2008, ref: 08/H0807/86

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Neurological, Primary Care Research Network for England; Subtopic: Not Assigned, Neurological (all Subtopics); Disease: Nervous system disorders, All Diseases

Interventions
The intervention will start with the offer of a clinic appointment with a nurse with special interest in epilepsy after the patient has been discharged following an A&E attendance. The nurse will assess the patient identifying the nature and extent of their problems and the factors relevant to their resolution. Family and/or carers will be included, provided the patient agrees.

The nurse will help the patient set goals, provide information and support and offer specific treatments.

Further details:
Our study is testing whether nurse led rehabilitation is more cost and clinically effective in meeting the needs of people with poorly controlled epilepsy who attend A&E as compared to usual care. To do this we are conducting a natural comparison of the outcomes of patients who have attended A&E for epilepsy in South London and receive either usual care or enhanced nurse led care. Patients attending Kings College Hospital are offered the opportunity to receive enhanced nurse led rehabilitation, whilst patients attending Guy's and St Thomas' Foundation Trust and University Hospital Lewisham constitute the group receiving usual care. For the enhanced nurse led rehabilitation, following a review of the literature that reflects current best practice, we have developed a protocol.

The Epilepsy Resource Pack (Epilepsy Action 2003) Epilepsy Task Force Service Development Kit was an essential tool in development. The protocol complies with the NICE guidelines (National Institute for Clinical Excellence 2004) and embraces the recommendations outlined in the epilepsy action plan. Its use provides the opportunity to carry out a comprehensive review of the person's epilepsy and promotes the formulation of an agreed personalised care plan. It allows for all the relevant information to be recorded and incorporates a checklist, a tool that is advocated in order to remind the individual and healthcare professional about the topics that should be discussed. With the individual's permission, the information will be shared with other healthcare professionals involved in their care, particularly their General Practitioner (GP). This joining-up is particularly important in areas of deprivation, where QOF evidence (Ashworth, Seed, Armstrong, Durbaba, & Jones 2007) shows that monitoring and epilepsy control rates are lower. The aim is to promote "seamless" service delivery involving information and communication across transitions. At the time of the appointment with the nurse specialist, individuals will have direct access to one of two "Expert Patients" in clinic who have been trained at the National Society for Epilepsy, and will be invited to join a users' group as recommended by the Department of Health initiative.

Patients will also be provided details of national self-help organisations, including Epilepsy Action and the National Society for Epilepsy. The protocol for rehabilitation provides a framework; in practice input will be personalised to individuals. Referrals will be made when indicated, for example to social services, psychology, neurology, occupational therapy, an employment officer, the learning disability team. Further input will be as judged by nurse and client, but will include at least one follow-up appointment three months later. The duration of the intervention will be 3 - 6 months. The nurse acts as a key worker, so the effect of the intervention might go on longer. For example if an individual was depressed, s/he might be referred to a therapist and attend for a series of sessions.

Patients are assessed at three time points: baseline, and then at 6- and 12-months post point of consenting.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Accident and Emergency re-attendance, measured at baseline, 6 and 12-month follow-up.

Secondary outcome measures
1. Seizure frequency, measured at baseline and 6 month follow-up
2. Seizure severity, measured at baseline and 6 month follow-up
3. Seizure impact, measured at baseline and 6 month follow-up
4. Psychological distress, measured at baseline, 6 and 12-month follow-up
5. Perceived stigmatisation, measured at baseline and 6 month follow-up
6. Quality of life, measured at baseline, 6 and 12-month follow-up
7. Self efficacy in managing epilepsy, measured at baseline, 6 and 12-month follow-up
8. Medication adherence, measured at baseline, 6 and 12-month follow-up
9. Satisfaction with information about medications, measured at baseline and 6 month follow-up
10. Knowledge of epilepsy, measured at baseline and 6 month follow-up
11. Quality-adjusted life years (QALYs), measured at baseline, 6 and 12-month follow-up

Overall study start date
04/06/2009

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Be aged 18 years or over, either sex
2. Have epilepsy that has been diagnosed and treated with medication
3. Be able to communicate in English sufficiently to complete questionnaires
4. Be resident and registered with a GP in either Southwark or Lambeth PCT

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 170; UK sample size: 170

Key exclusion criteria
1. Having no diagnosis; new epilepsy leads to a referral to a neurologist
2. Having already seen a specialist nurse for epilepsy in the prior year
3. Alcohol or other substance misuse
4. Other severe medical illness, such as psychosis or terminal cancer

Date of first enrolment
04/06/2009

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Neuroscience
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust (SLaM) (UK)

Sponsor details
Joint R&D Office
P005, Institute of Psychiatry (King's College London)
De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Service Delivery and Organistion (SDO)

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?
Results article	results	01/12/2012		Yes	No
Results article	results	01/10/2013		Yes	No