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Effects of a prenatal program group led to parental couples to prevent postpartum depression in women of middle and lower classes living in northern Catalonia and Southern France [Effetsdunprogrammeprénatal de groupeadresséauxcouplesparentauxpourpréveni

Submission date	Recruitment status	[ ] Prospectively registered
15/07/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/11/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/12/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Postnatal depression is a type of depression some women experience after having a baby. During pregnancy, women use healthcare centres very often and it is possible to detect their risk of having postnatal depression. The aim of this study is to assess the effects of a prenatal group program in women considered at risk of having postnatal depression.

Who can participate?
Pregnant women and their partners with an estimated family income of $ 30,000 Ca or less, with moderate or high risk factors for postpartum depression.

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. The intervention group attend a prenatal group program (ten sessions of two hours duration) to prepare the entire family for childbirth. The sessions are conducted by three nurse-midwives. The control group receive the usual maternal education program. Participants in both groups complete questionnaires so that we can compare the depressive postnatal symptoms of the women in the intervention group and the control group.

What are the possible benefits and risks of participating?
The intervention group participants benefit from prenatal sessions that may be attended with

young children. At the end of the study, all women received a box with various gift items: a book, diapers, bibs and bags for baby's things. There are no risks to participants. There are no medications and no advice that may endanger the participants.

Where is the study run from?
The study was carried out in three cities: Barcelona, Figueres (Spain) and Béziers (France).

When is the study starting and how long is it expected to run for?
March 2003 to June 2006.

Who is funding the study?
This study is financed by ADERMNCN, the Catalan government, the University of Montreal (Canada) and the University of Girona (Spain).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effects of a prenatal program group led to parental couples to prevent postpartum depression in women of middle and lower classes living in northern Catalonia and Southern France: a randomized longitudinal study

Study objectives
Compared with a group of women who did not participate in the program, women in the intervention group consists of ten weekly sessions and based on a psychosomatic orientation present at least, a rate 6% lower risk cases of postoartum depression (PPD), once assessed 4 weeks after delivery with the Edinburgh Postnatal Depression Scale (EPDS) scale cut-off point ≥ 12.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee for Biomedical Research, Clinic Barecelona (Comité ético de investigación biomédica, Clinic Barecelona), 17/07/2001, ref: 823

Study design
Randomized longitudinal study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Postpartum depression

Interventions
The intervention group and the control group are only one treatment that consists of ten sessions about preparation for the birth (two hours duration). These sessions are applied in groups of 6-8 couples in intervention group, with goals aimed at mothers, fathers, babies and the relationship between the participants. The groups are closed.

The control group received a single treatment; it is the usual maternal education program consists of ten sessions with women-focused goals: hygiene of pregnancy and childbirth preparation. These sessions are applied in groups of 10-14 women. The groups are open.

The number of participants in each study group is similar: n = 92 / n = 92.
The intervention program used the methodology developed by Tourné (2002). Claude-Emile Tourné is a French doctor of obstetrical medicine who designed a program to prepare the entire family to childbirth. The father, mother and siblings can participate in the sessions. The toys are available for children in the room; the experience is that the brothers listen carefully and prepare with their parents.

During these experimental sessions key questions are used, method is experimenting with different feelings and builds an individual model for this experience. The model base articulates psychosomatic perspective of childbirth, attachment theory and, cognitive theory in relation to beliefs and ideas are shared. The sessions are divided into three parts:
1. An informative part
2. Another part of discussion among participants
3. Some practical exercises

There are two sessions in which participants are those who argue the topics. During the sessions 4, 8 and 9 we displayed a 10-minute video about childbirth.

The sessions are conducted by three nurse-midwives previously prepared for the study by 28 hour formation. They dont know the variables studied and they never had access to the data of the participants.

The control group sessions were held on days and times different from the intervention group. He asked all participants to make all the possible prenatal sessions but this was not mandatory. The intervention group participants received a weekly phone call between sessions to reinforce participation. The control group participants had no calls.

Participants were chosen at random; they lived in different places and did not know each other. The population served in two of the three centers studied live in different peripheral areas of the city or in small towns. It is difficult for these people have contact.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Four variables associated with PPD were assessed:
1. Depressive symptoms with the Edinburgh Postnatal Depression Scale (EPDS) scale
2. Amount of social support received with the Functional Social Support Questionnaire
3. Stressful events based on Holmes and Rahe
4. Relationship with the partner from Spaniers dyadic adjustment scale (DAS)

The outcomes are measured 4 weeks after delivery.

Secondary outcome measures
1. We evaluated childbirth outcomes by specific trial questionnaires:
1.1. Preterm delivery
1.2. Infant birth weight
1.3. Somatic symptoms of the mother after delivery

1.4. Father participation in womens and childrens medical control
2. Also evaluated aspects of the couple relationship such as
2.1. Communication
2.2. Sharing of tasks
2.3. Involving the man in childbirth process
2.4. Finally the satisfaction of the couples who participated in the experimental group sessions

Measured at 5 - 9 weeks after delivery

Overall study start date
03/03/2003

Completion date
30/06/2006

Eligibility

Key inclusion criteria
The study participants were pregnant women and their partners. The average age of women was 29 years
1. Primiparous or multiparous children under 3
2. A family income ≤ $ 30,000 Ca, estimated from the type of job
3. Have moderate or high risk factors for postpartum depression assessed in the first trimester of pregnancy (use a specific screening tool validated in Europe by Riguetti-Veltema et al, 2006).
4. Have parental partner

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
n= 529 recruited; n= 220 (selected); finaly participants n=184

Key exclusion criteria
1. Evidence of substance abuse during pregnancy
2. Maternal psychopathology that would require women to receive psychological care to individuals during pregnancy
3. Not understanding the language (Spanish or French)
4. Belong to a privileged social class

Date of first enrolment
03/03/2003

Date of final enrolment

30/06/2006

Locations

Countries of recruitment
France

Spain

Study participating centre
University of Girona
Girona
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17071

Sponsor information

Organisation
ADERMNCN (Association for better childbirth in Northern Catalonia) (Spain)

Sponsor details
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Sponsor type
Not defined

Funder(s)

Funder type
Government

Funder Name
French association ADERMNCN (Association of diffusion studies and intervention to further childbirth in northern Catalonia)

Funder Name
The Catalan government, grants Integrated Action (ACI)

Funder Name
University of Montreal (Canada)

Funder Name
University of Girona (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration