ISRCTN10659460 https://doi.org/10.1186/ISRCTN10659460

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

Submission date
01/05/2024

Recruitment status
No longer recruiting

Registration date
03/05/2024

Overall study status
Completed

Last Edited
26/03/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Angela Abela

ORCID ID
https://orcid.org/0000-0002-9172-6530

Contact details
Department of Child and Family Studies
Faculty for Social Wellbeing
Old Humanities Building
Room 243
Msida
Malta
MSD2080
+356 (0) 23403601
angela.abela@um.edu.mt

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Screening, Treatment

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/

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

Funder(s)

Funder type
Government

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

Results and Publications

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 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?
Other unpublished results			26/03/2025	No	No
Participant information sheet			03/05/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		10/05/2024	14/05/2024	No	No