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EXPanding care fOr periNATal women with dEpression (EXPONATE)

Submission date
04/04/2013

Recruitment status
No longer recruiting

Registration date
15/05/2013

Overall study status
Completed

Last Edited
03/09/2019

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
Depression is common amongst women of child bearing age with an estimated prevalence (percentage of a population affected at a given time) of major and minor depression of between 8.5% and 11% during pregnancy and between 9.7% and 12.9% postnatally. Perinatal (period shortly before and after birth) depression is a substantial public health problem, not only because it is common but also because it is associated with long term adverse consequences for maternal and infant development. Maternal depression is a risk factor for pre-term birth and low birth weight, infant under-nutrition and stunting as well as higher rates of diarrhoeal diseases. Infants of depressed mothers also show poorer infant development, poorer interpersonal functioning, insecure attachment and increased rates of emotional and behavioural problems. Even though the importance of perinatal depression a public health issue is becoming increasingly recognized, particularly in high income countries, low- and middle-income countries (LMIC), where the burden of depression falls disproportionately on women of child-bearing age have yet to respond appropriately to this health challenge.
Most previous research on perinatal depression has focused on the consequences and treatment of postnatal depression and only few have examined antenatal depression. There are several reasons why it may be beneficial to study treatments for perinatal depression during pregnancy. Firstly, treating depression during pregnancy offers the prospect of preventing negative perinatal outcomes including: poorer clinic attendance, smoking, drinking alcohol, obstetric complications, low birth weight, prematurity, still birth, mother-infant bonding, cognitive and behavioural outcomes in the infants, and postnatal depression. Treatment may also reduce the potential direct effects of both maternal anxiety and depressive disorders on fetal development. Second, the use of antidepressant medication during pregnancy poses special difficulties due to the negative consequences of some antidepressants on the developing foetus. As a result of these effects, taking medicines during pregnancy is less acceptable to mothers. Third, antenatal depression is a far more common condition than postnatal depression and is a major risk factor for the latter. Finally, there may be a need to adapt the content of psychological treatment to the specific context of pregnancy. The treatment of perinatal depression needs to distinguish between the antenatal and postnatal periods. Different groups of professionals usually will be involved in the provision of care during the two time periods: obstetricians before and soon after childbirth and pediatricians during the postnatal period.
The main aim of the study is to determine whether a structured intervention package delivered

by midwives in routine perinatal care is better than care as usual in improving the outcome of perinatal depression both for the mothers and their infants and whether the intervention is cost-effective.

Who can participate?
Women aged between 16 and 45 years and a gestational age of between 16 and 26 weeks, who are consulting for routine ante-natal care and who, during assessment, are found to have moderate or severe major depressive disorder and who consent to participate. Study participants must meet a set of inclusion criteria to be included in the study.

What does the study involve?
Maternal and infant outcomes will be compared between women with depression during pregnancy who are selected from two groups of maternal clinics, one delivering usual care and the other delivering the intervention package. Patients selected from control arm will receive usual care as currently provided in the clinics. Patients selected from the intervention arm will receive an intervention package specifically developed for the study. The intervention package will consist of a guide for depression which has previously been contextualized and adapted for the Nigerian health system. The psychological component consists of psychoeducation, reactivation of social network, problem solving treatment (PST) and parenting skills. Outcome assessments are conducted on patients in their homes or chosen location of interview by research workers.

What are the possible benefits and risks of participating?
The benefits to patients include the increased likelihood of the recognition of depression among those with the disorder and the availability of treatment for the condition. For those in the intervention arm, a full complement of evidence-based treatment for depression will be provided. The increased recognition and enhanced treatment will likely lead to better outcome for mothers and their babies. The risk of patient distress during evaluation will be improved by proper trainting of the research staff. Any deterioration in the clinical condition of partiticipants, including suicidal risk, will be attended to by following protocol specificactions detailing a structured procedure for responding.

Where is the study run from?
The study will be conducted in Oyo State. The unit of allocation is maternal care clinics which are organized within local government areas.The study are being run from the Department of Psychiatry, College of Medicine, University of Ibadan.

When is the study starting and how long is it expected to run for?
The study will start in June 2013 and is expected to run for 30 months.

Who is funding the study?
Grand Challenges Canada.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UI/EC/12/0278

Study information

Scientific Title
EXPanding care fOr periNATal women with dEpression (EXPONATE): a cluster randomized controlled study

Acronym
EXPONATE

Study objectives
The primary hypothesis is that the intervention package will be more effective at alleviating depression at 6 months after childbirth compared to care as usual.

The secondary hypotheses are that:
1. The intervention package will be more cost-effective; and
2. Will lead to better infant outcomes (in regard to cognitions and growth) at 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ibadan/University College Hospital Joint Ethics Committee (Registration Number: NHREC/05/01/2008a), 18/12/2012, Approval Number: UI/EC/12/0278

Study design
Cluster randomized controlled study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Depression

Interventions
Intervention arm:
Patients in the intervention arm will receive a treatment package consisting of the WHO mhGAP-Intervention Guide for depression which has previously been contextualized and adapted for the Nigerian health system. The psychological component consists of psychoeducation, reactivation of social network, problem solving treatment (PST) and parenting skills. For EXPONATE, the PST will take account of specific issues relating to pregnancy, childbirth, marital relationships and parental roles. Relevant parent skills training will, for example, focus on positive mother-child interactions and emotional communication, infant nutrition information, etc.

All individuals consenting into the trial will receive, STEP1 consisting of a psychological intervention delivered by the community mid-wives (CMWs). Patients will receive 8 sessions approximately weekly. A session will last for about 45 minutes. The initial session is dedicated to psychoeducation in which the symptoms of depression, possible causes and treatments are discussed. The following 6 sessions contemplate teaching the basics of PST using examples provided in the manual and the person's own examples, especially those related to their marital and maternal roles and situations. Session 8 is dedicated to exploring support through social networks, especially in the context of catering for a new baby. We propose that all sessions occur within the woman's home unless she has a preference to be seen elsewhere, in which case we will arrange to meet in the MCC. (We are aware that psychological interventions have sometimes been delivered in group settings in some previous studies. However, individual sessions are to be used in EXPONATE because, in our previous pilot research, we found that adult Nigerians, especially women, are cagy about discussing personal issues in group settings).

In STEP 2, patients are reviewed 6 weeks after childbirth. Those with Edinburgh Postnatal Depression Scale (EPDS) < 11 continue on 4 fortnightly sessions of psychological treatment; those with EPDS ≥ 11 will receive a further 6 - 8 sessions of psychological intervention over 8 weeks.

Women who, at the completion of Step 2, continue to have EPDS ≥ 10 will proceed to STEP 3 where a review is conducted by the general practitioner (GP) with a view to initiating pharmacotherapy in combination with the on-going psychological intervention. Psychological

sessions conducted postnatally provide opportunities to revisit the issues discussed in the prenatal sessions, especially in the light of the reality of the new baby, explore further the issues of social (and marital) support, parenting skills, and finally, in the last two sessions, focused on integrating it all and preparing for the future. For patients who require medication, as assessed by the GP, the first line will be amitriptyline, which non-physician primary care providers in Nigeria are authorized to prescribe. If necessary, GPs can consult a psychiatrist by phone to receive advice on specific management problems.

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. CMWs will receive supervision from the GP when EPDS denotes moderate to severe depression during the first postnatal review, when there is no improvement after 6 8 postnatally, and in case of emergencies (e.g. suicidality or serious drug reaction). CMWs will receive automated clinical advice based on algorithms derived from the EPDS data. There will also be an automated system of voice messages for patients providing reminders for follow-up and encouragement in addition to live mobile telephone calls from CMWs. The automated system will allow clinical coordination and effective care by providing access to the diverse group of professionals (midwives, general physicians, obstetricians, and pediatricians) who may be involved in a particular patient care to the password-protected site. All telephone reviews and consultations will be on as-needed basis, structured, and following a manualized flow-chart that proceeds from the CMWs through to the GP and to the psychiatrist. The CMWs will co-ordinate all management procedures.

Duration of intervention: 8 weeks for Step 1, 8 weeks for Step 2 and 8 weeks for Step 3 for a cumulative total of 24 weeks. However, there is a period of about 6 weeks, shortly after childbirth, between the completion of Step 1 and commencement of Step 2. Thus, trial terminates at the end of 30 weeks for all patients since recruitment into the trial. However, patients on antidepressants will be encouraged and supported to continue medication for at least 6 months from initiation of such treatment as advised by clinical guidelines.

Control arm
Subjects who are recruited in the control clinics will be informed of the EPDS results and will be advised to show these to their health care providers. Usual care includes all services normally available in the clinics; including antidepressant medications, brief psychotherapeutic interventions, medical consultations, or external referral for specialty treatment. Although all these options are potentially part of usual care, in reality, unstructured counselling is often all a patient with recognized perinatal depression will receive. The study 'usual care' is enhanced because providers in the control arm will receive training on recognition and management of treatment prior to commencement of recruitment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Baseline assessments will be conducted within 72 hours of patients consenting to enter the trial.

Recovery from depression at 6 months after childbirth (i.e. no longer meets the criteria for DSM-IV major depression)

Secondary outcome measures
Baseline assessments will be conducted within 72 hours of patients consenting to enter the trial.

1. Score on EPDS at 3, 9 and 12 months
2. Disability, measured with the WHO Disability Assessment Schedule, at 3, 9 and 12 months
3. Service utilization, measured with Client Service Receipt Inventory
4. Postnatal version, at 3, 9 and 12 months
5. Infant outcome at 12 months measured with the Bayley Scale

Overall study start date
01/05/2013

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Women aged between the age of 16 and 45 years
2. Gestational age of between 16 and 26 weeks
3. Score 12 or more on the Edinburgh Postnatal Depression Scale
4. Confirmed Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) diagnosis of major depression using the short form of the Composite International Diagnostic Interview (CIDI)
5. Provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
916

Total final enrolment
686

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

Date of first enrolment
01/05/2013

Date of final enrolment

31/08/2015

Locations

Countries of recruitment
Nigeria

Study participating centre
University College Hospital
Ibadan
Nigeria
PMB 5116

Sponsor information

Organisation
University of Ibadan (Nigeria)

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ROR
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Funder(s)

Funder type
Government

Funder Name

Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Protocol article	protocol	30/06/2015		Yes	No
Results article	results	01/09/2019		Yes	No