

Kilifi Epilepsy Education Program (KEEP): An intervention to reduce the epilepsy treatment gap

Submission date 08/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/01/2010	Overall study status Completed	☐ Protocol
Last Edited 24/01/2014	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
083744; KEMRI/National Ethics Review Committee: 1455

Study information

Scientific Title
The efficacy of an education intervention for people with epilepsy and their caregivers (KEEP): a controlled randomised study

Acronym

KEEP

Study objectives

An intervention, targeting people with epilepsy (PWE), their caregiver and health care providers, has reduced the epilepsy treatment gap in Kilifi.

Ethics approval required

Old ethics approval format

Ethics approval(s)

KEMRI/National Ethics Review Committee approved on the 6th May 2009 (ref: 1455)

Primary study design

Interventional

Study design

Single centre interventional randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Epilepsy

Interventions

Each person with epilepsy is randomised to received the intervention or act as a control. Those that are allocated to the intervention will have a care giver identifier and this person together with the person with epilepsy will receive education at a designated session, which will be re-enforced at clinical attendance. In addition, the traditional healer that the person with epilepsy may consult will be approached to be involved in the education programme; the education programme includes information on the causes and medical treatment of epilepsy.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Adherence of PWE to antiepileptic drugs (AEDs) as measured by drug levels. Plasma phenobarbital or phenytoin concentrations will be measured using an Abbott TDx FLx fluorescence polarisation immunoassay analyser (Abbott Laboratories, Diagnostic Division, Abbott Park, IL, USA). Therapeutic levels of AEDs will be defined as plasma concentrations ranging between 10 - 40 µg/mL, for both phenobarbital and phenytoin. Detectable levels of AEDs will be defined as plasma concentrations of greater than or equal to 1 µg/ml for both phenobarbital and phenytoin. Assessed at one year and four years after study onset.

Key secondary outcome(s)

Assessed at one year and four years after study onset:

1. Seizure frequency, measured by a questionnaire
2. Quality of life of PWE, measured by quality of life questionnaire using Likert scale (0 = not at all, 1 = rarely, 2 = sometimes, 3 = most of the time, 4 = always)
3. Knowledge, beliefs and attitudes about epilepsy, measured by the Epilepsy beliefs and attitude questionnaire using Likert Scale (0 = dont know, 1 = not at all, 2 = believe a little, 3 = totally believe)

Completion date

01/08/2012

Eligibility

Key inclusion criteria

1. PWE and their caregivers
2. Both male and female, no age limits
3. Where the person with epilepsy is a child, only caregiver will participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. PWE who refuse informed consent
2. Children whose parents refuse informed consent

Date of first enrolment

01/08/2009

Date of final enrolment

01/08/2012

Locations

Countries of recruitment

Kenya

Study participating centre

KEMRI/Wellcome Trust Programme
Kilifi
Kenya
80108

Sponsor information

Organisation

University College London (UCL) (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 083744)

Results and Publications

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	01/02/2014		Yes	No