

# Systemic therapy with postnatal mothers presenting with anxiety and/or depression

<b>Submission date</b> 01/05/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study seeks to find out whether one of the policy measures in the Positive Parenting Strategy (i.e. that of providing therapeutic support to mothers suffering from anxiety and or depression during the postnatal period) is evidence-based. The study examines whether 12 sessions of systemic therapy offered to prenatal mothers suffering from anxiety and or depression who are randomly assigned to the intervention group would improve their levels of anxiety and/or depression when compared to those mothers who are randomly assigned the intervention group would improve their levels of anxiety and/or depression when compared to those mothers who are randomly assigned to the control group who receive support provided by the midwife.

### Who can participate?

Mothers aged 18 years and over with babies between 6 weeks and 12 months old.

### What does the study involve?

Those mothers who consent to participate in the study either when approached by the Liaison Midwives before leaving hospital after the birth of their child or when referred by the midwives in charge at the Perinatal Mental Health Service

### What does the study involve?

Those mothers who consent to participate in the study, are screened for depression and anxiety after the baby is 6 weeks old. The assessment includes a short questionnaire and questions to assess current mental health. Those mothers who after completing the questions are found to be suffering from anxiety and or depression are then asked to fill in more questionnaires and to sit for a psychiatric interview. Those mothers whose diagnosis indicates serious mental health difficulties such as psychotic disorders and mood disorders with psychotic features, suicidal behaviour disorder, substance use disorders, post-traumatic stress disorder, anti-social personality disorder and borderline personality disorder are excluded from the study and referred for treatment within the Perinatal Mental Health Service at Mater Dei Hospital or in the case of substance abuse disorders in the existing specialised centres available on the island. The remaining suffering from anxiety and or depression are randomly assigned into an intervention and control group. Mothers in the intervention group receive 12 online sessions

from a systemic therapist. Mothers in the control group receive telephone calls from the midwives.

What are the possible benefits and risks of participating?

Possible benefits are that the level of anxiety and or depression would go down. There are no perceived risks for postnatal mothers participating.

Where is the study run from?

Mater Dei Hospital Malta

When is the study starting and how long is it expected for?

June 2020 to February 2025

Who is funding the study?

Committee for Positive Parenting and the Wellbeing of Families (Malta)

Who is the main contact?

Prof. Angela Abela, [angela.abela@um.edu.mt](mailto:angela.abela@um.edu.mt)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

Nil known

# Study information

## Scientific Title

Systemic therapy with postnatal mothers presenting with anxiety and/ or depression: a randomised controlled trial

## Study objectives

1. Will 12 sessions in a systemic therapeutic modality significantly decrease symptoms of anxiety and/or depression in mothers forming part of the intervention (which also includes medication where needed) as opposed to those in the control group receiving treatment as usual (support by midwife & medication where needed)?
2. Will the therapeutic intervention also make a significant difference in Intervention Group mothers in terms of their evaluation of their couple relationship?

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 06/01/2021, Faculty (for Social Wellbeing) Research Ethics Committee and the University (of Malta) Research Ethics Committee (University of Malta, MSIDA, MSD2080, Malta; +356 23402340; research-ethics.fsw@um.edu.mt), ref: ID:753127.12.2020

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Screening, Treatment

## Participant information sheet

See study outputs table

## Health condition(s) or problem(s) studied

Postnatal anxiety and/or depression

## Interventions

Mothers who during the postnatal period score above the cutoff point on the Edinburgh Postnatal Scale (EPDS) (11 or higher) and or the Generalised Anxiety Disorder Assessment (GAD-7) 10 and up and wish to continue with the study are asked to sit for the Mini International

Neuropsychiatric Interview with borderline personality disorder module (MINI). The Mini helps to provide us with a more complete profile of the mothers and to exclude those falling in the exclusion criteria (see Exclusion Criteria below). Mothers who are eligible and who consent to continue with the study are assigned by the Statistician on the research team to either intervention or control group. This is carried out through minimisation to achieve balanced groups with respect to numbers and participant characteristics that are believed to be important for the study's outcome. In minimisation, participants are assigned to groups based on a set of predefined criteria or variables, such as labour status, relationship status, level of education completed, nationality, and financial impact of COVID-19. The allocation of participants is implemented by "MinimPy" which is an open-source desktop minimisation programme written in Python programming language with complete customisation of minimisation features for the allocation of patients to groups. For a complete description of the programme, please refer to: Saghae, M and Saga, S. (2011) Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials. Journal of Biomedical Science and Engineering,4,734 - 739.[Http://www.scirp.org?journal/jbise/](http://www.scirp.org?journal/jbise/)

Those in the intervention group receive 12 online sessions of systemic therapy. The sessions are spread over 19 weeks, the first 5 will take place every week, whereas the last 7 are offered on a fortnightly basis. Those needing medication are referred to a psychiatrist who prescribes medication if needed.

The mothers in the control group are followed by the midwife through monthly calls over the 19 weeks. Those needing medication are referred to a psychiatrist who prescribes medication if needed.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Level of anxiety and/or depression measured using EPDS, GAD-7 immediately after the end of the intervention

### **Secondary outcome measures**

Distress in couple relationship measured using the Revised Dyadic Adjustment Scale (RDAS), at post-intervention period

### **Overall study start date**

09/06/2020

### **Completion date**

28/02/2025

## **Eligibility**

### **Key inclusion criteria**

1. Mothers with babies between 6 weeks and 12 months old
2. Scoring above the cut-off point on GAD-7 and EPDS
3. Accepting to take part in the study

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

60

**Total final enrolment**

60

**Key exclusion criteria**

1. Lone parents meaning mothers
2. Mothers with psychotic disorders and mood disorder with psychotic features
3. Suicidal behaviour disorder
4. Substance use disorder
5. Alcohol use disorder
6. Post-traumatic stress disorder
7. Antisocial-social personality disorder
8. Borderline personality disorder
9. Criteria 2-8 were identified through the use of the MINI

**Date of first enrolment**

01/04/2022

**Date of final enrolment**

08/04/2024

**Locations****Countries of recruitment**

Malta

**Study participating centre****Mater Dei Hospital**

Triq Dun Karm

MSIDA

Malta

MSD2090

**Sponsor information**

**Organisation**

Committee for Positive Parenting and the Wellbeing of Families (Malta)

**Sponsor details**

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**Sponsor type**

Government

**Funder(s)****Funder type**

Government

**Funder Name**

Committee for Positive Parenting and the Wellbeing of Families (Malta)

**Results and Publications****Publication and dissemination plan**

Planned National Conference and subsequent publication in a peer-reviewed journal

**Intention to publish date**

31/08/2025

**Individual participant data (IPD) sharing plan**

The data set generated during the current study will be available upon request from the principal investigator Prof. Angela Abela (angela.abela@um.edu.mt).

The type of data that will be shared: Microdata (upon request) and the aggregated results once the data analysis is ready

Dates of availability: Once the data is checked and cleaned, ideally after the analysis

Whether consent from participants was required and obtained: Consent obtained: Data is anonymised

Comments on data anonymisation : names, surnames, addresses, age and any other factors that might detect who the person is will be all removed. Instead the index no of the person, the factors used for the minimisation process (labour status, education level , impact of COVID-19,

nationality , etc) and their corresponding measures pre- and post (EPDS, GAD-7, R-DAS etc ) will be retained.

Any ethical or legal restrictions: Not to our knowledge

Any additional comments : None

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			03/05/2024	No	Yes
<a href="#">Protocol file</a>		10/05/2024	14/05/2024	No	No
<a href="#">Other unpublished results</a>			26/03/2025	No	No