Supporting Mothers' Mental Health with Interpersonal Therapy

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Main Information

Primary registry identifying number
LBCTR2022024840

Protocol number
ISRCTN52076264

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
13/07/2021

Primary sponsor
University College of London (UCL)

Primary sponsor: Country of origin
UK

Date of registration in primary registry
23/05/2022

Date of registration in national regulatory agency
13/07/2021

Public title
Supporting Mothers' Mental Health with Interpersonal Therapy

Acronym
SUMMIT

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

Brief summary of the study: English

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.

Brief summary of the study: Arabic

الدراسة البحثية تهدف إلى اكتشاف ما إذا كان العلاج النفسي الذي يُعرف بالعلاج العلائقي الجماعي فعّالاً أم لا للنساء اللواتي الحديثات الإنجاب اللواتي يعانين من الاكتئاب أم لا. كما نودُّ أن نعرف ما إذا كان هذا النوع من المساعدة يساهم في تحسين علاقة الأم بطفلها وفي تعزيز نمو الطفل. وعلى الرغم من أن الدراسات التي أُجريت في الدول ذات الدخل المرتفع أظهرت فعالية هذا العلاج في معالجة اكتئاب ما بعد الولادة، نود أن نعرف ما إذا كان هذا فعّالاً في السياق المحلي. سوف نقارن بين مجموعتَين من الأمهات والأطفال، تخضع إحداها للعلاج العلائقي الجماعي فيما تتلقى الثانية خدمات رعاية أخرى متاحة في منطقتك لكي نرى أي خيار هو الأفضل.

Health conditions/problem studied: Specify

Maternal Depression - Child Development - Mother-Child Relationship

Interventions: Specify

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.

Key inclusion and exclusion criteria: Inclusion criteria

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)

Key inclusion and exclusion criteria: Gender

Female

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

45

Key inclusion and exclusion criteria: Exclusion criteria

Participant 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

Type of study

Interventional

Type of intervention

Behavioral treatment

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

0 (explanatory trials)

Study design: Purpose

Supportive care

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Not Applicable

Therapeutic indication

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.

Therapeutic benefit

The main benefits of g-IPT are a reduction in depression levels and a possible benefit to child developmental outcomes and the mother-child relationship.

Study model

N/A

Study model: Explain model

Study model: Specify model
N/A

N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
None retained

Biospecimen description
not applicable

Target sample size
35

Actual enrollment target size
35

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
01/02/2022

Date of study closure: Type
Anticipated

Date of study closure: Date
31/12/2022

Recruitment status
Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan
No

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

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
The National Institute for Health Research (NIHR)- UK

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Pardi Maradian	Bsalim	Lebanon	03-723070	pardi.maradian@nmhp-lb.com	NMHP-MoPH
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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Makased primary health center in Msaytbeh area	Dr Rabih El Chammay	psychiatrist	Approved
Lebanese Red Cross Center	Dr Rabih El Chammay	psychiatrist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	28/06/2021	Virginia El Khoury	cue@usj.edu.ib	+961 (0)1 421229

Countries of Recruitment

Name
Lebanon
Kenya

Health Conditions or Problems Studied

Condition	Code	Keyword
Maternal Depression	Mental disorder, not otherwise specified (F99)	PND

Interventions

Intervention	Description	Keyword
group interpersonal psychotherapy g-IPT	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.	g-IPT

Primary Outcomes

Name	Time Points	Measure
Severity of depression	baseline and at 8 (T2), 13 (T3), and 24 (T4) weeks post-treatment	Patient Health Questionnaire- depression module (PHQ-9)

Key Secondary Outcomes

Name	Time Points	Measure
Family circumstances	baseline (T1) and 13 weeks (T3)	family circumstances questionnaire
Height and weight measures of infants	baseline (T1) and 13 weeks (T3)	following WHO guidelines
Early childhood development outcomes	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	Caregiver Reported Early Development Index (CREDI) long form
Depression	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	Hamilton Depression Rating Scale (HRSD)
Anxiety	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	General Anxiety Disorder-7 (GAD-7)
Sleep	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	Sleep Condition Indicator (SCI)
Generic health status	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	Short-Form Health Survey (SF-36)
Infant's sleep	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	Brief Infant Sleep Questionnaire – Revised Short form (BISQ)
Infant's physical health	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	infant physical health questionnaire
Infant's cognitive development	24 weeks (T4)	Malawi Developmental Assessment Tool (MDAT)
Breastfeeding	baseline (T1), 8 weeks (T2), 13 weeks (T3) and 24 weeks (T4)	breastfeeding outcome measure
Social isolation	baseline (T1) and 13 weeks (T3)	Lubben Social Network Scale (LSNS-6)
Relationship satisfaction	baseline (T1) and 13 weeks (T3)	Couple Satisfaction Index (CSI-16)
Health outcome	baseline (T1) and 13 weeks (T3)	EQ-5D
Capability	baseline (T1), 13 weeks (T3) and 24 weeks (T4)	ICEpop CAPability measure for Adults (ICECAP-A)
Value of intervention	baseline (T1) and 13 weeks (T3)	SUMMIT patient cost questionnaire
Decision making	baseline (T1) and 13 weeks (T3)	Adreoni questionnaire
Household economic status	baseline (T1) and household shocks measured at 13 weeks (T3)	Economic House economic questionnaire
Participants' experience of the treatment	baseline (T1) and 13 weeks (T3)	emi-structured interview

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files