

# Psychoeducational intervention for perinatal depression: study protocol of a randomized controlled trial



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## Background and aims

- About 12% of women suffer from Perinatal depression (PD), which impacts negatively on children in terms of adverse neonatal outcomes and on the wellbeing of women and their family members. PD can have several detrimental effects including low birth weight, preterm birth, early childhood developmental delays, poor maternal fetal attachment, impairments in cognitive functioning, behavioral disturbances, and development of depressive disorders in the childhood or adolescence
- The management of patients with PD include a combination of pharmacological and psychosocial interventions, according to clinical severity.
- Several interventions have been developed for reducing the impact of risk factors and for preventing the development of PD, including professionally-based home visits, postpartum peer-based telephone support, interpersonal psychotherapy, and cognitive behavioral therapy
- To date, few studies have assessed the efficacy of family psychoeducational interventions in patients with PD.
- The aims of this study are: a) to assess the efficacy of a psychoeducational family intervention compared to the best treatment option (BTO) in women with PD and their family members; b) to identify predictive factors of PD; c) to improve relative's coping strategies and family functioning.

## Methods

All pregnant women attending the unit of Gynecology and Obstetrics of the University of Campania "L. Vanvitelli" will be screened for PD with the Edinburgh Postpartum Depression Scale (EPDS) (**Figure 1**). Women with a score >10 at EPDS will receive a full psychiatric assessment. Once diagnosis is made, they will be randomly allocated to either an experimental group, receiving a uni-familial psychoeducational intervention, or to a control group, receiving BTO (**Figure 3**). Patients will be assessed at baseline, 3, 6, 9 and 12 months post-randomization. At each time, patients will be evaluated through validated questionnaire, reported in **Figure 1**.

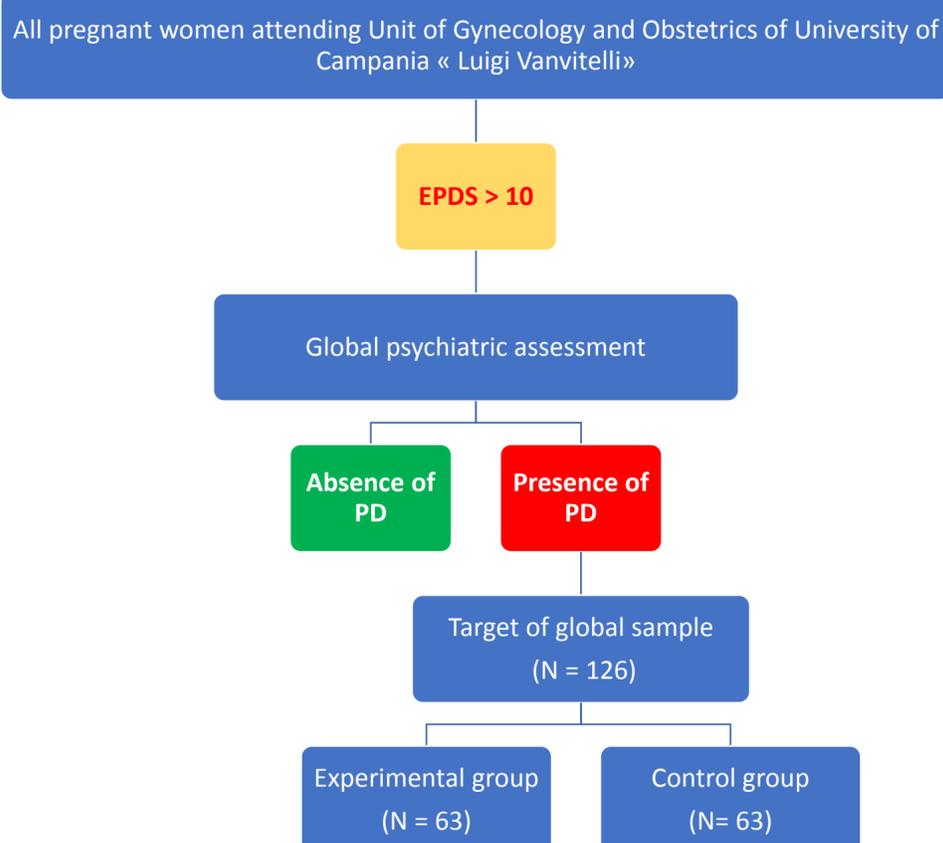


Figure 2 Multi-step recruitment procedure

## Screening Phase

- The Edinburgh Postnatal Depression Scale (EPDS)

## T0 (baseline) T1 ( 3 month) T2 ( 6 month) T3 (9 month) T4(12 month)

- The Hamilton Depression Rating Scale (HAM-D)
- The Hamilton Anxiety Rating Scale (HAM-A)
- The Global Assessment of Functioning (GAF)
- The Clinical Global Impression (CGI)
- The Manchester Short Assessment of Quality of Life (MANSA)
- The Family Assessment Device (FAD)
- The Family Coping Questionnaire (FCQ)
- The Pattern of Care Schedule (PCS)

Figure 1. Assessment tools adopted in the study's protocol.

## Results

Patients receiving the experimental intervention are expected to report a reduction of the severity of depressive symptoms in comparison to those receiving BTO, as well as an improvement in the level of family functioning.

## Conclusions

- PD represents a serious threat for mental health, also considering the detrimental consequences for children.
- It is an ethical imperative to identify new strategies for adequately treat PD and reduce the long-term negative impact on the mothers as well as their babies and family members.
- We hope that the experimental approach will help to improve the clinical, psychosocial and family management of PD.

## PSYCHOEDUCATIONAL FAMILY INTERVENTION

- Uni- familiar psychoeducational intervention, scheduled every 7- 10 days, consisting of 6 modules:
- Individual and family assessment
- Information on the clinical and epidemiological characteristics of the disorder
- Early warnings signs
- Management of suicidal behaviors
- Communication skills
- Problem solving skills

## BEST TREATMENT OPTION (BTO) ACCORDING TO NICE GUIDELINES

- Persistent subthreshold depressive symptoms/mild to moderate: self help and psychological counseling
- History of severe depression who initially presents with mild depressions: pharmacological treatment
- Moderate or severe depression: high intensity psychological intervention or pharmacological treatment or an integration of both interventions

Figure 3. Characteristics of the interventions.