



# 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 فعالاً أم لا للنساء اللواتي الحديثات الإنجاب اللواتي يعانين من الاكتئاب أم لا. كما نودُ 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 أجريت في الدول ذات الدخل المرتفع أظهرت فعالية هذا العلاج في معالجة اكتئاب ما بعد الولادة، نود أن نعرف ما إذا كان هذا فعالاً في السياق المحلي. سوف نقارن بين مجموعتين 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
Scientific	Rabih El Chammay	Achrafieh	Lebanon	03-390935	rabih.chammay@nmhp-lb.com	NMHP-MoPH

**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.lb	+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**