

# 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 parents pour prévenir le

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

**Protocol serial number**

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 postpartum depression (PPD), once assessed 4 weeks after delivery with the Edinburgh Postnatal Depression Scale (EPDS) scale cut-off point  $\geq 12$ .

### **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

### **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 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(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 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

### **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

### **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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes