ISRCTN53515024 https://doi.org/10.1186/ISRCTN53515024

Integration of mental health in primary care in Kenya

Submission date	Recruitment status	[ ] Prospectively registered
03/11/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/11/2013	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The study aims to measure whether a 40 hour mental health structured and standardised training course for front line health workers in Kenya can help them diagnose mental health problems better and facilitate the recovery of their clients over a three month follow up period.

Who can participate?
Men and women aged over 16 are eligible to participate in the study. People with learning disabilities, dementia and life threatening illness are excluded.

What does the study involve?
The study compares health workers and their clients from 50 health centres where staff have received the mental health training with health workers and their clients from 50 health centres where staff have not received the mental health training.
All clients receive their normal care from the health workers; the study is not testing a specific drug.

What are the possible benefits and risks of participating?
Participation in the study will enable researchers and health personnel to better understand the health needs of clients and the training needs of those who care for them. There are no personal rewards for participation but participants may benefit by understanding mental health care better.

Where is the study run from?
The study is run from Great Lakes University Kisumu, University of Nairobi and Kings College London. There are 100 health centres involved in Nyanza province.

When is the study starting and how long is it expected to run for?
The study is running between August 2010 and December 2011. Participants have already been recruited.

Who is funding the study?
UK Department for International Development and the Nuffield Foundation.

Who is the main contact?
Professor Rachel Jenkins, Kings College London

Contact information

Type(s)
Scientific

Contact name
Prof Rachel Jenkins

Contact details
Health Services Research Department
Instuitute of Psychiatry
King's College London
de Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0668
rachel@olan.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of the impact of a Kenya Medical training College delivered structured five day training programme on mental health core concepts, skills and competencies on mental health for primary care staff in Kenya

Study objectives
The training programme will have an impact on:
1.The competencies of primary care staff to recognise mental disorders and
2. On recovery (improved health and social outcomes and quality of life of clients)

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. King's College London Ethics Committee approved on 5th October 2009, ref: PNM/08/09-113
2. University of Nairobi Ethics Committee approved on 15th October 2009, ref: P53/02/2009
3. Great Lakes University Kisumu Ethics Committee approved on 1st April 2010, ref: GERC/002 /2010

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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
Mental health

Interventions
100 primary care centres randomly allocated to intervention and control arms. The health workers' ability to diagnose and the clients' recovery was assessed

All patients attending this clinic will be asked to undergo a brief general health questionnaire which takes less than five minutes to complete. Twelve patients selected at random will then also be asked to complete a set of more detailed questionnaires. These will be completed twice, once now and once more in ten weeks time.

Training course for health workers. Intervention arm received 40 hours of training comprising 5 units, (1) core concepts, (2) core skills, (3) common neurological disorders (4) mental disorders, (5) policy, legislation, human rights, Health Management Information System (HMIS), community linkages, roles and responsibilities. Teaching structured into 30 minute modules, each containing a short lecture, discussion and a role play. Both arms were able to attend other health training courses as normal throughout the period of the study

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient identification index measured 3 months post training

Secondary outcome measures
1. Client recovery in terms of change on:
1.1. General health Questionnaire
1.2. World Health Organization Disability Assessment Schedule (WHODAS) and
1.3. EQ5D (Quality of LIfe)
Assessed by change between status at 3 months and status at 6 months after the training of the health workers

Overall study start date
01/08/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
Clinics: Is that they are publicly funded and on the Ministry of Health list of primary care centres.

Patients:
1. Is that they have attended the clinic on the research day
2. That they are over 16

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200 clients and 100 health workers

Key exclusion criteria
1. Dementia and learning disability of such severity as to be unable to complete the questionnaires
2. Life threatening illness
3. Don't speak the languages spoken by the researchers
4. Refusal to consent

Date of first enrolment
01/08/2010

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
England

Kenya

United Kingdom

Study participating centre
Health Services Research Department
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
de Crespigny Park
London
England
United Kingdom
SE5 8AF
+44 (0)20 7848 0668
rachel.jenkins@kcl.ac.uk

Sponsor type
University/education

Website
http://kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name

Nuffield Foundation and Department for International Development (UK)

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	client results	23/01/2013		Yes	No
Results article	health worker results	04/02/2013		Yes	No
Results article	results	30/09/2013		Yes	No
Results article	results	05/11/2013		Yes	No