

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/03/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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Contact information

Type(s)

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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.lb), 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 & Girona, 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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

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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

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Study participating centre

Dar El Hawraa Primary Healthcare

Bir Abed, Dahyeh area

Beirut
Lebanon

-

Study participating centre

Ghbeireh Center

Ghbeireh Center, Ghbeireh

Beirut
Lebanon

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Study participating centre

Hariri Foundation Primary Healthcare Centre

Hariri Foundation, Tarik El Jdeedeh

Beirut
Lebanon

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Study participating centre
Rafic Hariri Public Hospital
Rafic Hariri Public Hospital, Jnah
Beirut
Lebanon
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Sponsor information

Organisation
University College London

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes