ISRCTN12733828 https://doi.org/10.1186/ISRCTN12733828

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

Submission date
09/05/2019

Recruitment status
No longer recruiting

Registration date
20/05/2019

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

ORCID ID
http://orcid.org/0000-0002-3162-9237

Contact details
Department of Clinical and Experimental Sciences
Section of Clinical Psychology
Observatory of Perinatal Clinical Psychology
University of Brescia
Viale Europa 11
Brescia
Italy
25123
+39 030 37 17 274
loredana.cena@unibs.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
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.

Overall study start date
07/01/2017

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 ≤6 months
2. Speak and read Italian

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
39

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
Rome
Italy
00167

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

Sponsor details
University of Brescia
Viale Europa 11
Brescia
Italy
25123
+393357309878
loredana.cena@unibs.it

Sponsor type
University/education

Website
https://www.unibs.it/node/12195

ROR
https://ror.org/02q2d2610

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Brescia

Results and Publications

Publication and dissemination plan
The findings of this study will be published in international peer-reviewed journals.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?
Protocol article		11/03/2020	14/06/2023	Yes	No