ISRCTN16775958 https://doi.org/10.1186/ISRCTN16775958

Responding to the challenge of depression among pregnant adolescents

Submission date
19/04/2019

Recruitment status
No longer recruiting

Registration date
30/04/2019

Overall study status
Completed

Last Edited
27/06/2022

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
Adolescent pregnancy remains a global public health issue. Perinatal adolescents have a high rate of depression, a condition with serious consequence for their wellbeing, the outcome of their pregnancy, and the growth and development of their infants. Even though effective interventions for perinatal depression are available, the unique characteristics of adolescent mothers, including their need specific parenting skills, make these interventions inadequate to meet their need for care.

Who can participate?
Pregnant adolescents with depression.

What does the study involve?
This study is on designing an effective and appropriate intervention package for perinatal adolescents with depression

What are the possible benefits and risks of participating?
Participants and others may benefit in the future from 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?
May 2018 to August 2019

Who is funding the study?
International Development Research Centre, Canada

Who is the main contact?
Dr Lola Kola
lola_kola2004@yahoo.com

Study website
https://www.idrc.ca/en/project/responding-challenge-adolescent-perinatal-depression

Contact information

Type(s)
Scientific

Contact name
Dr Lola Kola

ORCID ID
http://orcid.org/0000-0003-0678-796X

Contact details
Department of Psychiatry
University College Hospital Ibadan
Ibadan
Nigeria
5116
+234 8057943775
lola_kola2004@yahoo.com

Type(s)
Scientific

Contact name
Prof Oye Gureje

Contact details
WHO Collaborating Centre for Research and Training in Mental Health, Neurosciences and Substance Abuse
Department of Psychiatry
University of Ibadan
Ibadan
Nigeria
-
-
ogureje@com.ui.edu.ng

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Responding to the challenge of adolescent perinatal depression

Acronym
RAPID

Study objectives
Primary hypotheses
Among adolescents presenting with perinatal depression during pregnancy the intervention package will, at 6-months postpartum, produce significant improvement in parenting skills as assessed by the Infant-Toddler version of the Home Inventory for Measurement of Home Environment (HOME-IT) and in depression symptoms as assessed by the Edinburgh Postnatal Depression Scale (EPDS), compared to usual care.

For the purpose of this study, a 1.5-point difference on the HOME-IT total outcome scores and a 1.0-point difference on the EPDS total outcome scores between the two groups will be regarded as a clinically meaningful difference in parenting skills and in depressive symptoms, respectively.

Secondary hypotheses
The following secondary hypotheses will be tested:
Mothers receiving the study intervention will achieve a higher rate of remission from depression (EPDS score < 6) at six month postnatal compared to those receiving usual care.
The intervention package will lead to less maternal disability and better quality of life compared to care as usual at 3- and 6-months postnatal as assessed with the World Health Organization Disability Assessment Scale (WHO-DAS) and the World Health Organization Quality of Life-Bref (WHOQoL-Bref), respectively;
Compared to care as usual, the intervention package will lead to better mother-infant bonding as assessed with the Postnatal Bonding Questionnaire (PBQ) and to improved social support for infant care as assessed with the Parental Infant Care Social Support Scale (PICSS) at 6-month postnatal;
Compared to infants of mothers receiving care as usual, infants of mothers receiving the intervention package will, at 6 months of age, be more likely to have received exclusive breastfeeding, to have fewer reported illnesses, and to show better developmental indices including a greater mean mid-arm circumference and earlier achievement of developmental milestones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2018, 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
Single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Intervention Arm: Adolescents in the study intervention arm receive a manualized package of care that consists of:
1) behavioural activation and problem-solving treatment
2) parenting skills training
3) social and parenting skills support provided by a “neighborhood mother”
The behavioural activation and problem-solving treatment is delivered in 6 sessions during the antenatal period, consisting of 3 weekly sessions followed by 3 fortnightly sessions for those with EPDS scores 12 -17, or all 6 sessions delivered weekly for those with EPDS scores >17. Supplemental sessions may be delivered, if during the 6-week postnatal visit, the providers find that the mother still has significant levels of depression (EPDS 6 or more). The number and frequency of these sessions are determined by the providers based on the level of depression (see Figure). Treatment adherence is promoted by providers calling or sending text messages to their patients reminding them of appointments and agreed homework tasks from the PST sessions. This approach and the format of the problem-solving treatment are similar to what we used in our earlier RCT for perinatal depression.
The parenting skills training is delivered in two ways:
1) as a component of the problem-solving treatment which is provided in face-to-face sessions
2) through mobile phone calls and texts (as appropriate) delivered in the post-natal period
There is a core set of themes to guide the provider during the calls but attention to the particular needs or deficits of individual adolescent mothers is also be addressed during the calls. The core themes consist of: personal and health care needs during pregnancy, including nutrition, rest, exercise, avoiding alcohol and self-medication; preparing for childbirth; early signs of common ill health during pregnancy and in the infant; care of the newborn; infant feeding (including good and common bad practices to avoid); immunization schedule; stimulating and responding to infant’s needs; and dispelling cultural myths and taboos that are either harmful or unhelpful to good parenting. Much of the material to inform the contents of the parenting skills training has been designed to address deficits in parenting skills among adolescent mothers as observed in our previous RCT. The materials also reflect information obtained during the formative qualitative activities. Providers make fortnightly calls starting shortly after the 6-week postnatal clinic visit of mother and child and continue until at least the

6-month postnatal outcome assessment. (We will encourage providers to continue with this, as needed, even after the discontinuation of the mother from the trial at the end of 6-months postnatal period).

A third component of the intervention package is the engagement of a “neighborhood mother” in the provision of social support and complementary parenting skills training to the adolescent. The idea of a “neighborhood mother” came from the extensive preliminary qualitative interviews with the adolescents when two observations were made: 1) it is not uncommon to find that pregnant adolescents have been ostracized by their biological parents due to conflict related to the pregnancy and may not have support from the spouse’s parents either: and 2) as a result of this ostracization, the adolescent is often lacking in support from an experienced female who may themselves have nurtured children and can guide the adolescent in the basics of child care. For the purpose of this trial, the adolescent in the intervention arm is encouraged to identify a female in the neighborhood, who may or may not be biologically related, but who the adolescent can repose confidence in for needed social and instrumental support. The woman so identified is invited to the clinic with the adolescent for briefing by the maternal care provider and is enlisted to provide hands-on parenting skills training and support to the adolescent. The neighborhood mother agrees to work with the maternal care provider to address any identified skills deficits the adolescent may have. At each clinic visit and during postnatal phone calls, the provider checks with the adolescent how the relationship with the neighborhood mother is going. The provider also makes regular phone contacts with the neighborhood mother to exchange experience on progress with addressing the adolescent’s needs.

Control arm: Participants in the control arm receive usual care. As in the intervention clinics, providers in the control clinics have prior training in the use of the mhGAP-IG. Usual care for perinatal depression in these facilities thus consists of the basic specifications of the mhGAP-IG for treating depression and these include psychoeducation, reactivation of social network and addressing current psychosocial stressors. Providers decide on the number of sessions even though, if implemented according to the guide, patients with depression are expected to be seen a number of times. In this arm, there are no structured sessions of behaviour activation and problem-solving treatment, no structured parenting skills training, and no engagement of a “neighborhood mother” in the provision of care to the adolescent.

Outcome assessments are conducted in participants’ homes or at any other place of their preference. Outcome assessors have no involvement in the delivery of the intervention and conduct the assessment blind to the participant’s study arm.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 02/03/2020:
1. The difference in the level of depressive symptoms between the intervention and usual care groups as assessed with the Edinburgh Postnatal Depression Scale (EPDS) at 6 months postnatal
2. Level of parenting skills measured from the total and subscale scores of the Infant-Toddler version of the Home Inventory for Measurement of Home Environment (HOME-IT) at 6 months postnatal

Previous primary outcome measure:
1. Difference in parenting skills at 6 months as assessed with the Infant-Toddler version of the

Home Inventory for Measurement of Home Environment (HOME-IT)
2. Difference in the level of depressive symptoms as assessed with the EPDS.
Assessments of participants being conducted at baseline (within 72 hours following enrolment) and at 3-, and 6-month post-natal periods.

Secondary outcome measures

Current secondary outcome measures as of 02/03/2020:
1. Depression remission rates as assessed with the Edinburgh Postnatal Depression Scale (EPDS) conducted at 3 or 6 months postnatally with those with an EPDS score that has fallen <6 deemed as being in remission
2. Level of disability as assessed using the WHO Disability Assessment Scale conducted at 3 or 6 months postnatally
2. Maternal attitude and adjustment to pregnancy and motherhood as measured with the Maternal Adjustment and Maternal Attitude scale (MAMAS) conducted at 3 or 6 months postnatally
3. Quality of life using the short form of the WHO Quality of Life scale (WHOQoL-BREF) conducted at 3 or 6 months postnatally
4. The extent of mother-infant interactions assessed using the Postnatal Bonding Questionnaire (PBQ) conducted at 3 or 6 months postnatally
5. Contraceptive measures used (if any) after the index childbirth assessed through the family planning and new pregnancy questionnaire (designed by the investigators) conducted at 3 or 6 months postnatally
6. Availability of social support for the adolescent mothers as assessed by the Perinatal Infant Care Social Support scale (PICSS) conducted at 3 or 6 months postnatally
7. Infant health and development assessed by weight, height, and head circumference at birth, 3 and 6 months, and through nutritional history (breastfeeding), vaccinations received, and social, cognitive, and physical developmental milestones achieved, as recorded at 3 and 6 months

Previous secondary outcome measures:
Conducted at 3-, and 6-month postnatal periods:
1. Depression remission rates (EPDS score <6)
2. Level of disability as assessed using the WHO Disability Assessment Scale
3. Maternal attitude and adjustment to pregnancy and motherhood as measured with the Maternal Adjustment and Maternal Attitude scale (MAMAS)
4. Quality of life using the short form of the WHO Quality of Life scale, WHOQoL-Brief
5. Level of anxiety, using the Generalized Anxiety Disorder Assessment scale, GAD-7.
6. Mother-infant interactions are assessed using the Postnatal Bonding Questionnaire (PBQ)
7. Self-designed family planning and new pregnancy questionnaire (designed by the investigators) will assess what measures if any, the adolescents have taken to prevent getting pregnant soon after the index childbirth.
8. The perinatal infant care social support scale (PICSS) will rate the availability of social support for the adolescents as they navigate the challenge of motherhood.
9. Assessments of the infants will take place at birth (weight, height and head circumference) and at 3 and 6 months of age: nutrition (history of breastfeeding), vaccinations received, and the child's social, cognitive and physical developmental milestones).

The study instruments have been previously translated into the Yoruba language following standard protocols of iterative back translation. Most of the tools have been used in our RCT among perinatal women and found to have good psychometric properties.

Overall study start date

19/05/2018

Completion date
29/10/2020

Eligibility

Key inclusion criteria
Patients must satisfy all of the following to be considered for study entry:
1. Adolescents aged less than 20 years
2. Must score 12 or more on the Edinburgh Postnatal Depression Scale, a score that we have found to reliably identify persons meeting the criteria of DSM-V major depression of at least moderate intensity.
4. Fetal gestational age less than 36 weeks.
3. Provide signed informed consent (if less than 16 years of age, a parent or guardian must also provide signed consent).

Participant type(s)
Patient

Age group
Other

Sex
Female

Target number of participants
Based on the results of our recently concluded cluster randomized controlled trial of interventions for perinatal depression in primary care in Nigeria showing a standard deviation (SD) for the EPDS score of 4.5, we estimate that a mean difference of 2.0 in the EPDS score between the two arms at 6 months postnatal follow-up will represent a clinically significant difference in depression symptoms, giving a target effect size of 0.44. About 6 months into recruitment to the current trial, there was an imbalance in the ratio of participants recruited to the trial of about 1.5 in favor of the intervention arm. An uninflated sample size of 102 in the intervention arm and 68 in the control arm will be required to provide a power of 80% at an α level of 0.05. Based on prior experience, we expect to recruit seven adolescent participants per cluster over 18months. To take account of the cluster design, we inflate the estimated cluster size by 1+[(k – 1) × ICC)], where k is the cluster size for analysis and ICC is the intracluster correlation coefficient. In previous use of the EPDS, we obtained an estimate of 0.03 for the ICC. Using the resulting design effect of 1.18, the estimated inflated sample size is 200 (170 × 1.18). Taking account of a projected attrition not exceeding 15% at 6 months postnatal and a resulting sample size of 230, we plan to recruit from 30 clusters.

Key exclusion criteria
1. Immediate need for medical attention.
2. Actively suicidal (a structured approach for identifying risk of suicide in those enrolled in the trial and for responding appropriately to it is being implemented).
3. Unlikely to be in the neighborhood in the following 6 months

Date of first enrolment

19/05/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
Department of psychiatry University College Hospital Ibadan
Queen Elizabeth Road
Oritamefa
ibadan
Nigeria
5116

Sponsor information

Organisation
University of Ibadan College of Medicine

Sponsor details
University of Ibadan
ibadan
Nigeria
5116
+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

Research organisation

Funder Name
International Development Research Centre

Results and Publications

Publication and dissemination plan

Intention to publish date
06/06/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/02/2020	09/12/2020	Yes	No
Results article		22/06/2022	27/06/2022	Yes	No