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HeAlth System StrEngThening in sub-Saharan Africa (ASSET): Maternal Mental Health in the Western Cape, South Africa

Submission date
06/03/2020

Recruitment status
No longer recruiting

Registration date
11/03/2020

Overall study status
Completed

Last Edited
10/04/2024

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
Perinatal common mental disorders (CMD) such as antenatal and postnatal depression and anxiety are highly prevalent in the Western Cape, South Africa. Studies in Khayelitsha, a large peri-urban township settlement in Cape Town have reported a prevalence of depression of 39% in pregnant women, and 34.7% in postpartum women.

Perinatal depression in this setting is associated with a lack of partner support, intimate partner violence, low household income, and younger age.

Perinatal anxiety disorder has been reported in 23% of antenatal women in one deprived urban setting in Cape Town and was associated with a history of previous mental health problems, major depressive disorder, multiple pregnancies, food insecurity, unplanned or unwanted pregnancy, pregnancy loss and experience of threatening life events.

Perinatal CMDs have been associated with a number of adverse consequences, for both mother and child. These include preterm birth, low birth weight, diminished mother-infant bonding, infant under-nutrition, stunting and increased prevalence of diarrhoea.

While maternal and child health have been identified as key priorities for intervention by the South African Department of Health (DoH), no programmes for the treatment of perinatal CMD have as yet been introduced in a systematic manner within the public health sector.
The purpose of this study is to develop and evaluate the impact of a training, awareness, detection, referral, and treatment program that will take place in Midwife Obstetric Units (MOU) in the Cape Town metropolitan area. This is designed to strengthen the health system processes of care and outcomes for perinatal women with CMD and experiences of violence.

This will be achieved through:
1. Supporting the Western Cape DoH in the scaling up of a screening and counseling service for perinatal CMD, linked to the roll-out of the Practical Approach to Care Kit (PACK) guide for routine antenatal care

2. Collaborating with local stakeholders to develop and pilot an intervention for care and support of perinatal women with experiences of violence, integrated into routine healthcare, and linked to the scaled-up counseling service

Who can participate?
Professional staff involved in delivering the antenatal care in participating MOUs such as antenatal care nurses, facility managers, sub-structure and NGO trainers, outreach team nurse supervisors, and community health workers may be eligible to receive the training. Pregnant women attending antenatal clinics participating in the study may be able to participate in the cohort where the impact of the intervention will be assessed

What does the study involve?
The ASSET team will provide Master Training to the facility- and community-based trainers in all 4 sub-structures of the Cape Town metropolitan area. This will include training for antenatal care nurses, using the Maternal Case Record and Practical Approach to Care Kit (PACK) guidelines, which will be outsourced to the PACK trainers from the Knowledge Translation Unit at the University of Cape Town.

Health Promotion Officers will provide educational talks to perinatal women, their partners and family members in the waiting rooms of MOUs.

Antenatal care nurses will screen perinatal women for symptoms of depression and anxiety, as well as experiences of violence as part of patient-centered care at all clinic visits. They will then assess the severity of symptoms in women who screen positive and refer them accordingly. Women with mild to moderate symptoms of depression and anxiety will be referred to CHWs. Women who are identified as having severe symptoms of depression and anxiety will be referred to the Medical Officer and Mental Health Nurse. Women with social issues, including being at risk of ongoing violence, will be referred to the Social Worker. Community health workers will provide perinatal women with mild to moderate symptoms of depression and anxiety with 3 standardized counseling sessions

What are the possible benefits and risks of participating?
Some study participants, specifically perinatal women with experiences of depression, anxiety or violence, are a highly vulnerable group who may require specific support or interventions. For example, women with severe depression or anxiety may be at risk of suicide, and women who report experiences of violence may well be in ongoing danger from the perpetrator. In order to assess this risk, specific questions regarding suicidal thoughts and the risk of harm by others will be included in the initial interview.

In the event that a participant reports intent of self-harm, she will be referred to the psychiatric nurse in the facility for further assessment. In the event that a participant reports that she is in danger from a perpetrator of violence, she will be referred to a social worker and will follow statutory protocols for her protection.

Depending on the severity of the situation this may include the provision of safe housing. We will check that referral services are adequately equipped to manage these referrals and will facilitate support where necessary. A referral form will be created, and a list of organizations working in the area, together with their contact details will be provided to all women who are at risk of interpersonal violence or self-harm.

During training for the conduct of semi-structured interviews, fieldworkers will be briefed on standard protocols for these referral procedures and will be trained in the sensitive and supportive enquiry of the study participant's needs and wishes.

Although some study participants are a vulnerable group, the risks of harm associated with this study are minimal. Our experience from previous studies has shown that if interviews are conducted in a sensitive manner, women in these circumstances report finding the interviews supportive and helpful.

Where is the study run from?
The University of Cape Town (South Africa)

When is the study starting and how long is it expected to run for?
May 2018 to January 2022 (updated 2/10/2021, previously: March 2022; updated 24/03/2021, previously: March 2021)

Who is funding the study?
The National Institute of Health Research (UK)

Who is the main contact?
Prof Crick Lund
crick.lund@uct.ac.za

Contact information

Type(s)
Public

Contact name
Prof Crick Lund

ORCID ID
https://orcid.org/0000-0002-5159-8220

Contact details
Alan J Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
46 Sawkins Road
Rondebosch
Cape Town
South Africa
7700
+27 216850120
crick.lund@uct.ac.za

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
N/A

Study information

Scientific Title
Health systems strengthening to improve detection, referral and care for antenatal women with depression, anxiety or experiences of domestic violence in Cape Town, South Africa: a pilot study

Acronym
ASSET WP6

Study objectives
Current study hypothesis as of 27/10/2021:
As a result of the COVID-19 pandemic in South Africa, and the burden it placed on healthcare workers, the originally planned cluster randomized control trial could not be completed within the planned time period. The trial has been replaced with a pilot implementation study, aimed at assessing the implementation and clinical outcomes of several health systems strengthening interventions piloted at 3 purposively selected study sites.

Previous study hypothesis as of 24/03/2021:
As a result of the COVID-19 pandemic in South Africa, and the burden it placed on healthcare workers, the originally planned cluster randomized control trial could not be completed within the planned time period. The trial has been replaced with a pilot study, aimed at assessing the feasibility and acceptability of the intervention at 3 purposively selected study sites.

Previous Study hypothesis:
A health system strengthening intervention to improve detection, referral and treatment of antenatal women with depression, anxiety or experiences of domestic violence will lead to improved detection, referral, service uptake and mental health outcomes in antenatal in Midwife Obstetric Unit (MOU) intervention facilities than MOU control facilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/01/2020, Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (E52 Room 24, Old Main Building, Groote Schuur Hospital, Observatory, Cape Town, 7925, South Africa; marc.blockman@uct.ac.za; +27214066496), ref: 139/2018
2. Approved 15/01/2020, PNM Research Ethics Subcommittee, King's College London (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London SE1 9NH; rec@kcl.ac.uk; +442078484020), ref: MOD-19/20-14652

Study design
Interventional non randomised pilot trial

Primary study design

Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Antenatal depression and anxiety

Interventions
Current interventions, as of 24/03/2021:

The design of the intervention is outlined in a Process Map (available on request) and consists of five areas of intervention, namely: training, awareness, detection, referral, and treatment.

The intervention process is summarised as follows:
1. Training
The ASSET team will provide Master Training to the facility- and community-based trainers in all 4 sub-structures of the Cape Town metropolitan area
a. Facility-based substructure trainers will be responsible for cascading the training to facility-level staff
b. Community-based substructure trainers will be responsible for cascading the training to community health workers (CHWs) and their Coordinators at NGOs linked to the intervention sites
c. Training for antenatal care nurses, using the Maternal Case Record and Practical Approach to Care Kit (PACK) guidelines will be outsourced to the PACK trainers from the Knowledge Translation Unit at the University of Cape Town
2. Awareness
Health Promotion Officers will provide psycho-education talks to perinatal women, their partners and family members in the waiting rooms
3. Detection
Antenatal care nurses will screen perinatal women for symptoms of depression and anxiety, as well as experiences of violence as part of patient-centered care at all clinic visits
4. Referral
Antenatal care nurses will assess the severity of symptoms in women who screen positive and refer them accordingly (See Appendix 4 of Ethics protocol, available on request). Women with mild to moderate symptoms of depression and anxiety will be referred to CHWs. Women with severe symptoms of depression and anxiety will be referred to the Medical Officer and Mental Health Nurse. Women with social issues, including being at risk of ongoing violence, will be referred to the Social Worker.
5. Treatment
a. Women with no symptoms of distress will not need to be referred and will continue to receive the standard care package
b. Community health workers will provide perinatal women with mild to moderate symptoms of depression and anxiety with 3 standardized counseling sessions
c. Mental health nurses and medical officers will provide treatment as usual (medication and counseling as needed) to perinatal women with severe symptoms of depression, anxiety or suicidality
d. Social workers will provide perinatal women with treatment as usual (assistance with social issues)

The main time points for data collection for the study will be at baseline (18-30 weeks pregnant), follow-up 1 (36 weeks pregnant), and follow-up 2 (4-6 weeks post-birth). The specific processes of care will vary according to the intervention and control sites.

Previous interventions:
The unit of randomization in this cluster-randomized trial is a Midwife Obstetric Unit (MOU). There will be 7 MOUs assigned to the intervention arm and 7 MOUs in the control arm.

The design of the intervention is outlined in a Process Map (available on request) and consists of five areas of intervention, namely: training, awareness, detection, referral, and treatment.

The intervention process is summarised as follows:
1. Training
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Antenatal care nurses will screen perinatal women for symptoms of depression and anxiety, as well as experiences of violence as part of patient-centered care at all clinic visits
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Antenatal care nurses will assess the severity of symptoms in women who screen positive and refer them accordingly (See Appendix 4 of Ethics protocol, available on request). Women with mild to moderate symptoms of depression and anxiety will be referred to CHWs. Women with severe symptoms of depression and anxiety will be referred to the Medical Officer and Mental Health Nurse. Women with social issues, including being at risk of ongoing violence, will be referred to the Social Worker.
5. Treatment
a. Women with no symptoms of distress will not need to be referred and will continue to receive the standard care package
b. Community health workers will provide perinatal women with mild to moderate symptoms of depression and anxiety with 3 standardized counseling sessions
c. Mental health nurses and medical officers will provide treatment as usual (medication and counseling as needed) to perinatal women with severe symptoms of depression, anxiety or suicidality
d. Social workers will provide perinatal women with treatment as usual (assistance with social issues)

The control arm will receive no training from the ASSET team and will continue to provide standard care. From the results of the situation analysis, we know that the usual care processes may or may not include screening and referral, and no standardized counseling by lay health workers are available. At control sites, antenatal care nurses and lay health workers would not have received the ASSET training. Care as usual should include using the MCR to screen pregnant

women for symptoms of distress. However, no standardized referral pathways are available, so women who screen positive may be offered a referral to the mental health nurse, medical officer or social worker (if one is available). As per our standardized protocol, women who are detected as being at risk of suicide or domestic violence will be referred by the fieldworker to the Medical Officer/Mental Health Nurse/Social worker as appropriate.

When patients arrive for their first antenatal visit, a patient folder is prepared, and used by clinicians to keep a record of all visits during the pregnancy. In addition, each woman is given a Maternal Case Record (MCR) which is used to record all information relevant to the pregnancy and birth. The MCR is the property of the pregnant women from her first visit until she has given birth and is taken home with her after each visit. Various sections of the MCR are completed, in duplicate, at each facility visit. The original pages remain in the MCR while duplicates are placed in the patient folder.

Data will be collected From the findings of our situational analysis, we know that the majority of women attend antenatal care facilities for their 1st antenatal appointment when they are between 18 and 24 weeks pregnant. The first visit is the most comprehensive and women spend 4-6 hours completing a number of assessments. Follow-up visits occur monthly until 4 weeks before their estimated delivery date – when women are approximately 28 weeks, 32 weeks and 36 weeks pregnant. During the last month of pregnancy, women visit the facility weekly. Follow-up visits take 1-3 hours to complete. After the baby is born, the mother returns with her new baby for a follow-up visit when the baby is 5-7 days old.

The main time points for data collection for the study will be at baseline (18-24 weeks pregnant), follow-up 1 (36 weeks pregnant), and follow-up 2 (4-6 weeks post-birth). The specific processes of care will vary according to the intervention and control sites.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 24/03/2021:
Depression and anxiety symptoms, measured using the Edinburgh Postnatal Depression rating scale (EPDS) at baseline and 4-6 weeks after delivery of the infant

Previous primary outcome measure:
A 50% reduction in depression and anxiety symptoms, measured using the Edinburgh Postnatal Depression rating scale (EPDS) at 4-6 weeks after delivery of the infant

Key secondary outcome(s))
Current secondary outcome measures as of 24/03/2021:
1. Knowledge and attitudes of health workers measured using a pre- and post- knowledge test, Mental illness Clinicians' Attitudes Scale (MICA-4), Professional Quality of Life Scale (PROQOL) version 5, Effort-Reward Imbalance (ERI) scale, Enhancing Assessment of Common Therapeutic Factors (ENACT) tool administered before and after training and Training satisfaction survey following completion of training
2. Ability to detect and refer distressed perinatal women assessed using patient folder reviews and referral forms in the facilities collected monthly over 6 months
3. Enhanced counselling skills of lay health workers measured using Enhancing Assessment of Common Therapeutic Factors (ENACT) tool administered before and after training
4. Level of job satisfaction, stress and burnout in health workers involved in the intervention

measured through qualitative semi-structured interviews, Professional Quality of Life Scale (PROQOL) version 5, and Effort-Reward Imbalance (ERI) scale administered before and after training
5. Knowledge, attitudes and health-seeking behaviour of perinatal women, their partners and family members measured using knowledge, attitudes and health-seeking behaviour surveys, administered before and after morning talks in intervention facilities, and in routine queues in control facilities
6. Detection rates of distressed perinatal women assessed using patient folder reviews collected monthly over 6 months
7. Referral rates of distressed perinatal women assessed using patient folder reviews collected monthly over 6 months
8. Proportion of distressed perinatal women who receive treatment, assessed using referral forms and patient folders, assessed monthly over 6 months
9. Improvement on clinical, functioning and social outcomes, assessed using the Edinburgh Postnatal Depression rating scale (EPDS) and the World Health Organisation Assessment Schedule 2.0 (WHODAS 2.0) at baseline (18-30 weeks gestation), first follow-up (36 weeks gestation) and second follow-up (4-6 weeks after delivery of their baby)
10. Proportion of perinatal women that show improvement by equity measures (such as education, language and race) measured using the instruments listed above and a demographic questionnaire at baseline

Previous secondary outcome measures:
1. Knowledge and attitudes of health workers measured using a pre- and post- knowledge test, Mental illness Clinicians' Attitudes Scale (MICA-4), Professional Quality of Life Scale (PROQOL) version 5, Effort-Reward Imbalance (ERI) scale, Enhancing Assessment of Common Therapeutic Factors (ENACT) tool administered before and after training and Training satisfaction survey following completion of training
2. Ability to detect and refer distressed perinatal women assessed using patient folder reviews and referral forms in the facilities collected monthly over 6 months
3. Enhanced counselling skills of lay health workers measured using Enhancing Assessment of Common Therapeutic Factors (ENACT) tool administered before and after training
4. Level of job satisfaction, stress and burnout in health workers involved in the intervention measured through qualitative semi-structured interviews, Professional Quality of Life Scale (PROQOL) version 5, and Effort-Reward Imbalance (ERI) scale administered before and after training
5. Knowledge, attitudes and health-seeking behaviour of perinatal women, their partners and family members measured using knowledge, attitudes and health-seeking behaviour surveys, administered before and after morning talks in intervention facilities, and in routine queues in control facilities
6. Detection rates of distressed perinatal women assessed using patient folder reviews collected monthly over 6 months
7. Referral rates of distressed perinatal women assessed using patient folder reviews collected monthly over 6 months
8. Proportion of distressed perinatal women who receive treatment, assessed using referral forms and patient folders, assessed monthly over 6 months
9. Improvement on clinical, functioning and social outcomes, assessed using the Edinburgh Postnatal Depression rating scale (EPDS) and the World Health Organisation Assessment Schedule 2.0 (WHODAS 2.0) at baseline (18-24 weeks gestation), first follow-up (36 weeks gestation) and second follow-up (4-6 weeks after delivery of their baby)
10. Proportion of perinatal women that show improvement by equity measures (such as education, language and race) measured using the instruments listed above and a demographic questionnaire at baseline

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/03/2021:
Professional staff involved in delivering the antenatal care in participating MOUs such as antenatal care nurses, facility managers, sub-structure and NGO trainers, outreach team nurse supervisors, and community health workers

Patient cohort:
1. Pregnant
2. Attending antenatal clinics participating in the study
3. Score of ≥13 on the EPDS or, a randomly selected 30% of participants (per site) who score <13 on the EPDS

Previous inclusion criteria:
Training intervention:
Professional staff involved in delivering the antenatal care in participating MOUs such as antenatal care nurses, facility managers, sub-structure and NGO trainers, outreach team nurse supervisors, and community health workers

Patient cohort:
1. Pregnant
2. Attending antenatal clinics participating in the study
3. Score of ≥13 on the EPDS or, a randomly selected 20% of participants (per site) who score <13 on the EPDS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
Patient cohort:
1. Lack capacity to consent
2. Diagnosis of severe mental illness
3. ≥36 weeks gestation

Date of first enrolment
15/03/2020

Date of final enrolment
15/12/2021

Locations

Countries of recruitment
South Africa

Study participating centre
University of Cape Town
Alan J Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
46 Sawkins Road
Rondebosch
Cape Town
South Africa
7700

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Professor Crick Lund (crick.lund@uct.ac.za). Data will be anonymized quantitative and qualitative data and will be available 6 months after publication of the main trial findings. Access will be granted in keeping with institutional policies at the University of Cape Town and King's College London and data must be used for authentic public benefit research purposes. Consent will be obtained from participants to have their anonymized data shared with other researchers for this purpose only.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/05/2022	12/12/2022	Yes	No
Protocol article		07/05/2022	10/04/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)	Study protocol preprint	18/10/2021	27/10/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes