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Management of depression by primary care health workers in Lagos, Nigeria

Submission date
15/01/2017

Recruitment status
No longer recruiting

Registration date
31/01/2017

Overall study status
Completed

Last Edited
29/07/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Integrating treatment services for depression into primary care (first point of contact in the health care system) is widely acknowledged as the most feasible strategy to address the treatment gap for depression in low and middle income countries. This study is looking at a collaborative stepped care treatment program, which is a program that involves a range of different types of treatment. The aim of this study is to evaluate the clinical and cost effectiveness of this program when offered in primary care, and to see if the the addition of mobile phone support can help encourage patients to stick to their treatment.

Who can participate?
Adults who have been diagnosed with depression and attend 15 Primary Health Centers (PHCs) in Lagos, Nigeria.

What does the study involve?
Participating Primary Health Centers (PHCs) are randomly allocated to one of three groups. Those in the first group receive information leaflets about depression, its causes, symptoms, and ways of preventing it. Those in the second group receive the same information leaflet as the first group, as well as the collaborative stepped care (CSC) treatment program. This involves a complication of being educated about depression, as well as problem solving therapy. Participants that this does not work for are offered antidepressant medication and referral to a psychiatrist. Those in the third group receive the information leaflet and the CSC program with the addition of mobile phone-based support. This involves receiving regular text messages to remind participants about appointments, the importance of sticking to the program and what to do if their condition worsens. At the start of the study and again after four, six and twelve months, participants in all three groups are followed up to find out if there has been any changes in their mood and quality of life. The costs of the program and how well participants have been following it are also recorded.

What are the possible benefits and risks of participating?
All participants benefit from being screened for depression and will receive a depression information leaflet. Two thirds of the participants will receive treatment which may help in to reduce their depression symptoms. There are no notable risks associated with participating in this study.

Where is the study run from?
15 Primary Health Centers (PHCs) in Lagos (Nigeria)

When is study starting and how long is it expected to run for?
February 2013 to December 2016

Who is funding the study?
Grand Challenges Canada (Canada)

Who is the main contact?
Professor Abiodun Adewuya
abiodun.adewuya@lasucom.edu.ng

Contact information

Type(s)
Scientific

Contact name
Prof Abiodun Adewuya

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GMH-0084-04

Study information

Scientific Title
Collaborative stepped care intervention with mobile telephone support for primary care workers' management of depression in Lagos, Nigeria: A cluster randomized controlled trial

Acronym
DEP-CARE

Study objectives
1. Collaborative stepped care (CSC) intervention for depression in primary care will be more clinical and cost effective in reducing symptoms of depression compared with treatment as usual
2. CSC intervention with mobile telephone support will be more effective that CSC intervention only in reducing depressive symptoms but in improving other outcomes like treatment adherence, disability, quality of life, economic cost and stigma experience

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lagos State University Teaching Hospital Health Research and Ethics Committee, 11/06/2013, LREC/10/06/299

Study design
Three-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Participating centers are randomized to one of the three groups by an independent centre using minimization procedure to ensure even distribution of the PHCs as per their size.

Control group: Participants receive information leaflets about depression, its causes, symptoms and ways of preventing it.

CSC only group: Participants receive the collaborative stepped care (CSC) intervention. This involves the following:
1. Information leaflets about depression, its causes, symptoms and ways of preventing it

2. Psychoeducation focusing on educating the patient about their symptoms, the association of depression with interpersonal difficulties, the need to share emotional symptoms with the doctor and sharing personal difficulties with family members caring for them or other key people in their social network
3. Problem Solving Therapy in Primary Care (PST-PC) consisting of 6 sessions are offered to patients with unresolved mild depression, pregnant women, breastfeeding mothers, elderly, adolescents or those with co-morbid medical conditions and patients with moderate/severe depression not wanting medications
4. Antidepressants for moderate/severe depression, those not responding after 6 sessions of PST-PC or those not wanting PST-PC. Amitriptyline or Fluoxetine are the medications of choice and are given for 6 months.
5. Referral to mental health team for non-responders to antidepressants after 4 months, cases of depression with psychosis or suicidal ideations/attempts

CSC+ Mobile telephony support group: Participants receive the same collaborative stepped care (CSC) intervention as the CSC only group with the addition of mobile telephony support. This involves receiving:
1. Two text messages to remind patient about the next clinic appointment – the first text message delivered three days to the appointment and second text message delivered 24 hours to the appointment
2. One text message per week advising on the importance and benefits of adherence to PST-PC sessions and home works, and medication adherence
3. One text message per month outlining symptoms of relapse and need to consult doctor if such symptoms are noticed. This will be handled by the Community Health Workers (CHEWs)
4. Voice prompt and rescheduling of clinic attendance for a week later if patient misses a clinic appointment
5. A phone call from the Community Health Worker if patient misses the re-scheduled appointment

Follow up for participants in all groups involves scheduled clinic visits at the PHCs after four, six and twelve months.

Intervention Type
Mixed

Primary outcome measure
Depressive symptoms are measured using the Patient Health Questionnaire (PHQ-9) at 4, 6 and 12 months.

Secondary outcome measures
1. Disability due to the illness is measured using the Short form of the WHO Disability Assessment Schedule (WHODAS-S) at baseline, 6 and 12 months
2. Quality of life is measured using the Brief version of the WHO Quality of Life schedule (WHOQOL-Bref) at baseline, 6 and 12 months
3. Adherence to treatment instructions (clinic appointments and drug dosage) is measured using logs of attendance and tablet counts at 6 and 12 months
4. Death from suicide and rate of self-inflicted injuries at 6 and 12 months
5. Health economic cost is calculated using the Client Service Receipt Inventory at 6 and 12 months
6. Stigma experience by the patient will be measured using the 7-item Impact Scale of the Inventory of Stigma Experiences at baseline, 6 and 12 months

Overall study start date
01/02/2013

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Adults aged 18-60 years
2. Scoring >10 on PHQ-9 or persistent score of >5 but <10 on PHQ-9 for 2 weeks
3. Intend to stay in the project area for at least 16 months
4. Ready to consent to trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
A total of 15 clusters (5 clusters per arm) with a recruitment rate of 90 patients per cluster makes 450 patients in each arm and 1,350 patients overall

Total final enrolment
907

Key exclusion criteria
1. Children (below 18 years) and the elderly (above 60 years)
2. Patients with serious medical condition or disability necessitating specialist care
3. Patients having presently having any form of psychosis or under psychiatric care or showing suicidal ideation or attempt.
4. Patients with scores 5 or less on PHQ-9 on first visit or 2 weeks repeat screen
5. Patients not intending to stay in the project area for at least 16 months

Date of first enrolment
01/07/2014

Date of final enrolment
30/07/2015

Locations

Countries of recruitment
Nigeria

Study participating centre
Alausa Primary Health Center
30 Kadiri Street Oregun/Ikeja
Lagos
Nigeria
-

Study participating centre
r
78a, Akowonjo Road
Egbeda
Lagos
Nigeria
-

Study participating centre
Ifako Primary Health Center
1, African Church Road
Ifako-Ijaye
Lagos
Nigeria
-

Study participating centre
Ikosi-Isheri Primary Health Center
20 Ikosi Road
Ikosi-Isheri
Lagos
Nigeria
-

Study participating centre
Ilasa Primary Health Center
34 Ogunbowale street
Ilasa
Lagos

Nigeria
Lagos

Study participating centre
Iyana-Ejigbo Primary Health Center
1, Iyana Ejigbo Bus stop
Ejigbo
Lagos
Nigeria
-

Study participating centre
Kajola Primary Health Center
1, Akintan Street
Mascara
Ketu
Lagos
Nigeria
-

Study participating centre
Meiran Primary Health Center
2 Meiran Road Iyana Meiran Bus stop
Meiran
Lagos
Nigeria
-

Study participating centre
Ojodu Primary Health Center
1 Badamosi Street
Ojodu Berger
Lagos
Nigeria
-

Study participating centre
Ogudu Primary Health Center
175, Odudu Road

Lagos
Nigeria
-

Study participating centre
12) Oregun Primary Health Center
32 Kudirat Abiola way
Oregun Ikeja
Lagos
Nigeria
-

Study participating centre
Oshodi Primary Health Center
5 Ogunlana Street
Oshodi
Lagos
Nigeria
-

Study participating centre
Aregbesola Primary Health Center
Along Pipeline Okunola Road
Lagos
Nigeria
-

Study participating centre
Sango Agege Primary Health Center
1 Balogun Street
Sango Maternity center
Lagos
Nigeria
-

Sponsor information

Organisation
Lagos State University College of Medicine

Sponsor details
1-5 Oba Akinjobi Way. Ikeja
Lagos
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10010

Sponsor type
University/education

Website
www.lasucom.edu.ng

ROR
https://ror.org/01za8fg18

Funder(s)

Funder type
Research organisation

Funder Name
Grand Challenges Canada (GCC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Abiodun Adewuya (abiodun.adewuya@lasucom.edu.ng)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019	29/07/2019	Yes	No