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

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2014	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
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)

Study design
Single centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/08/2009

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

Age group
Other

Sex
Both

Target number of participants
We have identified 740 PWE in the Kilifi Demographic Surveillance System

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)

Sponsor details
Institute of Child Health
Guildford Street
London
United Kingdom
WC1N
cnewton@ich.ucl.ac.uk

Sponsor type
University/education

Website
http://www.ich.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

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

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	01/02/2014		Yes	No