

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 [Effets d'un programme prénatal de groupe adressé aux couples parentaux pour prévenir

Submission date 15/07/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/11/2011	Overall study status Completed	☐ Protocol
Last Edited 11/12/2015	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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?

Dr Maria Assumpta Ortiz
assumpta.ortiz@udg.edu

Contact information

Type(s)

Scientific

Contact name

Dr Maria Assumpta Ortiz-Collado

Contact details

University of Girona

Faculty of Nursing

Emili grahit, 77

Girona

Spain

17071

+34 (0)97 241 8971

assumpta.ortiz@udg.edu

Additional identifiers

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 postpartum 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 Barcelona (Comité ético de investigación biomédica, Clinic Barcelona), 17/07/2001, ref: 823

Primary study design

Interventional

Study design

Randomized longitudinal study

Study type(s)

Prevention

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 don't 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(s)

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.

Key secondary outcome(s)

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 women's and children's 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

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 $\leq$ \$ 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 Rigueti-Veltema et al, 2006).
4. Have parental partner

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Spain

17071

Sponsor information

Organisation

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

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration