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Cluster randomised trial to evaluate an intervention for depressed HIV-positive women in the perinatal period, to enhance child development and reduce maternal depression

Submission date
07/11/2017

Recruitment status
No longer recruiting

Registration date
14/11/2017

Overall study status
Completed

Last Edited
09/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Perinatal depression is very common amongst HIV-positive women, with up to 40% of HIV-positive mothers in parts of southern Africa being affected. It is associated with poor adherence to anti-retroviral therapy (ART), low clinic attendance, suicidal ideation and low rates of breastfeeding. Critically, perinatal depression is also associated with negative effects on parenting, which in turn adversely impacts children's cognitive and behavioural development and growth. Effective treatments for HIV-positive perinatal populations are urgently needed, and given that the prevalence of both HIV and perinatal depression is high in low-resource settings, treatments which take an integrated approach, targeting both depression and parenting, have substantial potential. Behavioural Activation (BA) has been shown to be as effective as Cognitive Behaviour Therapy (CBT), the gold standard psychological therapy for treating depression in high-income settings, and it has begun to be used successfully in low and middle-income countries (LMIC). BA is much simpler than CBT to deliver, especially by non-specialist healthcare workers with limited training in under-resourced settings. It does not require extensive training or complex skills from therapists, and can be delivered by lay counsellors. Further, BA fits with cultural concepts of depression in southern Africa that place environmental stressors as the cause. Thus, given that BA targets behavioural changes rather than beliefs and attitudes, it is relatively easy to adapt BA cross-culturally with potential to be widely used to treat depression in LMIC as well as High Income Countries (HIC). BA is based on the evidence that increased activity (i.e., activation), and the resulting positive consequences, leads to reduction of depressive symptoms. BA helps the individual to participate in activities that have been avoided but are meaningful for her, and schedules them to fit into her daily life. BA introduces small changes, building up the level of activity gradually towards long-term goals, making it feasible for perinatal women with little time to spare. The parenting intervention aims to help the mother increase the stimulation she provides to her baby. In particular, the mother is helped to focus on her baby’s cues and signals and she is given support in providing a range of activities to enhance her child’s development, especially cognitive development. The mother is helped to develop a responsive and close relationship with her baby. The programme begins

antenatally by providing the mother with information about parenting and how to plan and prepare for her baby. The programme was adapted from the 'Care for Child Development' package developed by UNICEF and WHO. The BA and the parenting programme were combined into a home-based integrated intervention package that can be delivered feasibly by lay counsellors. Thus the aim of this study is to investigate whether a home-based intervention, combining a psychological treatment for depression and a parenting programme, leads to better cognitive development in children at 2 years and reduces perinatal depression in HIV-positive women at 1 year after the birth, compared to enhanced standard of care.

Who can participate?
Pregnant women aged 16 and above who are HIV-positive, meet the criteria for depression, are conversant in either English or IsiZulu, and who plan to live with their child for the intensive period of the study, up to 9 months postnatal

What does the study involve?
Participants are randomly allocated to one of two groups based on area in which they live. One group receives the proposed intervention comprising the combined behavioural activation and parenting programme, with four sessions during pregnancy, six sessions in the 9 months following the birth of the child, and one booster session when the child is 16 months old.The other group receive enhanced standard of care, which includes four telephone support and advice calls, two during pregnancy and two after birth, where the participant is given advice and guided, if necessary, to existing services that they may need. All participants are also given a parenting information leaflet (published by UNICEF South Africa), in addition to the usual care provided at clinics. Maternal depression is assessed 12 months after the birth and child cognitive development is assessed at child age 24 months.

What are the possible benefits and risks of participating?
Some of the possible benefits to participants include reduced maternal depression and anxiety, improved adherence to antiretroviral treatment and increased rates of exclusive breastfeeding. For the child, improved cognitive and language development, a reduction in child behavioural difficulties, and improved health through compliance to immunization and reduced diarrhoea are some of the possible benefits. Given the nature of this study and the target population, a range of adverse situations are expected such as relationship problems/conflicts, feelings of hopelessness and suicidal thoughts as these are commonly associated with depression. To address this, there is a protocol in place to manage such situations appropriately.

Where is the study run from?
The centre from which the intervention will be run is the Africa Health Research Institute (AHRI) situated in Somkhele, KwaZulu-Natal, South Africa with research support from the University of Oxford in the United Kingdom and the University of Witwatersrand, situated in Johannesburg, South Africa.

When is the study starting and how long is it expected to run for?
April 2017 to March 2024

Who is funding the study?
This study is funded by the Joint Global Health Trials Panel; DfID, MRC UK, & the Wellcome Trust, and administered by the MRC UK

Who is the main contact?
1. Professor Alan Stein, alan.stein@psych.ox.ac.uk
2. Dr Tamsen Rochat, tamsen.rochat@wits.ac.za

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MR/P006965 Award

Study information

Scientific Title

Cluster randomised trial to evaluate an integrated behavioural activation and parenting intervention for depressed HIV-positive women in the perinatal period, to enhance child cognitive development at 24 months of age and reduce maternal depression at 12 months postnatal

Acronym
Insika Yomama (Pillar for Mothers)

Study objectives
The hypothesis for this trial is that a psychological intervention, integrating behavioural activation for perinatal depression and a parenting programme, will lead to better cognitive development in children at 24 months and reduced maternal depression in HIV-positive women at 12 months postnatal, compared to enhanced standard of care (ESoC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Human Sciences Research Council (HSRC), South Africa, 20/02/2018, ref: #REC 5/23/08/17
2. Oxford Tropical Research Ethics Committee (OxTREC), 06/12/2017, ref: #31-17

Study design
Single-centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Perinatal depression in women with HIV infection

Interventions
Participants are randomised by cluster, based on homestead location at enrolment, with outcome assessors blind to treatment allocation:
1. 10-session home-based counselling intervention delivered by lay counsellors that combines Behavioural Activation (BA) for depression with a parenting programme, adapted from the Care for Child Development (CCD) package. The intervention includes 4 sessions in the third trimester of pregnancy, and 6 sessions in the first nine months post-delivery, with a booster session at 16 months. The first session will be up to 2 hours, and subsequent sessions will be up to 1 1/2 hours each.

2. Enhanced standard of care (ESoC) which comprises of two antenatal and two postnatal support and advice telephone calls.

Intervention Type
Behavioural

Primary outcome measure
Co-primary outcome measures:
1. Child cognitive development, measured using the Bayley Scales of Infant and Toddler Development III (cognitive subscale) at child age 24 months
2. Maternal depression, measured using the Edinburgh Postnatal Depression Scale (EPDS) at 12 months postnatal

Secondary outcome measures
Current secondary outcome measures as of 14/12/2022:
1. Maternal depression, measured using the Edinburgh Postnatal Depression Scale (EPDS) at the end of pregnancy and child age 24 months
2. Generalized Anxiety Disorder 7-item (GAD-7) scale at the end of pregnancy and child age 24 months
3. Adherence to ART, measured as viral load (VL) and viral suppression post-initiation of treatment over the entire trial period
4. Exclusive breastfeeding to 6 months by self-report in an interview at 6 months postnatal
5. Compliance with immunisation schedule over the 24-month postnatal period, by maternal report at interview and clinic record at 12 weeks, 12 and 24 months postnatal
6. Any instances of infant diarrhoea in the preceding two weeks, assessed by the maternal report in an interview at 12 weeks, 6 months, 12 months and the 24 months
7. Cognitive and emotional stimulation at home, assessed by Multiple Indicator Cluster Survey 6 (MICS6) at 12 and 24 months
8. Infant behaviour, assessed using the Parent-Child Dysfunctional Interaction subscale and Difficult Child subscale of the Parenting Stress Index Short Form (PSI-SF) at child age of 12 months, and the Externalising Subscale of the Child Behaviour Checklist (CBCL) at 24 months
9. Infant language development, measured using the BSID-III language sub-scale at child age 24 months
10. Child growth - height and weight for child age measured at 24 months

Previous secondary outcome measures:
1. Maternal depression, measured using the Edinburgh Postnatal Depression Scale (EPDS) at the end of pregnancy and child age 24 months
2. Generalized Anxiety Disorder 7-item (GAD-7) scale at the end of pregnancy and child age 24 months
3. Adherence to ART, measured as viral load (VL) and viral suppression post-initiation of treatment over the entire trial period
4. Exclusive breastfeeding to 6 months by self-report in interview at 6 months postnatal
5. Compliance to immunisation schedule over the 24-month postnatal period, by maternal report at interview and clinic record at 12 weeks, 12 and 24 months postnatal
6. Any instances of infant diarrhoea in the preceding two weeks, assessed by maternal report in interview at 12 weeks, 6 months, 12 months and the 24 months
7. Maternal contingent responsiveness to infant cues and cognitive and emotional stimulation at home, assessed by video observation of mother-child interaction at child age 12 and 24 months
8. Infant behaviour, assessed using the Difficult Child subscale of the Parenting Stress Index (PSI) at child age 12 months, and the Child Behaviour Checklist (CBCL) at 24 months

9. Infant language development, measured using the BSID-III language sub-scale at child age 24 months
10. Child growth - height and weight for child age measured at 24 months

Overall study start date
01/04/2017

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/12/2022:
1. Pregnant women, 23-33 weeks gestation at the time of enrolment
2. Participant is willing and able to give informed consent for participation in the trial
3. Aged 16 years and above
4. Diagnosed HIV-positive
5. Mother meets criteria for antenatal depression as defined by 9 and greater on the EPDS
6. Living, or planning to live, within the study area at the time of delivery and for at least 9 months after delivery (the intensive therapy period)
7. Mother conversant in isiZulu or English

Current inclusion criteria as of 25/01/2019 to 14/12/2022:
1. Pregnant women, <33 weeks gestation at time of enrolment
2. Participant is willing and able to give informed consent for participation in the trial
3. Aged 16 years and above
4. Diagnosed HIV-positive
5. Mother meets criteria for antenatal depression as defined by 9 and greater on the EPDS
6. Living, or planning to live, within the study area at the time of delivery and for at least 9 months after delivery (the intensive therapy period)
7. Mother conversant in isiZulu or English

Previous inclusion criteria:
1. Pregnant women, <33 weeks gestation at time of enrolment
2. Participant is willing and able to give informed consent for participation in the trial
3. Aged 16 years and above
4. Diagnosed HIV-positive
5. Mother meets criteria for antenatal depression as defined by 13 and greater on the EPDS
6. Living, or planning to live, within the study area at the time of delivery and for at least 9 months after delivery (the intensive therapy period)
7. Mother conversant in isiZulu or English

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
48 - 60 clusters with 9-11 women per cluster, 528 total

Total final enrolment
320

Key exclusion criteria
1. Any significant disease, disorder or disability which, in the opinion of the Principal Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial. This includes hospitalisation for at least three days for severe psychiatric illness (specifically bipolar disorder, schizophrenia and any other psychoses), or a life-threatening or other serious physical illness (excluding HIV and tuberculosis)
2. Current suicidal ideation/thoughts with specific plans and means identified
3. Substance or alcohol use disorder
4. Currently receiving a psychological treatment for mental health problems
5. Participant planning to move away from the study area before 9 months postnatal
6. Mother not planning to cohabit with the infant

Date of first enrolment
04/04/2018

Date of final enrolment
13/07/2021

Locations

Countries of recruitment
South Africa

Study participating centre
Africa Health Research Institute (AHRI)
Africa Centre Building
Via R618 to Hlabisa
Somkhele
Mtubatuba
South Africa
3935

Sponsor information

Organisation
The University of Oxford

Sponsor details

University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Joint Global Health Trials Panel, DFID, Wellcome Trust & MRC UK

Results and Publications

Publication and dissemination plan
The study protocol and statistical analysis plan will be available. The aim is to publish the trial results in a high-impact journal within 12 months of the data collection being completed.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 14/12/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Alan Stein (alan.stein@psych.ox.ac.uk) after de-identification. Individual participant data for this trial will be available in accordance with the information outlined below:

Individual participant quantitative data that underlie the results reported in each publication arising from the trial will be made available after de-identification. Any video, audio or qualitative data will not be available.

Data will be available beginning 9 months and ending 36 months following the main article publication to researchers who provide a methodologically sound proposal that proposes to achieve aims in the approved proposal and /or for individual participant data meta-analysis. Data is documented and stored on the Africa Health Research Institute (AHRI) Data Repository (https://data.ahri.org) with a digital object identifier (DOI) and can be accessed with permission and in line with AHRI policies and procedures. Data requestors will need to sign a data access

agreement before any data can be shared. In addition, Study Protocol and Statistical Analysis Plan documents will be available.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Alan Stein (alan.stein@psych.ox.ac.uk) after de-identification. Data will be available between 12 months until 48 months after publication to researchers who provide a methodologically sound proposal to either achieve the aims in the approved proposal or for individual participant data meta-analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)	version 1.0	28/04/2021	19/10/2021	No	No
Statistical Analysis Plan		06/11/2023	29/11/2023	No	No
Protocol article		03/08/2024	09/08/2024	Yes	No