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Implementing and evaluating group interpersonal therapy for postnatal depression in Lebanon and Kenya

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
09/02/2022

Overall study status
Completed

Last Edited
13/12/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is the most common mental health issue affecting women of childbearing age. 20% -25% of women in low and middle-income countries (LMICs) experience depression during pregnancy or shortly after childbirth. This can be very distressing and affects not only the mother but also her child. Women with depression often struggle to respond to their children's needs. Research shows that as a result of this children of women with postnatal depression (PND) have poorer learning, or cognitive development, and more emotional and behaviour problems as they grow up. This is especially true in LMICs, where families may also be struggling with many other challenges that can affect children's development negatively. Many women in LMICs have very little contact with healthcare services, so antenatal services can be a key opportunity to reach women in need of mental health support. However, currently treatment for PND is rarely available in many LMICs. The World Health Organisation recommends a therapy called interpersonal psychotherapy (IPT) to treat depression. There is research from high-income countries showing that IPT and group-IPT (g-IPT) is an effective treatment for PND, but it is not known whether it works in an LMIC context, or whether it also benefits child development. This study aims to explore the feasibility of conducting a randomised controlled trial to study the effectiveness of g-IPT in two LMIC for women with PND.
The study consists of two phases: conceptual mapping and a feasibility study. In the first phase, researchers in Kenya and Lebanon will work with the core team in the UK to explore how members of the community think about maternal depression, and how local factors may affect maternal mental health and access to treatment. With input from service users, a group-based adapted version of g-IPT will be developed to fit the local culture and setting of both countries. In the second phase a feasibility randomised control trial (RCT) will be conducted comparing g-IPT to high-quality standard care (HQ-SC). The initial aim of the study is to assess the feasibility of critical elements of a trial to evaluate g-IPT as a form of treatment for post-natal depression in women living in LMICs.

Who can participate?
Mothers aged 18 years or older who are currently experiencing postnatal depression and have an infant aged 6 to 35 weeks old.

What does the study involve?
Participants are randomly allocated to receive g-IPT or treatment as usual (HQ-SC). The g-IPT will involve attending individual and group sessions for 3 months. Levels of depression in each group are compared to assess the effectiveness of the therapy intervention, and other possible differences between the groups are examined. The data is collected every 5/6 weeks by researchers through the use of questionnaires, interviews, and charts. The collected data is then analysed in order to find out whether g-IPT is a feasible form of treatment for post-natal depression for women living in LMICs.

What are the possible benefits and risks of participating?
Successful feasibility outcomes would pave the way for a large scale RCT to assess the wider benefits of g-IPT for postnatal depression. The main benefits of g-IPT are a reduction in depression levels and a possible benefit to child development.

Where is the study run from?
The feasibility study takes place in Kenya and Lebanon, with support and supervision from University College London (UK)

When is the study starting and how long is it expected to run for?:
January 2021 to November 2022

Who is funding the study?
National Institute for Health Research (NIHR0 Research and Innovation for Global Health Transformation (RIGHT) programme (UK)

Who is the main contact?:
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Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 2

Study information

Scientific Title
Evaluating the impact of group interpersonal psychotherapy compared to high-quality standard care for mothers with postnatal depression in Lebanon and Kenya on child developmental outcomes, maternal depression and the mother-child relationship

Acronym
SUMMIT

Study objectives
There is research from high-income countries showing that interpersonal psychotherapy (IPT) and group-IPT (g-IPT) is an effective treatment for postnatal depression (PND), but it is not known whether it works in low to middle-income countries (LMIC) contexts, or whether it also benefits child development. This study aims to determine the feasibility of conducting a randomised controlled trial of the effectiveness of g-IPT in two LMIC for women with PND through a conceptual mapping process and feasibility trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/03/2021, University College London Research Ethics Committee (2 Taviton Street, University College London, UK; +44 (0)2076798717; ethics@ucl.ac.uk), ref: 18773/001
2. Approved 28/06/2021, Saint Joseph University Secretariat of the University Ethics Centre (USJ Medical Sciences Campus, Hotel-Dieu de France, B.P 16-6830 Achrafieh, Beyrouth - Liban, Lebanon; +961 (0)1 421229 cue@usj.edu.ib), ref: CEHDF 1854
3. Approved 29/10/2021, Kenyatta National Hospital (PO Box 20723, Code 00202, Kenya; +254 (0)726300 9; uonknh_erc@uonbi.ac.ke) and the University of Nairobi (KNH – UoN) (Faculty of

Health Sciences, PO Box 19676, Code 00202, Kenya; +254 (0)20 2726300; uonknh_erc@uonbi.ac.ke), ref: KNH-ERC/A/404

Study design
Two-country individually randomized feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Following the completion of the baseline outcome measures, participants will be randomly allocated to either Group Interpersonal therapy (g-IPT) or High-Quality Standard Care (HQ-SC), using a secure, web-based platform.

Intervention arm: g-IPT has proven to be an effective treatment for common mental health disorders, and one that can be used as a preventative intervention. The principle of g-IPT is that depression is triggered and worsened by interpersonal problems and adversities. It focuses on the recovery from the current depressive episode through clarification of the relationship between the onset of current depressive symptoms and interpersonal problems and skill-building that lead to more effective management of these problems. The mothers in the intervention arm will receive 3 months of adapted g-IPT, to include (a) a focus on the mother-infant relationship and (b) support via SMS or WhatsApp.

Control arm: All participants will receive psychoeducation in the form of a guided introduction to a WHO-approved self-help illustrated guide to coping with adversity together with information on nutrition for mothers and babies.

Conceptual mapping:
Analysis of interview and focus group data will use thematic analysis. The aim of this analysis is to define mental health with people who live within the research sites, to explore local meanings and understandings of maternal mental health and postnatal depression, and to identify the factors which affect maternal mental health and health-seeking behaviour. Audio data will be transcribed. Analysis will be completed by local researchers using NVivo or directly onto Word documents with themes and key quotations listed in an Excel spreadsheet. Local researchers will review 10% of the data to check for consistency. This session will be followed by a collective code cleaning and prioritisation workshop. These agreed-upon codes will inform the design of a culturally-adapted g-IPT for testing during the RCT.

Intervention Type
Behavioural

Primary outcome(s)
Severity of depression measured using the Patient Health Questionnaire – depression module (PHQ-9) at baseline and at 8 (T2), 13 (T3), and 24 (T4) weeks post-treatment

Key secondary outcome(s))
1. Family circumstances assessed using the family circumstances questionnaire at baseline (T1) and 13 weeks (T3)
2. Height and weight measures of infants following WHO guidelines at baseline (T1) and 13 weeks (T3)
3. Early childhood development outcomes measured using the Caregiver Reported Early Development Index (CREDI) long form at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
4. Depression measured using the Hamilton Depression Rating Scale (HRSD) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
5. Anxiety measured using the General Anxiety Disorder-7 (GAD-7) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
6. Sleep measured using the Sleep Condition Indicator (SCI) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
7. Generic health status measured using the Short-Form Health Survey (SF-36) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
8. Alcohol consumption measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline (T1) and 13 weeks (T3)
9. Infant's sleep measured using the Brief Infant Sleep Questionnaire – Revised Short form (BISQ) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
10. Infant's physical health measured using the infant physical health questionnaire at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
11. Infant's cognitive development measured using the Malawi Developmental Assessment Tool (MDAT) at 24 weeks (T4)
12. Breastfeeding assessed using the breastfeeding outcome measure at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)
13. Social isolation assessed using the Lubben Social Network Scale (LSNS-6) at baseline (T1) and 13 weeks (T3)
14. Relationship satisfaction measured using the Couple Satisfaction Index (CSI-16) at baseline (T1) and 13 weeks (T3)
15. Health outcome assessed using EQ-5D at baseline (T1) and 13 weeks (T3)
16. Capability measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline (T1), 13 weeks (T3) and 24 weeks (T4)
17. Value of intervention measured using the SUMMIT patient cost questionnaire at baseline (T1) and 13 weeks (T3)
18. Decision making measured using the Adreoni questionnaire at baseline (T1) and 13 weeks (T3)
19. Household economic status measured using the Economic House economic questionnaire at baseline (T1) and household shocks measured at 13 weeks (T3)
20. Participants' experience of the treatment assessed using a semi-structured interview at baseline (T1) and 13 weeks (T3)

Completion date
30/11/2022

Eligibility

Key inclusion criteria
Feasibility trial:
1. Aged 18 years or older
2. Female

3. Postnatal depression as indicated by a score of 12 or more on the PHQ-9 at baseline
4. Mother with an infant aged 6 - 35 weeks old at the time of screening

Conceptual mapping:
Lebanon inclusion criteria:
1. Mothers who have recently given birth, living in one of the two research sites, of Palestinian, Syrian or Lebanese nationality
2. Fathers who have recently had a child, living in one of the two research sites, of Palestinian, Syrian or Lebanese nationality
3. Healthcare workers without mental health expertise, who work in one of the two research sites
4. Healthcare workers with mental health expertise, who work in one of the two research sites
5. Religious leaders from the Sunni, Shi'a, Christian, Druze communities, working in one of the two research sites
6. Key informants, such as staff working in local or national organisations in a related field (mental health, maternal health and early childhood health)

Kenya inclusion criteria:
1. Mothers who have recently given birth, living in one of the two research sites
2. Fathers who have recently had a child, living in one of the two research sites
3. Healthcare workers without mental health expertise, who work in one of the two research sites
4. Healthcare workers with mental health expertise, who work in one of the two research sites
5. Religious leaders working in one of the two research sites
6. Traditional midwives working in one of the two research sites
7. Key informants, such as staff working in local or national organisations in a related field (mental health, maternal health and early childhood health)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Feasibility trial:
1. Mothers with psychotic conditions including bipolar disorder, anorexia nervosa or substance dependency
2. Mothers whose babies have severe physical health problems or neurodevelopmental problems

Conceptual mapping:
1. Mothers with psychotic conditions including bipolar disorder, anorexia nervosa or substance

dependency
2. Mothers whose babies have severe physical health problems or neurodevelopmental problems

Date of first enrolment
31/01/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Kenya

Lebanon

Study participating centre
Huruma Lions Health Centre
Nairobi
Kenya
Not applicable

Study participating centre
Riruta Health Centre
Nairobi
Kenya
Not applicable

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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 data-sharing plans for the current study are unknown and will be made available at a later date

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes