ISRCTN17416582 https://doi.org/10.1186/ISRCTN17416582

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

Submission date
12/09/2023

Recruitment status
No longer recruiting

Registration date
20/09/2023

Overall study status
Completed

Last Edited
25/02/2025

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 during the prenatal 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 to the control group who receive support provided by the midwife.

Who can participate?
Mothers aged 18 years and over attending their first prenatal visit at Mater Dei Hospital (normally after the 12th week of pregnancy) or 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. 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 interviews. Those mothers whose diagnosis indicates serious mental health difficulties such as psychotic disorders and mood disorder 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 MaterDei 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 midwife.

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 antenatal mothers participating.

Where is the study run from?
Mater Dei Hospital (Malta)

When is the study starting and how long is it expected to run for?
June 2020 to May 2024

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)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Systemic therapy with prenatal 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 amongst 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 Research Committee (University of Malta, MSIDA, MSD2080, Malta; +356 (0)23402340; research-ethics.fsw@um.edu.mt), ref: ID:753127.12.2020

Study design
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
Antenatal anxiety and/or depression

Interventions
Current interventions as of 01/05/2024:

Mothers who during the prenatal period score above the cutoff point on the Edinburgh Postnatal Scale (EPDS)_ (13 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 section on exclusion criteria below). Mothers who are eligible and who consent to continue with the study are assigned by the Statistician on our research team. The allocation of participants to either intervention or control group is carried out through minimization 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.

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Previous interventions:

Mothers who during the antenatal period score above the cut-off point on the Edinburgh Postnatal Depression Scale (EPDS) (13 or higher) and/or the Generalised Anxiety Disorder Assessment (GAD-7) (10 or higher) were assigned by the Statistician on the research team. The allocation of participants to either intervention or control group was carried out through minimization in order to achieve balanced groups with respect to numbers and participant characteristics that are believed to be important for the study's outcomes. In minimization, subjects were 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 was implemented by “MinimPy” which is an open-source desktop minimization program written in Python programming language with complete customization of minimization features for the allocation of patients to groups. For a complete description of the program used, please refer to the following journal:
Saghae, M. and Sagaei, 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 on a weekly basis, 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 phone calls over the 19-week period. 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) post-intervention period

Overall study start date
09/06/2020

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Expecting a baby and not exceeding 20 weeks of pregnancy to be able to receive the intervention (over a 19-week period) and be post-tested before giving birth
2. Scoring above the cut-off point on GAD 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. Anti-social personality disorder
8. Borderline personality disorder
Criteria 2 -8 were identified through the use of the MINI

Date of first enrolment
01/03/2022

Date of final enrolment
14/12/2023

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

Sponsor details
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Sponsor type
Government

Website
https://familja.gov.mt/entitajiet-pubblici/kumitat-ghal-trobbija-pozittiva-u-t-tishih-tal-familja/

Funder(s)

Funder type
Government

Funder Name
Committee for Positive Parenting and the Wellbeing of Families

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact systemic journal

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan
The dataset 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 anonymization: names, surnames, addresses, age and any other factors that might detect who the person will be all removed. Instead the Index No of the person, the factors used for the minimization process (labour status, education level, impact of COVID-19, nationality, etc.) and their corresponding measurements pre- and post- (EPDS, ANRQ 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?
Participant information sheet		07/09/2023	14/09/2023	No	Yes
Protocol file			24/04/2024	No	No
Other unpublished results			27/01/2025	No	No