ISRCTN94230307 https://doi.org/10.1186/ISRCTN94230307

Scaling up care for depression in mothers before and after giving birth to improve the health of mother and child

Submission date
29/11/2019

Recruitment status
No longer recruiting

Registration date
03/12/2019

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The huge treatment gap for mental disorders in low- and middle-income countries (LMIC) necessitates the need for task-sharing approaches in scaling up care for mental disorders. Previous work has shown that primary care workers (PHCW) can be trained to recognize and respond to common mental disorders but there are lingering questions around sustainable implementation and scale-up in real-world settings. The study aims to train primary care providers on the identification and treatment of depression in pregnant women and new mothers. It also aims to assess changes in the identification and treatment practices of primary care providers before and after their training, as well as the cost-effectiveness of the training programme.

Who can participate?
Psychiatrists, supervising physicians, senior primary care workers (nurses and community health extension workers) and pregnant women who are making their first antenatal visit to maternal care clinics.
What does the study involve?
It involves the determination of the effectiveness of training frontline primary care providers to identify and treat perinatal depression.

What are the possible benefits and risks of participating?
Participants and others may benefit in the future from the information learned in this study. No identified risk is associated with participating in this study.

Where is the study run from?
Department of Psychiatry, University College Hospital Ibadan, Nigeria

When is the study starting and how long is it expected to run for?
November 2014 to November 2020

Who is funding the study?
Innovating for Maternal and Child Health in Africa Initiative - a partnership of Global Affairs Canada (GAC), the Canadian Institutes of Health Research (CIHR) and Canada's International Development Research Centre (IDRC).

Who is the main contact?
Prof. Oye Gureje
oye_gureje@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Oye Gureje

ORCID ID
http://orcid.org/0000-0003-0094-5947

Contact details
WHO Collaborating Centre for Research and Training in Mental Health
Neurosciences and Substance Abuse
Department of Psychiatry
University of Ibadan
Ibadan
Nigeria
200212
+234 8033464284
oayinde@brandeis.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Scaling up Care for Perinatal Depression for Improved Maternal and Infant Health (SPECTRA): a hybrid trial of the impact of cascade training of primary maternal care providers in Nigeria

Acronym
SPECTRA

Study objectives
The delivery of MhGAP to primary care workers through cascade training will lead to an improved detection rate of perinatal depression by the primary care workers and improved patient outcome and will be cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2016, UI/UCH Ethics Committee (University of Ibadan/University College Hospital, Ibadan, Queen Elizabeth Road, Oritamefa, Ibadan, Nigeria; uiuchirc@yahoo.com; 234-2-2413922), ref: NHREC/05/01/2008a

Study design
Interventional non-randomized before and after study design

Primary study design
Interventional

Secondary study design
Before and after study design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Perinatal depression

Interventions
Current interventions as of 12/08/2020:
The main intervention will be the Mental Health Gap Action Programme (mhGAP) training which will be delivered to frontline primary care providers in maternal care clinics through a cascade training programme involving trainers of trainers (psychiatrists) and trainers (senior primary care providers).

To assess pre-training level of care provided by the frontline primary care providers, a cohort of patients will be recruited and followed up by trial research assistants in the maternal clinics before the cascade training is carried out and another cohort will be recruited after the cascade training. These pre-training and post-training cohorts of patients will be recruited to determine how many of them will be detected to have perinatal depression by the primary care workers before and after the training, how many of them will recover from perinatal depression

following treatment before and after the training and if the MhGAP cascade training programme is effective. Each of the women will have a baseline assessment conducted in their home (or any other place of their choice) within 72 hours of being screened and outcome assessments at 3 and 6-month post-delivery.

Previous interventions:
The main intervention will be the Mental Health Gap Action Programme (mhGAP) training which will be delivered to frontline primary care providers in maternal care clinics through a cascade training programme involving trainers of trainers (psychiatrists) and trainers (senior primary care providers). The MhGAP is designed to assist low- and middle-income countries in their efforts to scale up the coverage of mental health services for their citizens. The Depression module of the MhGAP intervention guide (MhGAP-IG), which is a manual designed to facilitate the recognition and management of a set of priority mental, neurological, and substance use (MNS) disorders in non-specialist settings, will be used to train the frontline primary care workers to identify and treat perinatal depression. The mhGAP-IG depression module provides detailed guideline for the management of moderate to severe depression with special consideration for pregnant or breastfeeding women. The mhGAP-IG emphasizes the use of psychosocial interventions for depression in pregnant and breast-feeding women with the lowest effective dose of an antidepressant being used when there is no response to psychosocial treatments. In line with this, interventions for perinatal depression in this study will include psychoeducation, addressing current psychosocial stressors and reactivating social networks.

One Training of Trainers (ToT) workshop will be conducted by two psychiatrists (Master Trainers) with experience in the training of providers in the use of mhGAP-IG and perinatal mental health. The trainers will be trained in the use of mhGAP-IG to manage perinatal depression (with a range of severity) and suicidality and how to train the end users and provide supervision and support to them. Subsequent to the ToT, the trained trainers will conduct training workshops with the end-users of mhGAP-IG. This training will utilize the training materials developed by the Master Trainers and will be supervised by the Master Trainers. Each training workshop will be facilitated by at least two of the trained Trainers. Each 2-day workshop will be attended by no more than 20 participants to ensure effective and interactive training. Participants will be tested pre- and post-training. They will also provide structured ratings on the content and delivery of the training. At the end of each training workshop, the Master Trainer will have a de-briefing session with the Trainers during which a review of the workshop will be conducted and lessons learnt noted.

A subset of the frontline primary care providers will be given a booster MhGAP training six months after the initial training and they will be provided a screening tool to assist them in identifying perinatal depression in routine clinical work. All the frontline providers will be given supportive supervision on their job.

To assess pre-training level of care provided by the frontline primary care providers, a cohort of patients will be recruited and followed up by trial research assistants in the maternal clinics before the cascade training is carried out and another cohort will be recruited after the cascade training. These pre-training and post-training cohorts of patients will be recruited to determine how many of them will be detected to have perinatal depression by the primary care workers before and after the training, how many of them will recover from perinatal depression following treatment before and after the training and if the MhGAP cascade training programme is effective. Each of the women will have a baseline assessment conducted in their home (or any other place of their choice) within 72 hours of being screened and outcome assessments at 3 and 6-month post-delivery.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 12/08/2020:
Primary implementation outcome:
Perinatal depression identified using Edinburgh Postnatal Depression Scale before and after cascade training

Primary effectiveness outcome:
Remission rates from depression defined as an EPDS score of 5 or less at 6 months postpartum

Previous primary outcome measures:
Depression measured using the Edinburgh Postnatal Depression Scale at baseline and 3 months

Secondary outcome measures

Current secondary outcome measures as of 12/08/2020:
1. Level of disability assessed with the WHO-DAS at 6 months postpartum
2. Infant growth and development outcomes:
2.1. Gestational age at birth, place of delivery, infant birth weight and head circumference, obtained from enquiry from the perinatal women and from direct measurement of the infants by research assistants at birth
2.2. Infant well-being assessment at 3 months, 6 months and 1 year post-delivery

Secondary implementation outcomes: a range of mixed-methods assessments will be conducted as follows:
1. Pre and post-test of providers on knowledge of and attitude to perinatal depression with knowledge of depression scale and depression attitude questionnaire after each training session
2. Assessment of knowledge retention using knowledge of depression scale and depression attitude questionnaire at 6 months after training
3. Supportive supervision of clinics with a structured checklist throughout implementation
4. Assessment of quality of intervention using the Enhancing Assessment of Common Therapeutic factors (ENACT) during implementation
5. Qualitative interviews during and after implementation

Previous secondary outcome measures:
1. Patient outcomes: (within 72 hours of being screened and outcome assessments at 3 and 6-month post-delivery)
1.1. Service utilisation, income, accommodation and other cost-related variables measured using the Client Service Receipt Inventory– Postnatal version (CSRI-PND))
1.2. Disability measured using the World Health Organization Disability Assessment Scale (WHO-DAS)
1.3. Patient care measured using the Patient Assessment of Chronic Illness Care questionnaire
2. Assessment of quality of intervention: Extent to which providers are using the skills acquired during the training measured using the Enhancing Assessment of Common Therapeutic factors (ENACT) rating scale
3. Assessment of contextual factors affecting delivery of intervention: Qualitative interviews will be conducted with selected PHCW (N =20) and patients who recover from depression and remain well through the follow-up period (N = 15) and those who fail to make consistent recovery (N = 15) to understand contextual factors that enable/inhibit the delivery of effective treatment using the mhGAP-IG
4. Process evaluation:

4.1. The training process:
4.1.1. Changes in knowledge and attitude of the trainers measured using pre and post-test questionnaires, knowledge of depression scale, and depression attitude questionnaire administered before and after the training sessions. We will evaluate the extent to which trainers demonstrate fidelity to the training procedure when they train the PHCW.
4.1.2. Master trainers will sit-in at the training workshops delivered by the trained trainers as non-participant observers. During these observations, the master trainers will document their assessment of the training procedure using a semi-structured observation pro forma specifically designed for this purpose. Some of the cascade training sessions will be video-recorded.
4.2. The Trainees: changes in the knowledge and attitude of the trainees' measured pre and post-training:
4.2.1. Pre- and post-test questionnaires
4.2.2. Selected items from the Knowledge of depression scale
4.2.3. Depression attitude questionnaire
4.2.4. Satisfaction with training- a semi-structured questionnaire designed to capture: what they liked most about the training, what they had not understood about training topics, what they would do differently as a result of the training
4.2.5 Changes in practice after the training
4.2.6 Retention of knowledge and changes in attitude (at 3, 6, 12 months after training) using Post-test questionnaire, Knowledge of depression scale and the Depression attitude questionnaire

Overall study start date
03/11/2014

Completion date
30/11/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/08/2020:
Trainers of trainers:
1. Psychiatrists experienced (Master Trainers) with experience in the training of providers in the use of mhGAP-IG and perinatal mental health

Trainers:
1. Supervisory physicians
2. Senior nurses
3. Senior community health officers

Perinatal women:
1. Consecutive women making their first antenatal visit
2. Consent to participate in trial
3. Score 10 or more on the Edinburgh Postnatal Depression Scale (EPDS)
4. Female
5. Adult aged between 18 and 65 years

Previous inclusion criteria:
Trainers of trainers:
1. Psychiatrists experienced (Master Trainers) with experience in the training of providers in the

use of mhGAP-IG and perinatal mental health
2. Male and female
3. Adult aged between 18 and 65 years

Trainers:
1. Supervisory physicians
2. Senior nurses
3. Senior community health officers
4. Currently working in maternal clinics where the study is being conducted
5. Male and female
6. Adult aged between 18 and 65 years

Perinatal women:
1. Consecutive women making their first antenatal visit
2. Consent to participate in trial
3. Score 10 or more on the Edinburgh Postnatal Depression Scale (EPDS)
4. Female
5. Adult aged between 18 and 65 years

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Trainers: 44; Trainees: 200; Mothers cohort 1: 167, cohort 2: 334

Total final enrolment
898

Key exclusion criteria
Current exclusion criteria as of 12/08/2020:
Perinatal women:
1. Suicidality
2. Patient too ill to cope with interview

Previous exclusion criteria:
Perinatal women:
1. Severe depression (EPDS score 18 or more)
2. Suicidality
3. Patient too ill to cope with interview

Date of first enrolment
01/08/2016

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
Department of psychiatry University College Hospital Ibadan
Queen Elizabeth Road
Oritamefa
Ibadan
Nigeria
200212

Sponsor information

Organisation
University of Ibadan

Sponsor details
College of Medicine
Ibadan 5116
Ibadan
Nigeria
200212
+234 22914130
Provost@com.ui.edu.ng

Sponsor type
University/education

Website
https://com.ui.edu.ng/

ROR
https://ror.org/03wx2rr30

Funder(s)

Funder type
Government

Funder Name
International Development Research Centre

Alternative Name(s)
Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Publication and dissemination plan
1.Scientific publications
2. Conference presentations
3. Policy engagement meetings

Intention to publish date
15/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Oye Gureje (oye_gureje@yahoo.com). Anonymised participant-level data may be made available on reasonable request for an agreed-upon period of time.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/09/2021	15/08/2022	Yes	No
Results article		20/11/2023	21/11/2023	Yes	No
Results article		08/02/2024	09/02/2024	Yes	No
Results article		12/02/2025	13/02/2025	Yes	No