

Training primary mental health workers in Malawi, to enable them to treat patients with mental health problems and assess the impact on the number of cases treated for malaria and non-specific musculoskeletal pains

Submission date 26/01/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/08/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There are different types of mental health disorders and some are more common than others. The common mental health disorders include depression and anxiety while the less common ones include psychotic illnesses such as schizophrenia. Mental health disorders if not detected and treated early have an enormous cost, as it can increase the risk of suicide, and impair family and social relations and overall productivity at work. Research done on people attending primary care clinics in both developed and developing countries shows that about 25% of them suffer from mental health disorders and in some cases, this reaches as high as 40%. Many people attending primary care clinics who have mental health disorders are missed by the doctors working in these clinics and research done in developed countries shows that about 50% of those with mental health disorders are missed. The number of people with mental health disorders who are missed in developing countries is much higher than that in developed countries and only around 0% to 5% are treated, meaning that over 90% of people with mental health disorders are missed and treated for something else. People with mental health disorders who are missed are mainly treated for physical illnesses and this is so because mental health disorders like depression sometimes present with physical symptoms like body pains and headache. Training of doctors working in primary care on how to detect and manage people with mental health disorders has been shown to increase the number of people with mental health disorders who are treated in primary care clinics. There are different training programs which are used to train doctors working in primary care in mental health. The trainings differ in content and the way they are conducted. The aim of this study is to assess a training program which was specially made for training doctors working in primary care clinics in mental health and see its impact on the number of people with mental health disorders attending primary care that are detected and treated for mental health disorders. We would also like to see if the increase in the number of people being treated for mental health disorders will have an impact on the number of people wrongly being treated for malaria and non-specific muscle pains.

Who can participate?

All adult patients aged 16 years or over who are attending primary care clinics can participate in the study.

What does the study involve?

The study will compare two training programs in mental health used to train doctors working in primary care clinics. Doctors working in the intervention group are going to be trained using a special training program which was developed for training doctors working in primary care clinics in Kenya, while those in the control group will be trained using a training program which has routinely been used to train doctors working in primary care in Malawi. The impact of the training will be assessed by looking at the ability of the doctors to detect patients with mental health disorders. Patients will complete questionnaires to see if they have a common mental disorder or not and their diagnosis as written by the doctor will be recorded.

What are the possible benefits and risks of participating?

For those patients who participate and are found to have a mental health disorder, they will be given treatment for it. The primary care doctors will get extra knowledge and skills in mental health for taking part in the study. There are no risks to both patients and doctors who take part in the study.

Where is the study run from?

The study will be carried out in one of the 28 districts of Malawi, known as Machinga district, and all 18 primary care clinics belonging to the government and missionary organisations which have outpatient services will take part. The people conducting the study are based at Zomba Mental Hospital in Malawi.

When is the study starting and how long is it expected to run for?

The study will start in October 2008 and finish in March 2009. The study will be recruiting participants for 6 months.

Who is funding the study?

The study is being funded by the Ministry of Health in Malawi.

Who is the main contact for the study?

Dr Felix Kauye
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Contact information

Type(s)

Scientific

Contact name

Dr Felix Kauye

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Primary mental health workers training and its impact on service delivery in a developing country (Malawi): a cluster-randomised controlled trial

Study objectives

1. Integration of mental health in primary care using a specially designed mental health training toolkit will lead to a 15% increase in the proportion of psychiatric patients being treated at primary health care level in a designated district in the southern region of Malawi
2. Increased detection and good management of mental health problems will lead to reduced cases of clinically misdiagnosed malaria i.e. percentage of cases of clinically diagnosed malaria seen over total number of cases seen in intervention arm compared to control arm
3. Increased detection and good management of mental health problems will lead to reduced cases of non-specific musculoskeletal pains seen in clinics i.e. percentage of cases of non-specific musculoskeletal pains over total cases seen in clinics in intervention arm compared to control arm

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Kings College Research Ethics Committee, 28 February 2008, ref: 07/08-102
2. National Health Sciences Research Committee of Malawi, 14 February 2008, ref: 501

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Diagnostic

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

Common mental disorders i.e. depression and anxiety, malaria and non-specific musculoskeletal pains

Interventions

Randomisation of the project was done at clinic level and all health workers and patients working and attending clinics that were randomised to a particular arm, belonged to that arm. The clinics were randomised by pair matching based on average daily attendances and the actual randomisation was done by a statistician from University of Liverpool in the United Kingdom who had no knowledge of the study area.

The treatment was in the form of trainings in mental health which the health workers working in the clinics underwent. The training in the intervention arm takes 5 days while the routine training for the control arm takes 3 days. After the trainings, data will be collected from the clinics until the allocated number of patients to be enrolled in the study for that clinic is reached.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of cases diagnosed with depression, anxiety, malaria and non-specific musculoskeletal pains

1. The proportion of patients with depression as identified by the SCID who are correctly identified by PHC workers

1.1. Before and after intervention training in the intervention arm

1.2. Between intervention and control arms after intervention trainings in the intervention arm

2. The proportion of patients with a diagnosis of anxiety identified and treated by PHC workers

2.1. Before and after intervention training in intervention arm

2.2. Between intervention and control arms after intervention trainings in the intervention arm

Integration of mental health in primary care using the specially designed toolkit will directly lead to improvement in other health outcomes in the designated district in the southern region of Malawi.

Secondary outcome measures

The differences in proportion of patients treated for clinically diagnosed malaria and non-specific musculoskeletal pains respectively by PHC workers in control and intervention arms

Overall study start date

01/10/2008

Completion date

30/03/2009

Eligibility

Key inclusion criteria

1. All health centres with outpatient services in the designated district
2. All primary health workers working in the health centres
3. Consecutive adult attendees aged 16 years and above at the Health Centres

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Baseline = 837, Post-intervention = 2600

Key exclusion criteria

1. Health centres with no outpatient services
2. Primary health workers working in health centres with no outpatient services
3. Patients below 16 years and critically ill

Date of first enrolment

01/10/2008

Date of final enrolment

30/03/2009

Locations

Countries of recruitment

Malawi

Study participating centre

Zomba Mental Hospital

Zomba

Malawi

N/A

Sponsor information

Organisation

Ministry of Health (Malawi)

Sponsor details

c/o Zomba Mental Hospital

P.O. Box 38

Zomba

Malawi

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Sponsor type

Government

Website

<http://www.malawi.gov.mw/>

ROR

<https://ror.org/0357r2107>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health (Malawi)

Funder Name

Commonwealth Scholarship Commision (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