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STEPped-CARE intervention for depression in primary care

Submission date
06/08/2013

Recruitment status
No longer recruiting

Registration date
23/09/2013

Overall study status
Completed

Last Edited
20/05/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is estimated that depressive disorders (illnesses involving low mood) will become the third most burdensome health problem in the low income countries after HIV/AIDS and childbirth-related conditions. Even though effective treatments for depression are available, previous studies in Nigeria showed that about four out of five people with severe mental disorders, particularly depression, had received no treatment in the previous year. The Nigerian health system, similar to that in most of sub-Saharan Africa, has a shortage of human and material resources. For example, there is less than one psychiatrist to one million population and the few available specialists are concentrated in urban areas. A way to manage this limitation is to integrate mental health into primary health care, where services are mostly provided by non-physician primary health care workers. This strategy is much more likely to be viable and affordable because these resources already exist, are less expensive, and are accessible. However, this strategy also has some limitations. A new model to address the treatment gap for depression must therefore provide a more efficient way of allocating existing resources to give effective treatment. Stepped-care models claim to maximize efficiency by allocating available resources strictly according to needs, offering greater resources to those with complex or severe problems. In this model, non-physician primary care providers deliver the bulk of essential mental health service and receive structured and targeted supervision and support from physicians and more highly trained mental health specialists on the specific needs of the patients. The proposed study aims to compare the effectiveness and cost-effectiveness of this model, in which the supervision and support are provided with the use of mobile phones, with care as usual.

Who can participate?
Participants will be adults, aged 18 years or over, consulting the participating primary health care clinics during the study.

What does the study involve?
Patients will be randomly allocated to one of to two groups: intervention group and control group. Patients in the intervention group will receive manual-driven psychological and antidepressant treatments from primary care providers as well as medical or specialist assessments and care based on the severity of their depression. Patients in the control arm will

receive care as usual, enhanced by further training of the providers, in that group, on the nature and management of depression. Recovery from depression will be assessed at 12 months. Changes in cost-effectiveness, disability and quality of life will also be measured.

What are the possible benefits and risks of participating?
Participants in both groups will benefit from improved care of depression. The risk associated with detailed and possible troubling assessment of sensitive emotional issues will be managed by the use of well-trained research staff and the availability of a structured medical response to severe distress that may be experienced by participants.

Where is the study run from?
The study will be run from the primary health care clinics (PHCs) in four selected local government areas in Oyo State, Nigeria. Patient recruitment will be conducted in 20 PHCs drawn from two urban and two rural local government areas.

When is the study starting and how long is it expected to run for?
The study will start in November 2013 and is expected to run until October 2016.

Who is funding the study?
The study is funded jointly by the Medical Research Council (UK), the Wellcome Trust (UK), and the Department for International Development (DFID) (UK).

Who is the main contact?
Professor Oye Gureje
ogureje@comui.edu.ng

Contact information

Type(s)
Scientific

Contact name
Prof Oye Gureje

Contact details
Department of Psychiatry, University College Hospital
Ibadan
Nigeria
PMB5116
+234 2 815 0258
ogureje@comui.edu.ng

Additional identifiers

Protocol serial number
UI/EC/10/0041

Study information

Scientific Title

A cluster randomized controlled trial of a STEPped-CARE intervention for depression in primary care

Acronym
STEPCARE

Study objectives
A stepped-care intervention program for depression delivered mostly by non-physician primary health care workers, in which medical and specialist supervision and support are provided with the use of mobile phones, will be more effective and cost-effective than care as usual at improving clinical outcome and quality of life at 12 months.

Added 12/02/2015:
This is the Main Phase of the project. A Pilot Phase has been conducted in 6 clusters that are not included in the Main Phase. For the pilot, 165 subjects were enrolled to the intervention arm and 69 to the control arm. The objectives of the pilot were:
1. To study the organizational structure of primary care service in regard to the provision of care for persons with depression.
2. To explore the understanding of depression and expectations for its treatment by primary care providers, patients, and their relatives. In particular, to explore views about psychological and pharmacological interventions.
3. To develop an intervention package consisting of problem solving treatment, psychoeducation, and structured support by physicians and psychiatrists, using mobile telephony.
4. To assess the feasibility of and different strategies for recruiting and randomizing of patients for a controlled intervention trial.
5. To assess the fidelity of delivering the intervention by primary care providers.
6. To explore strategies for improved recruitment and retention of subjects.
7. To explore strategies for adequate staff and organizational support for the trial
8. To assess satisfaction with the intervention by patients and staff.
9. To explore the factors associated with patient retention in the study and adherence with the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ibadan/University College Hospital Joint Ethics Committee

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
Patients are randomised to two arms: an intervention arm in which a manualized stepped-care intervention package is provided and a control arm delivering usual care.

The intervention to be provided incorporates components of the World Health Organization mhGAP-Intervention Guide for depression, contextualized and adapted for the Nigerian health system, and Problem Solving Treatment (PST). All individuals consenting into the trial receive STEP 1 consisting of a psychological intervention delivered by the primary health care workers (PHCWs). Those individuals with PHQ-9 ≥ 15 at baseline are immediately assessed (with General Physician (GP) support) for medication. At 8 weeks all patients are assessed again with the PHQ-9 and those not responding or whose symptoms worsen (PHQ-9 ≥11 and/or a decrease of less than 50% on PHQ-9 baseline score) are moved to STEP 2 consisting of an assessment in consultation with a GP with a view of initiating pharmacotherapy. Those who were already on medication but met the same criteria are also assessed with a view to modifying medication regime. STEP 1 or the psychological component consists of psychoeducation, reactivation of social network, and PST. This intervention is delivered in 8-weekly sessions to all people entering the program. The initial session is dedicated to psychoeducation in which the symptoms of depression, possible causes and treatments are discussed. The following 5 sessions contemplate teaching the basics of PST using examples provided in the manual and the person's own examples. Session 6 is dedicated to exploring support through social networks and the last two sessions are about integrating it all and preparing for the future. All sessions are face-to-face in the clinic.
STEP 2 consists of assessment and eventual prescription of antidepressants. The first line will be amitryptiline, which non-physician primary care providers in Nigeria are authorized to prescribe. If patients do not improve after this step their cases can be discussed with a psychiatrist by the GP in the final STEP 3 in the sequence covering up to 6 months. All the steps, clinical decisions, and actions to be taken are detailed in a manual. All supervision and consultations with doctors will be through mobile phones except when a face-to-face review is deemed necessary and feasible. PHCWs will receive supervision from the GP when PHQ-9 denotes severe depression; there is no improvement at 8 week; and in cases of emergencies (e.g. suicide risk or serious drug reaction). All telephone reviews and consultations will be on as-needed basis, structured, and following a manualized flow-chart that proceeds from the PHCWs through to the GP and to the psychiatrist. The PHCWs will co-ordinate all management procedures. Prior to recruitment of patients, providers in the intervention arm will be offered a training on the recognition of depression, the delivery of the manualized intervention package, as well as procurement and documentation of support and supervision using mobile phones.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome will be the proportion of participants recovering from depression at 12 months from entering the trial (who no longer meets the DSM-V criteria for major depression)

Key secondary outcome(s)
Secondary outcomes will be conducted at 3, 6 and 9 months and will consist of:
1. PHQ9 scores (in order to address the possibility that even though individuals may have recovered from a major depressive disorder, significant depressive symptoms may still persist

2. Disability as assessed using the WHO Disability Assessment Scale (since there is evidence that disability may follow a different trajectory from that of symptoms among persons with depression)
3. Quality of life as measured by WHO Quality of Life instrument (in view of the evidence that health-related quality of life is a different and important dimension of illness experience other than disability and may more accurately capture personal views of impairment). Service use information, that provides data for computation of cost of care, will be collected using the Service Use Questionnaire.

Completion date
31/10/2016

Eligibility

Key inclusion criteria
Consecutive attendees who consent will be screened while waiting to see primary care providers. Those who screen positive will be assessed for inclusion and exclusion, and if eligible, invited to enter the study. Patients much satisfy all of the following to be considered for study entry:
1. Adults, aged 18 years or over, with a score of 11 or more on the Patient Health Questionnaire (PHQ-9)
2. Confirmed 5th edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-V) diagnosis of depression using the Composite International Diagnostic Interview (CIDI)
3. Provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
1178

Key exclusion criteria
1. Immediate need for medical attention
2. Pregnant
3. Actively suicidal
4. Presence of bipolar or psychotic disorder or severe substance dependence
5. Unlikely to be in the neighbourhood in the following 12 months

Date of first enrolment
01/12/2013

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
Nigeria

Study participating centre
University College Hospital
Ibadan
Nigeria
PMB5116

Sponsor information

Organisation
University of Ibadan (Nigeria)

ROR
https://ror.org/03wx2rr30

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust (UK) (WT ref: 100070)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	01/05/2015		Yes	No
Results article	results	01/07/2019	20/05/2019	Yes	No
Protocol article	protocol	07/07/2015		Yes	No