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Implementing and evaluating group interpersonal therapy for postnatal depression in Lebanon and Kenya - individually randomised superiority trial

Submission date
14/09/2023

Recruitment status
No longer recruiting

Registration date
27/09/2023

Overall study status
Completed

Last Edited
27/03/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] 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 (World Health Organization, 2016). There is research from high-income countries showing that IPT and group-IPT (g-IPT) is an effective treatment for PND but we do not know whether it works in a LMIC context, or whether it also benefits child development. This study aims to explore the effectiveness of g-IPT in two LMIC for women with PND.
The trial directly follows on from two earlier phases of work; conceptual mapping phase and a feasibility study phase. We have used what we have learned from our previous research to inform this full randomised controlled trial that will compare Group Interpersonal Therapy (g-IPT) versus High-Quality Standard Care (HQ-SC).

Who can participate?
New mothers aged 18 years or older who are experiencing post-natal depression and have an infant aged 6-35 weeks old.

What does the study involve?
Mothers who choose to participate will be randomly allocated to one of two groups: treatment

(g-IPT) or control (HQ-SC). All participant will initially receive HQ-SC and then those allocated to treatment group will go on to receive 8 sessions of g-IPT. At 8, 13, 24, 36 and 52 weeks after their first clinical contact (the first session of HQ-SC), participants will be contacted to provide some data in the form of questionnaires and interviews. This will include data such as their mental health, depressive symptoms and sleep patterns, as well as their child's development. The data will then be analysed to assess whether g-ITP has a greater impact than standard care on the effects of post-natal depression on the mother and the development of the child.

What are the possible benefits and risks of participating?
A possible benefit of participating is a reduction in depression symptoms and in turn possible improvement in the child's development after going through g-ITP. However, a possible risk is that the group discussions might trigger stressful memories or emotions due to the sensitive nature of the topics.

Where is the study run from?
The 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?
October 2022 to December 2024

Who is funding the study?:
National Institute for Health Research (NIHR) Research and Innovation for Global Health Transformation (RIGHT) programme.

Who is the main contact?
Principal Research Coordinator, University College London
Dr Elizabeth Simes, e.simes@ucl.ac.uk

Study website
https://www.ucl.ac.uk/psychoanalysis/research/summit%20

Contact information

Type(s)
Principal Investigator

Contact name
Prof Peter Fonagy

Contact details
University College London
26 Bedford Way
London
United Kingdom
WC1H 0AP
+44 (0)2076791943
p.fonagy@ucl.ac.uk

Type(s)
Public

Contact name
Dr Elizabeth Simes

Contact details
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 7HB
+44 (0)2031083254
e.simes@ucl.ac.uk

Type(s)
Public

Contact name
Ms Ciara O'Donnell

Contact details
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 7HB
+44 (0)2031083254
ciara.o'donnell.16@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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: SUMMIT (SUpporting Mothers' Mental health with Interpersonal Therapy)

Acronym

SUMMIT

Study objectives
The study aims to assess whether or not culturally-adapted group interpersonal therapy (g-IPT) delivered in community settings in Kenya and Lebanon has a greater impact than high quality standard care (HQ-SC) on child developmental outcomes, maternal depression and the mother-child relationship.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 17/10/2022, University College London Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street University College, London, WC1H 0BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: ref: 23699/001

2. Approved 29/11/2022, Saint Joseph University Secretariat of the University Ethics Centre (Medical Sciences Campus, Hotel-Dieu de France, B.P 16-6830 Achrafieh, Beyrouth - Liban, Beirut, 1107 2180, Lebanon; +961 (0)1 421229; cue@usj.edu.ib), ref: ref: CEHDF 1854

3. Approved 23/11/2022, Kenyatta National Hospital and University of Nairobi Ethics Committee (KHN-UON ERC) (Kenyatta National Hospital, PO Box 20723, Code 00202; University of Nairobi (KNH – UoN), Faculty of Health Sciences, PO Box 19676, Code 00202, Nairobi, N/A, Kenya; +254 (0)726300 9; uonknh_erc@uonbi.ac.ke), ref: ref: KNH/ERC/Mod&SAE/425

Study design
Individually randomized superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Post-natal 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.

Group Interpersonal therapy (g-IPT): Interpersonal therapy was designed as a structured and time-limited treatment for depressed adults. The principle of g-IPT is that depressive episodes are triggered by issues in the patient's interpersonal relations (e.g. loss of a loved one, disputes, social isolation). It has proven to be an effective treatment for common mental health disorders, and one that can be used as a preventative intervention. For this study, g-IPT has been adapted for cultural relevance for Kenya and Lebanon and will be further adapted for new mothers with infants. There will be 8 sessions of g-IPT offered to participants randomised to the intervention arm.
High-Quality Standard Care (HQ-SC): 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. This will provide participants with a stress management guide for coping with adversity which equips them with practical skills to cope with stress.

Intervention Type
Behavioural

Primary outcome measure
Infant's cognitive development measured using the Malawi Developmental Assessment Tool (MDAT) (Gladstone et al. 2010), at 52 weeks (T6)

Secondary outcome measures
1. Severity of depression measured using the Patient Health Questionnaire – depression module (PHQ-9) (Kroenke & Spitzer, 2002) at baseline (T1), 8 weeks (T2), 13 weeks(T3), 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
2. Family circumstances assessed using the family circumstances questionnaire at baseline (T1), 13 weeks (T3) and 52 weeks (T6)
3. Maternal sensitivity and indicators of family care assessed using the Family Care Indicator (FCI) (Kariger et al., 2012) at baseline (T1), 8 weeks (T2), 13 weeks(T3), 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
4. Early childhood development outcomes measured using the Caregiver Reported Early Development Index (CREDI) long form (McCoy et al., 2018) at baseline (T1), 13 weeks (T3) and 36 weeks (T5)
5. Anxiety measured using the General Anxiety Disorder-7 (GAD-7) (Spitzer et al., 2006) at baseline (T1), 8 weeks (T2), 13 weeks(T3), 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
6. Sleep measured using the Sleep Condition Indicator (SCI) (Espie et al., 2014) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
7. Infant's sleep measured using the Brief Infant Sleep Questionnaire – Revised Short form (BISQ) (Mindell et al., 2019) at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
8. Infant's physical health measured using the infant physical health questionnaire at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
9. Breastfeeding assessed using the breastfeeding outcome measure at baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4), 36 weeks (T5) and 52 weeks (T6)
10. Social isolation assessed using the Lubben Social Network Scale (LSNS-6) (Lubben & Gironda, 2000) at baseline (T1), 13 weeks (T3) and 52 weeks (T6)
11. Relationship satisfaction measured using the Couple Satisfaction Index (CSI-4) (Funk & Rogge, 2007) at baseline (T1), 13 weeks (T3) and 52 weeks (T6)
12. Health outcome assessed using EQ-5D (Soeteman et al., 2008) at baseline (T1), 13 weeks (T3), 24 weeks (T4) and 52 weeks (T6)
13. Capability measured using the ICEpop CAPability measure for Adults (ICECAP-A) (Al-Janabi et

al., 2012) at baseline (T1), 13 weeks (T3), 24 weeks (T4) and 52 weeks (T6)
14. Value of intervention measured using the SUMMIT patient cost questionnaire (Rose-Clarke et al., 2020) at 13 weeks (T3)
15. Household economic status measured using the Economic House economic questionnaire at baseline (T1) and household shocks measured at 13 weeks (T3)
16. Demographic information covering socio-economic status, maternal education, maternal parity and teen parent status using the DUMMIT demographic questionnaire at baseline (T1)
17. A brief semi-structured qualitative interview to explore outcomes such as changes in understanding or, or attitudes towards, post-natal depression at baseline (T1), 13 weeks (T3) and 52 weeks (T6)

Overall study start date
17/10/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
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

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
412

Key exclusion criteria
1. Mothers with psychotic conditions including bipolar disorder, anorexia nervosa or substance dependence
2. Mothers whose babies have severe physical health problems or neurodevelopmental problems will also be excluded

Date of first enrolment
02/01/2023

Date of final enrolment

30/11/2023

Locations

Countries of recruitment
Kenya

Lebanon

Study participating centre
Huruma Lions Health Centre
Huruma Lions Health Centre, Nairobi
Nairobi
Kenya
-

Study participating centre
Riruta Health Centre
Riruta Health Centre, Nairobi
Nairobi
Kenya
-

Study participating centre
Githurai Health Centre
Githurai Health Centre, Nairobi
Nairobi
Kenya
-

Study participating centre
Kangemi Health Centre
Kangemi Health Centre, Nairobi
Nairobi
Kenya
-

Study participating centre
Mbagathi Hospital
Kenyatta National Hospital, Nairobi
Nairobi

Kenya
-

Study participating centre
Kenyatta National Hospital
Kenyatta National Hospital, Nairobi
Nairobi
Kenya
-

Study participating centre
Makased Center Primary Healthcare Centre
Msaytbeh, Beirut
Beirut
Lebanon
-

Study participating centre
Howard Karagheusian Commemorative Center
Marash Street, Karagheusian Avenue, Karagheusian Building, Burj Hammud
Beirut
Lebanon
-

Study participating centre
Dar Al Fatwa Primary Healthcare Centre
Ebn Rashed street, Aicha Bakkar
Beirut
Lebanon
-

Study participating centre
Dar El Hawraa Primary Healthcare
Bir Abed, Dahyeh area
Beirut
Lebanon
-

Study participating centre

Ghbeireh Center
Ghbeireh Center, Ghbeireh
Beirut
Lebanon
-

Study participating centre
Hariri Foundation Primary Healthcare Centre
Hariri Foundation, Tarik El Jdeedeh
Beirut
Lebanon
-

Study participating centre
Rafic Hariri Public Hospital
Rafic Hariri Public Hospital, Jnah
Beirut
Lebanon
-

Sponsor information

Organisation
University College London

Sponsor details
1-19 Torrington Place
London
England
United Kingdom
WC1E 7HB
+44 20 7679 4234
rosemary.varley@ucl.ac.uk

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Publication and dissemination plan
The results of the study will be disseminated through publications in peer reviewed journals as well as presentations, newsletters, and articles.

Intention to publish date
31/12/2025

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?
Protocol article		26/03/2024	27/03/2024	Yes	No