

# Early screening and prompt intervention to identify and treat maternal mental health problems before and after giving birth

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<b>Registration date</b> 20/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The most common mental disorders in women during the perinatal (months before and after giving birth) period are depression and anxiety. In Italy, a few studies have been undertaken to evaluate the extent of perinatal depression and anxiety, and there is still a scarcity of research and intervention programmes regarding prevention of these conditions. The main aims of this study are:

- 1) to evaluate the prevalence of maternal perinatal depression and anxiety in a large sample of women attending healthcare centres in Italy
- 2) to investigate the psychosocial risks and protective factors associated with maternal perinatal depression and anxiety
- 3) to evaluate the influence of maternal depression and anxiety on the baby
- 4) to evaluate the effectiveness of manualized psychological interventions to treat perinatal depression and anxiety in a large sample of mothers in Italy.

### Who can participate?

Mothers who are either pregnant or have given birth in the last six months can take part.

### What does the study involve?

This five-phase study comprises a perinatal mental health awareness period, a screening period (up to the baby's first vaccination), a psychological evaluation, an intervention period (10 weeks' duration), and a post-intervention follow-up (up to twelve months from the end of intervention). The intervention consists of group-based cognitive behavioural therapy and focuses on the mothers' life events and mood and on practical issues. This clinic-based group intervention is led and facilitated by a licensed psychotherapist and consists of ten weekly sessions of 90 minutes exclusively dedicated to the mothers, three sessions involving the fathers, and another three sessions dedicated to mother-child interaction.

### What are the possible benefits and risks of participating?

Early intervention on perinatal depression and anxiety can reduce the direct and indirect costs of damage to the mother in terms of personal, social and working life, and, above all, reduce the

direct and indirect costs that may arise due to the impact on child development. For the individual subjects of the study, the expected benefits are the more prompt identification and treatment of anxiety and depressive disorders or other psychiatric disorders, where present, with the consequent possible improvement of mental health outcomes and greater psychological well-being.

There were no risks associated with participation in any aspect of the described study.

Where is the study run from?

Department of Clinical and Experimental Sciences, University of Brescia, Italy

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

March 2017 to June 2018

Who is funding the study?

University of Brescia, Italy

Who is the main contact?

Prof. Loredana Cena,  
loredana.cena@unibs.it

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Loredana Cena

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

## **Study information**

**Scientific Title**

Early screening and prompt intervention to identify and treat maternal perinatal depression and anxiety

**Study objectives**

Milgrom and colleagues' psychological intervention is effective to cure perinatal depression and anxiety in a sample of women in Italy

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 27/06/2017, Ethical Committee of the Healthcare Centre of Bologna Hospital (Ospedale "Maggiore" - Largo Bartolo Nigrisoli, 2 - Bologna (40133), Italy; +39 513172412; marinella.lenzi@ausl.bologna.it), ref: 77808

**Study design**

Prospective cohort study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Perinatal depression and anxiety

**Interventions**

Screening for depression and anxiety was performed once during the pre- or post-partum period, depending on the characteristics of each healthcare centre. All mothers completed the Psychosocial and Clinical Assessment Form, the EPDS - Edinburgh Postnatal Depression Scale and the PHQ-9 - Patient Health Questionnaire-9 to evaluate depressive symptoms and the STAI - State-Trait Anxiety Inventory to evaluate anxiety. Mothers were required to complete the psychodiagnostic evaluation within one week of the date of positive screening results. All mothers underwent an interview with a clinical psychologist. Within the following week, in the case of clinician-generated diagnosis of perinatal depression and/or anxiety (according to the DSM-5 criteria), these mothers were further assessed using the Mini-International Neuropsychiatric Interview (MINI) Plus to confirm the diagnosis. Depressed and/or anxious mothers were invited to participate in the intervention phase of the study.

The intervention is based on the model developed in Australia by Milgrom to reduce maternal prenatal and postnatal depression, anxiety and parenting difficulties. Moreover, this model provides for the simultaneous assessment of the neurobiological, psychological and social factors that contribute to developing psychological vulnerability in the perinatal period. The

intervention consists of group-based cognitive behavioural therapy and focuses on the mothers' life events and mood and on practical issues. This clinic-based group intervention is led and facilitated by a licensed psychotherapist and consists of ten weekly sessions of 90 minutes exclusively dedicated to the mothers, three sessions involving the fathers, and another three sessions dedicated to mother-child interaction. Although the intervention took place primarily in groups, in the event of impossibility of organising a group of at least three participants within a few weeks of the psychodiagnostic evaluation, or where a mother was unable to participate regularly in weekly group sessions due to health or organisational reasons, each healthcare centre offered the option of individual treatment. This solution allowed a more flexible approach than group treatment, since the programme could be adapted to the specific situation of the mother in question. The content of the individual counselling was the same as that of group-based counselling and consisted of ten sessions of 60 minutes. In both cases, information and activity material were distributed between sessions.

The study involved a one-year recruitment period and a one-year follow-up period. The methodological strategy includes: self-report questionnaires on maternal depression, anxiety, health status, quality of life, and psychosocial risks; a self-report questionnaire to measure the infant's temperament; a clinical interview; a structured diagnostic interview; and a psychological intervention

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Changes in the patients' clinical conditions measured using EPDS, PHQ-9, STAI, MINI-Plus and a clinical interview were re-evaluated after baseline at three points of follow-up (end of intervention, 6th month and 12th month)

### **Key secondary outcome(s))**

1. Quality of life measure using the World Health Organization Quality of Life (WHOQOL) BREF
2. Babies' traits in temperament assessed using QUITs - Italian Questionnaires of Temperament

Changes in the patients' clinical conditions were re-evaluated after baseline at three points of follow-up (end of intervention, 6th month and 12th month) using WHOQOL-BREF and QUITs.

### **Completion date**

30/11/2019

## **Eligibility**

### **Key inclusion criteria**

Mothers were eligible for inclusion in the study if they met the following criteria:

1. Pregnant, or had a biological newborn aged  $\leq 6$  months
2. Speak and read Italian

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Psychotic symptoms
2. Exhibited non-suicidal self-harming or suicidal behaviour
3. Issues with drug or substance abuse

**Date of first enrolment**

29/03/2017

**Date of final enrolment**

27/06/2018

**Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Mani di Scorta Clinic and Family Center**

via Arioli Dolci 12

Treviolo Bergamo

Italy

24048

**Study participating centre**

**LHA of Bologna Child and Adolescent Neuropsychiatry (Mental Health Department - Pathological Addictions) Neuropsychiatry of Infancy and Adolescence (Mental Health Department - Pathological Addictions) in the NICU (Maternal and Child Department)**

via Castiglione 29

Bologna

Italy

40124

**Study participating centre**

**Maggiore Hospital Physiological Pregnancy and Breastfeeding Department**

via Largo Bartolo Nigrisoli 2

Bologna

Italy

40133

**Study participating centre**

**Clinical Institute City of Brescia OU Obstetrics and Gynecology**

Via Gualla 15

Brescia

Italy

25128

**Study participating centre**

**Umberto I Hospital OUC Obstetrics and Gynecology, Physiological Pregnancy Clinic**

viale Diaz n. 7/9

Enna

Italy

94100

**Study participating centre**

**LHA of Toscana Centro Family Clinic and Pediatric Surgeries**

V.le Michelangelo 41

Florence

Italy

50122

**Study participating centre**

**Carlo Poma Hospital Clinical Psychology Department; NICU**

Strada lago paiolo 1

Mantua

Italy

46100

**Study participating centre**

**San Giuseppe Hospital OU Obstetrics and Gynecology**

Via San Vittore 12

Milan

Italy

20123

**Study participating centre**

**GruppoPsychè Association, Maggiore della Carità Hospital OU Obstetrics and Gynecology**

C.so Mazzini 18

Novara  
Italy  
28100

**Study participating centre**  
**Cristo Re Hospital OUC Obstetrics and Gynecology**  
Via delle Calasanziane 25  
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**Study participating centre**  
**LHA of Turin 3 Assistive Process, Perinatal Psychology, Specialist Clinic of Perinatal Psychology, and Vaccine Clinic**  
Via Martiri XXX Aprile 30  
Collegno Torino  
Italy  
10093

## **Sponsor information**

**Organisation**  
Department of Clinical and Experimental Sciences, Section of Clinical Psychology, Observatory of Perinatal Clinical Psychology

**ROR**  
<https://ror.org/02q2d2610>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
Università degli Studi di Brescia

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		11/03/2020	14/06/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes