Universitat de Girona
Facultat de Medicina

Comparison between Mum-Baby Interaction Therapy and Interpersonal Therapy on Women with Postpartum Depression

A multicentre, randomized, open and controlled clinical trial

END OF TERM PROJECT

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Vull agrair a la meva tutora clínica Isabel Mitjà la seva dedicació i bona disposició a ajudar-me i aconsellar-me,

Així com a la resta del servei de Subaguts per acollir-me a l'estància de pràctiques, sobretot a la Dra. Cristina Gisbert per transmetre'm la passió per la psiquiatria.

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Ad líbitum.

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ABSTRACT

INTRODUCTION: Postpartum Depression (PPD) is a mental disorder defined as a set of feeling as sadness, guilt, inhibition, handicapped and loss of vital impulse that can appear during pregnancy or puerperia. It affects approximately 10-22% women, but it is an underdiagnosed and undertreated entity. PPD has negative consequences on women and on their children, as they have more risk of behavioural and emotional problems. During pregnancy and puerperia, women are frequently reluctant to take any drugs for depression. Psychotherapies for PPD have shown efficacy in reducing depressive symptoms, above all, the Interpersonal Therapy (IPT). However, it has the limitation that does not improve the link between women and their children, which is an important factor for the healthy development of children. The Mum-Baby Interaction Therapy (MBIT) has its central component on the mother and child relationship, but it does not have enough evidence of efficacy.

HYPOTESIS: Women with PPD who completed the MBIT resulted in a non-inferiority outcome in the primary variable of Edinburgh Postnatal Depression Scale (EPDS) and in a better improvement of the mother-infant link evaluated with the Postpartum Bonding Questionnaire (PBQ), when compared to those who completed the IPT.

OBJECTIVES: The main aim of this study is to assess the non-inferiority efficacy of the MBIT on women with PPD, in comparison with the IPT, measured with the principal variables of EPDS and PBQ. Secondary objectives are to assess if the following covariables are confounding factors: age, TPAL, unintended pregnancy, single mother, low socioeconomic status, antecedent of gender violence victim, antecedent of a depressive episode, antecedent of an eating disorder, substance abuse, body shape concern, sleeping disturbances and pharmacological treatment for PPD.

METHODS: We will perform an open, controlled, randomized and multicentred clinical trial with two intervention groups: MBIT and IPT. Both interventions will be conducted by therapists specialized in each psychotherapy. They will last between 3 and 4 months.

Key words: *postpartum depression, antenatal depression, screening, psychotherapy, interpersonal therapy, mum-baby interaction therapy.*

ABBREVIATIONS

PPD: Postpartum Depression

EPDS: Edinburgh Postnatal Depression Scale

BSQ: Body Shape Questionnaire

PSQI: Pittsburgh Sleep Quality Index

PBQ: Postpartum Bonding Questionnaire

SSRI: Selective Serotonin Reuptake Inhibitors

CBT: Cognitive-Behavioural Therapy

IPT: Interpersonal Therapy

MBIT: Mum-Baby Interaction Therapy

CSM: Centre de Salut Mental

CAP: Centre d'Atenció Primària

INTRODUCTION

MAJOR DEPRESSION DISORDER

The concept of depression is used in three spheres: symptom, syndrome and illness. First, as a symptom, it can accompany other psychic disorders. Second, as a syndrome, it groups a set of processes characterized by sadness, inhibition, guilt, handicapped and loss of vital impulse. Third, as an illness it is defined as a biological disorder in which an aetiology, symptoms, curse, prognostic and specific treatment can be delimited. The central axis of depression is a vital and deep sadness that surrounds the person and it can affect all intra and interpersonal relations. The symptoms can be englobed in five areas: affectivity, thought-cognition, conduct, biological rhythms and somatic disorders (1). In depressive episodes, either mild, moderate or severe, the ability to enjoy, to be interested and to concentrate is reduced, and it is frequent to feel tired even when doing small efforts. Sleeping and appetite are usually altered, and self-esteem and self-confidence are almost always reduced leading to ideas of guiltiness and uselessness. All these symptoms barely vary, and the mood does not respond to external circumstances. Sometimes depressive episodes are accompanied by somatic symptoms (2). According to CIE-10 criteria, the specification of somatic syndrome can be stablished when four or more of the following symptoms are present:

1. Loss of interest or ability to enjoy important activities that used to be pleasant.
2. Absence of emotional reactions to events or activities that used to produce emotional reactions.
3. Waking up on the morning two or more hours earlier than usually.
4. Worsening of depressive mood in the morning.
5. Objective presence (observed by others) of psychomotor slowdown or agitation.
6. Loss of appetite.
7. Loss of weight (5% or greater in the last month).
8. Remarkable decrease in libido.

Women are twice as likely to have a depression episode on their lives in comparison to men. This difference in prevalence between women and men is greater during the reproductive years (3,4), that leads to think of the role that sex hormones may play.

During pregnancy and postpartum, steroid hormones fluctuate dramatically. Progesterone levels are twenty times higher and oestradiol levels are two-hundred times higher throughout pregnancy, both hormones drop at postpartum. Great reductions of oestradiol levels are associated to an elevation of the serotonin transporter, what means a reduction of serotonin in neocortex of women, and that has long been implicated in the aetiology of depression. Moreover, levels of androgens and oestrogens are increased in women with depressive mood four weeks after the partum. Cortisol also plays an important role on depression, as the hypothalamus-pituitary-adrenal axis works abnormally leading on a hypersecretion and abnormal diurnal secretion of cortisol. Another important hormone related to the ethology of postpartum depression is oxytocin. It has been found that women with high risk for postpartum depression had lower levels of oxytocin during the third trimester (5).

PERINATAL DEPRESSION

The perinatal distress is defined as the psychological disorders of depression and anxiety (6). Perinatal depression includes both postpartum depression (occurring after birth) and antenatal depression (occurring during pregnancy). There is some controversy over the postpartum time when depressive symptoms are considered perinatal, and not a depressive syndrome unrelated to maternity. DSM-5 does not consider that depressive symptoms can develop beyond 4 weeks postpartum, neither distinguishes between antenatal and postpartum depression (5,7). CIE-10 considers that postnatal depressive symptoms can develop until the sixth week after the partum (8). But 4 or 6 weeks postpartum for perinatal depression is too limited. Some studies consider that depression during the first year should be considered postpartum depression, as it is observed that the greatest incidence occurs during the second and third month postpartum (5,9).

Postpartum depression (PPD) affects approximately 10-22% of women in Spain (10). During the year 2017, there were 6993 new-borns in the province of Girona. This means that between 699,3 and 1538,5 women have had PPD (11). But only the 11% express their depressive complaints, and if they are questioned, they normally feel stigmatized and minimise their symptoms, due to the social pressure about the joy of being pregnant

(12,13).

For the screening of PPD, the most used tool is the Edinburgh Postnatal Depression Scale (EPDS) (14). The EPDS is a 10 item self-report test that evaluates depressive symptoms in a 4-point Likert scale ranging from 0 to 3. Higher punctuations mean higher intensity of symptomatology. This scale was initially used only on PPD, but later it was also validated for its antenatal use. The sensibility is 86%, and the specificity is 76%. A punctuation of 12 or greater is considered as a high risk of perinatal depression (6,12), although a cut-off score of 10 or a positive response to suicidal ideation is also criteria for further evaluation (15). For the diagnosis a full mental health assessment by psychiatrist is required, as a positive result on EPDS means high risk for PPD, but it does not confirm the diagnosis (4).

Prenatal care offers the opportunity to screen, asses and treat PPD, due to the frequent and regular clinical appointments. Some studies recommend using the EPDS to screen depression at least once during the perinatal period, but some others also recommend screening it at both times, antepartum and postpartum (16). In fact, there is evidence of the effectiveness of the implementation of screening for PPD, due to the positive effects on maternal mental health and the benefits of optimizing the trajectory after screening. (17,18). Besides screening, it is also necessary an intervention directed to a further mental health evaluation for those women who tested positive with the EPDS (16). It has been demonstrated that screening and treating PPD is cost-effective, when it is compared to no screening (19).

CYCLE OF DEPRESSION DURING PREGNANCY

There is a cycle during pregnancy between depression and anxiety. Early symptoms of depression lead to higher anxiety on late pregnancy, which increases the risk of PPD (6). In fact, depressive symptoms in early pregnant women is the greatest risk factor for PPD, however 40% of women have their first depression episode during postpartum (5).

On the evaluation of distress symptomatology during the pregnancy period, it has been seen that there are two peaks of symptoms. The first one around the 16th week of pregnancy, due to the concern of miscarriage, morning symptoms, and the overall

adjusting physic, hormonal and emotional changes. Then there is a decrease during the middle pregnancy and increases again between the 32 and 36 weeks. This second time can be explained by physical discomfort and imminent upcoming labour and birth process (6).

RISK FACTORS FOR POSTPARTUM DEPRESSION

Some of the PPD risk factors are the following: perceived body dissatisfaction, past eating disorders, unintended pregnancy (12,20,21) and previous depression or other psychiatric illness (5,22,23). Women concerned with their body shape had a 3 time greater risk of suffering PPD, and this risk was 5 times higher in women with non-intended pregnancy compared to the intended ones (12). The perceived body dissatisfaction can be determined with the Body Shape Questionnaire (BSQ), that is a 34-item scale, which evaluates body shape concerns. It is scored on 6-point Likert, scores greater than 80 indicate a body image concern (12).

Moreover, unemployment, low income and non-college education are 11 times more likely than women without low socioeconomic status factors to experience depressive symptoms at three moths postpartum (15,22,24,25).

Other described factor risks are marital conflict, lack of spousal support, having no partner and having a reduced social support (20,22,26). A less described but more important factor risk is the domestic violence (23).

Sleep disturbances are also related to PPD. This sleep disturbances are insomnia, poor sleep quality, decreased sleep efficiency, increased wakefulness and greater number of awakenings (27). These sleeping symptoms can be measured with the Pittsburgh Sleep Quality Index (PSQI). It is an 18-item self-report scale that evaluates subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleeping medication and daytime dysfunction. It is scored on 4-point Likert scale ranging from 0 to 3. Global scores from 5 and more indicate poor sleep quality (6).

It is not clear whether the multiparity or the primiparity is a risk factor, some studies find more primiparous depressed mothers, and some other find a relation between multiparity and PPD. Both hypotheses are well explained. On the one hand, primiparity

can be a risk factor due to the insecurity and fear of not doing well the in mothering role (21). On the other hand, multiparity supposes an increased workload and responsibility for the mother (12,20).

CONSEQUENCES OF UNTREATED DEPRESSION

PPD causes women great suffering and has negative consequences for their social relationships (28), the infant and the family system (9). Social beliefs about maternity consider this period as a joyful experience, so women with depression feel an incongruence on their ability to feel gratification in the mothering role, to connect with their infant and to carry out the overwhelming tasks of baby-caring (29). That conduces them to be less responsive to their infants and to experience more parenting stress (30). Moreover, these women have more risk for smoking and alcohol or illicit substance abuse. Suicide in women during puerperium is lower than in general population, nevertheless it is an important cause of maternal mortality (3,9).

The depressive symptoms does not only affect to the mother, it has also consequences for the development of their infants (13,28,29). In fact, it is a good predictor of behavioural and emotional problems, impaired cognitive development and social skills deficit in their children (3,15,28,30). Clinically elevated depression or anxiety in both periods, ante and postnatal, increases in 2 to 3 times the risk of behavioural child problems. There are more risk factors, such as lower birth weight, male sex of the child, being a younger mother, having a lower educational attainment and smoking habits. But even controlling these variables, the risk of behavioural problems is higher in children whose mothers had PPD. The main reason for this is the deficient parent-child relationship and postnatal environment. That is why interventions on PPD are important, not only for the mother's symptoms, but also for the child's mental health (5,29,31). For this reason, treatment for PPD should target the mothers' depressive symptoms, and also, the mother-infant relationship (30). The link between women and their child is evaluated with the Postpartum Bonding Questionnaire (PBQ), which is a 25-item self-report scale to be rated each item in six options from "*Siempre*" (always) to "*Nunca*" (never). It consists of the following four scales: 1) general factors of altered link (12 items), 2) rejection and pathological hate (7 items), 3) anxiety focused on baby-care

(4 items) and 4) abuse risk (2 items). Positive statements as "*Me siento cercana*" (I feel close) are scored from 0 ("*Siempre*") to 5 ("*Nunca*"), and negative statements as "*Me siento distante*" (I feel distant) are scored from 5 ("*Siempre*") to 0 ("*Nunca*"). The cut-off score for scale 1 is 12, for scale 2 it is 17, for scale 3 it is 10 and for scale 4 it is 4 (32–34).

PHARMACOLOGICAL TREATMENT

Psychotropic drugs taken during pregnancy can cross the placenta, reaching the foetal central nervous system. But the effects on the foetus are not only on their brain, other tissues and organs can also be modified, causing different congenital anomalies (35). In fact, selective serotonin reuptake inhibitors (SSRI) taken during pregnancy are associated to disrupted motor and language development in the offspring, and it is also associated to an increased risk for attention deficit hyperactivity disorder, congenital heart defects and pulmonary hypertension (5).

Although SSRI are effective on major depression syndrome, psychopharmacologic treatment is cautiously used, not only during pregnancy, but also in the postpartum period, due to the secretion in breast milk (29). Most women are reluctant to take medication, because of the concern for infant exposure by the breastfeeding (26,36,37). Nevertheless there is evidence that antidepressants are relatively safe for infants (28). Another added problem for pharmacological treatment is that it takes from 4 to 8 weeks to be effective (38).

PSYCHOTHERAPY DURING PREGNANCY AND PUERPERIA

Psychological therapies have been more studied in PPD than in antenatal depression and have shown moderate efficacy for the first one. On the other hand, there is little evidence for treatment in antenatal depression, in which the results are not conclusive or show low efficacy (39). Cognitive-Behavioural Therapy (CBT) is the most used intervention in PPD, though Interpersonal Therapy (IPT) has shown to be more effective (15,37). Other studies prove that IPT, CBT and pharmacological therapy are equally effective in reducing depressive symptoms (28,29,36).

1. COGNITIVE-BEHAVIOURAL THERAPY (CBT)

In this kind of therapy there are so many different techniques, all based on learning theories focused on the interaction between emotion, thoughts and behaviour, with the objective of changing the last two. The paper of the patient is active, and the therapist is directive, through coping strategies (39,40).

There are three generations of cognitive-behavioural therapies. From the first therapies in the fifties, there has been an evolution until the most recent ones from the nineties. The first generation of therapies are based on the functional behaviour analysis, which aim specific behaviour objectives. The second generation has the cognitive process as the central component, changing emotions and behaviour. The third-generation therapies are based on a behaviourism strategy, which focus on the confrontation of behavioural and experiential avoidance, emphasizing the context and the functionality (39).

The modalities designed for PPD are second-generation therapies organized in group format, but they can be also applied individually at home visits (40). Some of the objectives of this therapy are to increase pleasurable activities, to learn relaxation techniques, to restructure unrealistic expectations, to improve non-adaptive behaviours and to replace unreasonable thoughts and beliefs (38,39).

Other strategies can be added to this therapy, like including the partner, explaining to them what PPD is and its consequences, symptoms and treatment, and offering strategies in order to improve couple relationship. Mum-Baby Interaction Therapy (MBIT) and Problem Resolution Therapy can also be included, for these women who experience important daily difficulties (39,41). Another modality of CBT for women who are depressed during the puerperia and who also have sleeping disturbances has shown good improvements in sleep quality (42).

Third-generation therapies have also been designed for PPD. There is the behavioural activation therapy in an online format, which uses the TRAP layout (Trigger, Response, Avoidance Patterns) so the avoidance behavioural pattern can be identified and analyse, TRAC layout (Trigger, Response, Alternative Coping) and ACTION (evaluate, decide to continue avoiding or acting, try, integrate new activities, observe de results, never leave)

so they could stablish new routines (39). When comparing behavioural activation to second-generation CBT, the first one is as effective as, but less costly, due to less training needed by mental health workers (15).

Another kind of CBT is the metacognitive, which focuses on the anxious concern and rumination, according to the great comorbidity that PPD and anxiety have (6,39). This therapy uses the attentional training technique in order to exercise the attentional focus and change the negative beliefs. The Mindfulness Therapy is also used, in which the mother observes her thoughts neither changing nor analysing them. There is a programme called MBSR (Mindfulness-Based Stress Reduction) designed as a complement for the treatment of disorders related to stress. It has demonstrated to reduce the psychological discomfort. An adaptation for pregnancy and postpartum exists, with the aim of helping the participants to practice the plenty attention and develop greater self-confidence and sense of wellbeing during this vital transition. This therapy has been used in prevention during pregnancy and as treatment for pregnant women with generalised anxiety disorder (39). An antenatal CBT intervention has been also studied for prevention of PPD, and it has shown to be effective on reducing its incidence (43).

Although there are some studies, that compared CBT with pharmacological treatment, and showed that it was effective, the best evidence for psychotherapy as an effective treatment for PPD is for IPT (36).

2. INTERPERSONAL THERAPY (IPT)

The fundament of IPT is the reciprocal relationship between interpersonal problems and depressive symptoms. Its goals are the resolution of these problems and improving the social network of support (37). This kind of therapeutic intervention is pragmatic, specific, problem-focused, short-term and highly effective (36). What is specific from interpersonal therapy is the kind of strategy that has been used. It consists in three phases with concrete objectives and proceedings. In the first phase, the diagnosis is stablished, and we also make a relation with the present interpersonal situation and with one of these areas: interpersonal conflicts, transition roles, complicated mourning or social isolation. On the second phase, an approach is made to the problem area

chosen, with the aim of replacing relational styles with more adaptive ones. On the final phase, the recognition and consolidation of the therapeutic gains is promoted (28,36,39).

The interpersonal therapy has some adaptations for the treatment of PPD. There are maternity related aspects evaluation on the initial phase and a special emphasis is also made to the relations between the mother and her baby, couple, family and friends (44). In the intermediate phase, some specific themes are included, such as the lack of perceived support, criticism by relatives related to the baby care, difficulties in combining mother's role with other roles (social or professional) or changing of priorities after maternity (28,36,39). This adaptation is applied in a twelve-session weekly format, and there is a new application based on telephonic intervention, which is a more flexible intervention and has an easier access. There are also brief versions, with a duration of eight sessions (39). Another adaptation includes the woman's partner, but there is no difference found in efficacy when the partners were included in the interventions (37).

Interpersonal psychotherapy has been used as a preventive therapy in pregnant women with one risk factor for PPD. A four-session interpersonal psychotherapy group has shown success in preventing PPD on women with economic problems during the following 3 months to the partum (24,37).

There is also another modality of interpersonal therapy directed to depressed women during pregnancy. In this case, there is a new problem area added: complicated pregnancy (unwanted, medical or obstetric problems, multiple pregnancy, congenital anomalies) (39).

The group format of the IPT has some advantages, like the decreasing social isolation, normalizing the own difficulties, obtaining social reinforcement and reducing stigma. For this reason, the group format of IPT is more effective than the individual setting (37). These group interventions are aimed at pregnant teenagers with depressive symptoms, and pregnant women with risk of postpartum depression (39,44).

IPT have shown significant improvement in depressive symptoms (30,37), in psychosocial functioning and in their relationships with their partners, but there is not a

significant improvement in the relationship between women and their children (28,29). That may be explained by some hypothesis. One explanation could be that the target of the IPT does not include the mother-infant relationship. Another possible explanation is that the relationship between mothers and their children was formed in a depressive context (30). Nevertheless, there is level I evidence for IPT as a treatment for PPD. The reasons are that it is focused on the important interpersonal changes and challenges that women experience during the postpartum period, and it emphasizes interpersonal disputes and role transitions (36,37).

3. PSYCHODYNAMIC THERAPY (PDT)

This therapy has its origin in Freud and psychoanalysis, whose emphasis is on unconscious conflicts mostly originated during childhood. The difference between classic psychoanalysis and psychodynamic therapy is that the last one focuses on the actual problem of the patient. It consists on a brief intervention that requires that the patient has a good interpersonal relation, communication ability and high motivation (39). Some of the common themes are: how experience from the past influence on actual functionality, identification of recurrent patterns, emotional expressions, insight facilitation, among others (41). On the application to PPD, the focus of the therapy are the maternal representations of her baby and the exploration of the aspects of the early attachment of the mother history (39).

Some studies have compared CBP with PDT, and they have shown an equal effectiveness, but none of them resulted in change either in the mother-child interaction quality or in infant cognitive development (29).

4. SOCIAL SUPPORT THERAPY (SST)

This therapy has the theorical foundation on Carl Rogers, who defended that everyone has its own means for healing, resolving their problems and growing, if they are in the correct conditions. The therapist should be empathic and show unconditional positive acceptance. As a treatment for postpartum depression a programme of domiciliary visits was made, with the objective of helping women through a better understanding of their circumstances from an empathic focus, not judging, higher tendency to listen than to

lead and offering support (39).

There is a study that resulted in not decreasing maternal depressive symptoms, but they showed increased attentiveness to their infant (29).

5. MUM-BABY INTERACTION THERAPY (MBIT)

There are two type of therapeutic orientation, psychodynamic mum-baby therapy and interactional mum-baby therapy, both focused on the first year of live (39).

- The Psychodynamic Mum-Baby Therapy is focused on maternal representations addressed in a declarative mode. The aim is to identify and to resolve negative experience that happened during the childhood of the depressed mother, which may affect the ability to care effectively about her child. In this therapy, which is carried out at home, there is a part of observation while the mother lies down with her baby and interacts with him or her, while the therapist and the women dialogue. This favours a reflexive posture which makes it easier respond in a sensible way. Later they can also discuss about the interactions and feelings related to this experience (39).
- The Interactional Mum-Baby Therapy aims to intervene on behaviour, reinforcing healthy interaction patterns and competences, and modifying the dysfunctional ones. This therapy also helps the parents to recognise and deploy their capabilities, to enjoy more the relation with their baby, and to understand his or her needs and behaviours (45). It is carried out by video-intervention: a short video of the parents and the baby is recorded, and then the therapist gives feedback to the parents (39). Other modalities of this therapy include massage, relaxing techniques and other themes as talks focused on the baby. Above all, massage has been proved to decrease depressive symptoms and increase positive affection to infants. Moreover, children who have received massages from their mothers showed improved emotional regulation, increased social relatedness and greater face to face contact (29).

There is literature that suggests that both individual and group psychosocial interventions are effective in reducing depressive symptoms. But there are no trials

which target the mother-infant relationship, infant's social-emotional functioning, and family functioning (29). In fact, there is not enough evidence on the efficacy of the MBIP (39).

JUSTIFICATION

According to the high prevalence of the Postpartum Depression (PPD), and the fact that is an under-diagnosed and undertreated entity, a protocol of screening and early diagnosis seems to be necessary, as well as an effective intervention for women with PPD. Since screening protocols have already shown evidence of efficacy, and in our area, there is not a protocol stablished, the implementation of screening for PPD should be seriously considered.

Untreated PPD increases the risk of behavioural and emotional problems, impaired cognitive development and deficit of social skills on children. All these consequences are explained by the lack of an efficient and healthy relationship between parents and children.

Pregnancy and puerperia are two periods in which women prefer not to take medicines, because of the risk of transmitting those drugs to their children via placenta or by the breastfeeding. For this reason, women with PPD have bad adherence to the pharmacological treatment and prefer the psychotherapy's alternative.

There are so many types of psychotherapy explained above (cognitive-behavioural therapy, interpersonal therapy, psychodynamic therapy, social support therapy and mum-baby interaction therapy). The Interpersonal Therapy is the one with more evidence of efficacy, but it has the limitation of not improving the relationship between mothers and their children. For this reason, the Interaction Mum-Baby Therapy could be effective in strengthening the mother-infant link.

HYPOTHESIS

Women with Postpartum Depression (PPD) who completed the Mum-Baby Interaction Therapy (MBIT), in comparison with those who completed the Interpersonal Therapy, results in a non-inferiority outcome in primary variable of Edinburgh Postnatal Depression Scale (EPDS) and in a better improvement of the mother-infant link evaluated with the Postpartum Bonding Questionnaire (PBQ).

OBJECTIVES

MAIN OBJECTIVE

The main objective of this study is to assess the non-inferiority efficacy of the MBIT in primary variable of EPDS, compared to the IPT on women with PPD.

SECONDARY OBJECTIVES

- To find the real prevalence of PPD in the province of Girona.
- To asses if MBIT on women with PPD improves the variable PBQ in comparison to IPT.
- To determine if women's age is a confounding factor for PPD.
- To determine if multiparity or primiparity are confounding factors for PPD.
- To determine if being a single mother is a confounding factor for PPD.
- To determine if unintended pregnancy is a confounding factor for PPD.
- To determine if a low socioeconomic status is a confounding factor for PPD.
- To determine if sleeping problems are a confounding factor for PPD.
- To determine if the antecedent of having suffered from gender violence is a confounding factor for PPD.
- To determine if the antecedent of a depressive episode is a confounding factor for PPD.
- To determine if the antecedent of any eating disorder is a confounding factor for PPD.

- To determine if having body shape concern is a confounding factor for PPD.
- To determine if the antecedent of drug abuse is a confounding factor for PPD.
- To determine if the pharmacological treatment for PPD taken during the intervention is a confounding factor.

METHODS

TRIAL DESIGN

The study protocol describes a multicentred, controlled, randomized control trial, assessing the non-inferiority efficacy of the MBIT compared to the IPT in women with PPD. Due to the nature of the intervention, this study is open-label.

STUDY POPULATION

The population of this trial will be women who have had a positive result on EPDS during pregnancy or postpartum. The timing to administer the EPDS will be four moments, divided into two periods: pregnancy and puerperia. The first two times the test will be administered are at the 18th and 32nd gestational weeks, and after the partum, the test will be passed two more times, first right before the hospital discharge after partum, and second, on the paediatric revision at the third month postpartum. They will also meet the inclusion and exclusion criteria, that are presented below:

INCLUSION CRITERIA	EXCLUSION CRITERIA
Patients with a positive result on EPDS in any time the test is passed	Being on a decompensation of any mental disease
Aged between 15 and 45 years old	Being deaf and/or mute, or any other problems for communication skills
Informed consent signature	Impossibility for patient's follow-up
	Any obstetrician problem on the women or in the foetus
	Not speaking Catalan or Spanish

SAMPLE SIZE

In a two-sided test contrast with a level of significance (alfa) of 5%, a statistical power of 80%, assuming a loss of 15% and supposing that the effect of this intervention will be moderate, 225 women for each arm are required, this is a total of 450 women.

The computations were carried out with the Prof. Marc Saez' software based on the library 'pwr' of the free statistical environment R (version 3.5.1).

Statistical analysis by intention to treat will be performed. We considered a 15% of dropout rate, this missing data will be also imputed.

DATA COLLECTION

The sample size has been estimated for the primary comparison of the MBIT versus IPT on the change on EPDS punctuation. The primary efficacy variable is the EPDS punctuation change from baseline to four months.

The participant centres will inform about the number of patients with a positive result on EPDS that meet the inclusion criteria for this trial, which will allow an evaluation of the variability of this study.

Consecutive patients who meet the eligibility criteria, and who consent to participate in the study, will be randomly assigned into one of two groups: MBIT or IPT.

- **RANDOMIZATION**

  The assignation will be carried out according to the last number of the ID: women with even numbers will do the MBIP, and women with odd numbers will complete the IPP.

DESIGN AND PROCEDURE

This trial involves the participation of several health centres and hospitals, as well as the participation of different disciplines. Nursing midwifes and paediatricians are involved in the phase in which participants are being recruited. Nursing and midwifes will pass the EPDS on the visit of the second trimester of pregnancy, which will be approximately the 18th gestational week. The EPDS will be administered again on the third trimester of pregnancy visit, about the 32nd gestational week. The third time the EPDS is passed is just before the discharge after the childbirth at the hospital, and the fourth time will be on the paediatricians visit approximately when the child has three months of life. To

accomplish this, the participation of all the hospitals and CAPs with services on midwifery and paediatricians of the province of Girona are needed.

This phase of recruitment is also a screening of PPD, thereby the test is not administered alone, it is accompanied with a semi-structured interview, where the risk factors are evaluated. During the interview, the following items will be asked:

- Age.
- TPAL (multiparity or primiparity).
- Intended or unintended pregnancy.
- If she has a partner, or if she is a single mother.
- If she has any low socioeconomic status factor (unemployment, low income or non-college education).
- If she has ever suffered from gender violence.
- If she has ever had a depressive episode in any moment of her live.
- If she has suffered from any eating disorder (anorexia nervosa, bulimia).
- If she is a frequent user of any drug (alcohol, cocaine, tetrahydrocannabinol).

Moreover, those women will fill up two more questionnaires, in order to determine how much the sleeping disturbances and the perceived body shape intervene on PPD. These questionnaires are Body Shape Questionnaire and Pittsburgh Sleep Quality Index, and they will be administered just once, in the visit with the psychiatrist, before the psychotherapy starts.

For the evaluation of the EPDS, the answers of the first two questions are punctuated in this order: 0, 1, 2 and 3; whereas for questions from 3 to 10, the order of the punctuations is inversed (3, 2, 1 and 0). All the punctuations are added in order to give the total punctuation. All women with a positive result on EPDS at any time, considered as a punctuation of 12 or greater, will go to a visit with the psychiatrist, who will evaluate the woman and confirm or discard the diagnosis of PPD (or antenatal if it is before the partum). Additionally, if in question number 10 any response other than *"En ningún momento" (at no time)* is marked, it is necessary that the psychiatrist conducts further evaluation, even if the total punctuation is less than 12, as it shows a risk of autolytic attempt for the woman.

The aim of the visit with the psychiatrist is to confirm the diagnosis, in order to calculate the real prevalence of PPD in Girona. However, all women with punctuations of 12 and over will entry on this study, since this punctuation means high risk of PPD, regardless of the psychiatrist confirming the diagnosis or not. The psychiatrist will also evaluate the need of a pharmacological treatment as a complement to the psychotherapy, and a follow-up plan will be determined apart from the one from the psychotherapist. The visit with the psychiatrist will take place in the Mental Health Centre (CSM, *Centre de Salut Mental*) of the county that each participant belongs to. The Mental Health Network of Girona is divided in seven counties: Alt Empordà, Baix Empordà, Gironès i Pla de l'Estany, Garrotxa, Ripoll, Selva Interior and Selva Marítima (Annex 7). All women who accept the psychotherapy and sign the informed consent, will be assigned to one of the two groups of psychotherapy (Mum-Baby Interaction Therapy, or the control group with Interpersonal Therapy). Women who are assigned to the MBIT will complete a psychiatrist follow-up until they give birth (only the ones who have a positive result on EPDS before partum), as this therapy is focused on the mum and baby relationship. On the other hand, women who are assigned to the IPT will complete a psychiatrist follow-up until a group with a minimum of five women in the same county is created for doing the psychotherapy, as this one is done in a group format.

The Postpartum Bonding Questionnaire will be filled out just before the discharge after the childbirth by all women who scored 12 or greater in EPDS before the partum. Those women who had a positive result on EPDS during the postpartum (just after the childbirth or in the three months revision with the paediatrician), will fill out the PBQ when EPDS results positive. This test will be filled out again when the psychotherapy is finished, approximately four months after it began.

For the psychotherapy it is required that the psychologist has a previous formation on Mum-Baby Interaction Therapy and on Interpersonal Therapy. There will be one psychologist specialized on each therapy for each county, that makes a total of 14 psychologists (7 for MBIT and 7 for IPT). Nurses, midwifes, paediatricians and psychiatrists will also have a short formation on PPD and its screening.

The Interpersonal Therapy will consist of eight group sessions plus two individual sessions, one at the beginning and the other at the end of the therapy, and another optional session for couples. Each group will be formed with a minimum of five women with PPD and one psychotherapist. The role of the psychotherapist will be active and supportive. Having therapy in a group format helps on decreasing the social isolation, normalizing their situation and obtaining social support. The therapy groups will take place weekly, each one will last 45 minutes. The complete therapy will last 15 weeks, that is near four months. The following topics will be addressed in each session:

- **Individual session (pretherapy).** In this first session, the objectives are to explain the therapy procedure, the expectations of attendance and active participation, to start a description of the current problems and to define the objectives of the therapy.
- **Group sessions (1 and 2).** In these two sessions, the psychotherapist will coach about depression, interpersonal therapy and the structure of the group. Participants are supposed to talk about role transitions: exploring losses and changes and developing a balanced perspective about the new and the old role.
- **Optional session for couples.** The topic of this session is the psychoeducation about PPD and communication strategies.
- **Group sessions (3 to 7).** These sessions will focus on interpersonal goals. Techniques such as role games, communication analysis or emotional facilitation will be applied. These strategies will be addressed to the common problem areas, which are role transition, interpersonal disputes, duel and interpersonal deficits.
- **Final group session (8).** The aims of this session are to review and consolidate the achieved progress, to give feedback to all the participants, to anticipate future difficulties and to express how they feel about the group ending.
- **Individual session (posttherapy).** This session will take place six weeks after the final group session. The participant and the psychotherapist will check and consolidate the progress and evaluate the maintenance treatment. A relapse prevention plan will also be developed.

The Mum-Baby Interaction Therapy will consist of ten individual sessions conducted weekly at home, each of which will last 45 minutes. The complete therapy will last 10

weeks, which is nearly three months, in accordance with the family. The ten sessions will be divided into two groups: the first five will be orientated in the psychodynamic version, and the last five in an interactional orientation.

- **Psychodynamic session (1).** In this first session, the aims are to explain the therapy procedure, to talk about what PPD is and to fix the objectives they want to achieve with the therapy.
- **Psychodynamic sessions (2-4).** In these sessions, the therapist will ask the mother to lie down comfortably on the couch or on a rug with her baby onto her, so they can interact if it is necessary. The aim is to identify and resolve the negative experiences that happened during the woman's childhood, and how these experiences affect her baby-care.
- **Psychodynamic session (5).** In this session, the woman and the psychotherapist will discuss about the observations related to the mum-baby interaction that the therapist has observed during the other sessions. The mother will also have time for expressing how she felt during the experience.
- **Interactional session (6).** From now on, the therapy will be carried out with both parents if it is possible. In this first session, the therapist and the parents will analyse the dysfunctional interactions and how they could modify them.
- **Interactional session (7-9).** In these sessions, the healthy interactional patterns will be strengthened. The therapist will help the parents to recognize their abilities related to baby-care, so that they can feel competent and enjoy the relationship with their infant. The baby behaviour will also be observed by the parents and the therapist, with the aim of understanding the baby signals, changing the perception of the parents and promoting the shared positive affect. A part of a game-interaction of the parents with their child will be recorded for the following session.
- **Interactional session (10).** In this session, a video-feedback for the parents will be given, so parents can review and consolidate the achieved progress. A plan for anticipating future difficulties or preventing a possible relapse will be determined.

After both psychotherapies finish, the EPDS will be administrated again to all the women, approximately four months after the psychotherapy started (it is compulsory that the psychotherapy has finished for doing the EPDS again). In the same visit, the PBQ will be filled out again. This way, there will be data on both variables (EDPS and PBQ) pretherapy and posttherapy.

VARIABLES

Independent variables

In this study the independent variables are the Mum-Baby Interaction Therapy (MBIT) and the Interpersonal Therapy (IPT).

The **MBIT** is a type of psychotherapy that aims the improvement of the relationship between women and their infants, while improving the depressive symptoms. It will be applied in ten individual weekly sessions, that will last a total of three months.

The **IPT** is a type of psychotherapy, whose objective is the resolution of interpersonal problems of the mother, that will help to improve the symptoms of the PPD. It will be applied in ten (or eleven, if the couple session is carried out) group weekly sessions, that will last a total of four months (because the last one will be carried out one month after the penultimate session).

Dependent variables

The principal two dependent variables are the Edinburgh Postnatal Depression Scale (EPDS) and the Postpartum Bonding Questionnaire (PBQ).

The **EPDS** (Annex 1) is a 10-item self-report test that evaluates the intensity of depressive symptoms on PPD. It is punctuated in a 4-point Likert scale. For the first two questions, the order of the punctuation is from 0 to 3, and for questions 3 to 10, the order is inversed, that is from 3 to 0. The total punctuation is the sum of all the items. Scores of 12 and over mean high risk for PPD and requires a further evaluation from the psychiatrist. On the question number 10, any response that does not score 0 means risk of autolytic attempts. For this reason, it also requires further evaluation. It is a

quantitative continue variable, whose options are from 0 to 40.

The **PBQ** (Annex 2) is a 25-item self-report test that determines if the relationship between women and their infant is healthy or pathologic. It is punctuated in a 6-point Likert scale. There are two types of statements: positive and negative ones. The positive ones, as "*Me siento cercana*", are punctuated from 0 ("*Siempre*") to 5 ("*Nunca*"); and the negative statements, as "*Me siento distante*", are scored from 5 ("*Siempre*") to 0 ("*Nunca*"). The 25 items are orderly divided in 4 subscales that evaluate different topics: general factors of altered link (12 items), rejection and pathological hate (7 items), anxiety focused on baby-care (4 items) and abuse risk (2 items). The cuts-off for each topic are 12 for the first one, 17 for the second one, 10 for the third one, and 4 for the last one. It is a quantitative continue variable, whose options are from 0 to 150.

Co-variates

The co-variates of this study try to find a casual relation between the following items with the aetiology of PPD, in order to define them as confounding factors or not. All these co-variates will be dated on the semi-structured interview conducted in the screening.

- **Age**. All ages will be collected to analyse if women with PPD are condensed in any range of age. It is a discrete quantitative variable.
- **TPAL**. This data will be collected as multiparity or primiparity, as a dichotomous qualitative variable. The aim is to analyse if each one of them is a confounding factor.
- **Unintended pregnancy** is supposed to be a confounding factor for PPD. It is a dichotomous qualitative variable: intended or unintended pregnancy.
- Being a **single mother** may reflect the lack of social support, that leads to PPD. It is a dichotomous qualitative: single or couple. What is important is if the woman has any support at home or she will raise her baby alone.
- Low income, unemployment and non-college education are factors of **low socioeconomic status**, and they may also be confounding factors for PPD. During the interview the presence of any of the appointed three factors will be collected

as presence of low socioeconomic status. It is a dichotomous qualitative variable: presence or absence of low socioeconomic status.

- **Gender or domestic violence**. It may be a confounding factor for PPD. It is a dichotomous qualitative variable: presence or absence of gender/domestic violence.
- **Antecedent of a depressive episode**. It is supposed to be a confounding factor for PPD. It will be collected as dichotomous qualitative variable: presence or absence of a depressive episode on the past.
- **Substance abuse**. Addiction to any kind of drugs could be a confounding factor for PPD. It is a dichotomous qualitative variable: abuse of any drug (tetrahydrocannabinol, cocaine, alcohol, between others) or absence of drugs-abuse. Smoking will not be considered as a substance abuse.
- **Antecedent of eating disorders**. It is supposed to be a confounding factor for PPD. It is a dichotomous qualitative variable: presence or absence of any eating disorder (anorexia nervosa or bulimia).
- **Body shape concern**. Women with PPD are supposed to be more concerned about their body shape than women without depression. It is measured with the Body Shape Questionnaire (Annex 3). It is a 34-item self-report scale, scored with a 6-point Likert scale. Each item is punctuated from 1 "*Nunca*" (never) to 6 "*Siempre*" (always). The global score is the sum of the 34 questions, it can go from 34 to 204. The interpretation of the results is: no concern with the shape if it is less than 80, mild concern if it is from 80 to 110, moderate concern with shape if it is 111 to 140 and marked concern with shape if it is over 140. But in this study, the body shape concern will be considered as a dichotomous qualitative variable: concerned (over 80) or not concerned (less than 80).
- **Sleeping disturbances**. It may be a confounding factor for PPD. It is measured with the Pittsburgh Sleep Quality Index (Annex 4), that is an 18-item self-report scale with a 4-point Likert ranging from 0 to 3. The last 5 questions are not included in the total score, because they are not self-report, and they must be answered by the bedroom partner, if it is possible. The other 18 self-reported questions are divided into seven components, which evaluate different items of the sleep quality. Most of these questions have four options, ranged from 0 ("*No*

me ha ocurrido en el ultimo mes") to 3 ("*Tres o más veces a la semana*"), meaning no sleep problems and severe sleep disturbances, respectively. For the correct interpretation of this test, it is necessary to follow these instructions:

Components	Questions	Punctuation
Subjective Sleep Quality	Nº 6	It has 4 options scored from 0 to 3.
Sleep Latency	Nº 2	0 – 6 to 15 min. 1 – 16 to 30 min. 2 – 31 to 60 min. 3 – more than 60 min.
	Nº 5a	It has 4 options scored from 0 to 3.
	Sum of both scores (It can be from 0 to 6).	0 – 0 1 – 1 or 2 2 – 3 or 4 3 – 5 or 6
Sleep Duration	Nº 4	0 – more than 7 hours 1 – 6-7 hours 2 – 5-6 hours 3 – less than 5 hours
Usual Sleep Efficiency	Calculate the hours spent in bed with the responses to questions 1 and 3.	
	Calculate the Usual Sleep Efficiency = $\frac{sleeping\ hours}{hours\ spent\ in\ bed}$ x 100	0 – >85% 1 – 75-84% 2 – 65-74% 3 – <64%
Sleeping Disturbances	Questions 5b to 5j. All of them have 4 options scored from 0 to 3. Sum all the punctuations (it can go from 0 to 27).	0 – 0 1 – 1 to 9 2 – 10 to 18 3 – 18 to 27

Hypnotic Drug Use	Nº 7	It has 4 options scored from 0 to 3.
Diurnal dysfunction	Nº 8 and nº 9, both have 4 options scored from 0 to 3. Sum both punctuations (it can go from 0 to 6).	0 – 0 1 – 1 or 2 2 – 3 or 4 3 – 5 or 6
TOTAL PUNCTUATION	Sum all the punctuations of the squares **shaded in blue** (it can go from 0 to 21).	

Total punctuations over 5 indicate poor sleep quality. This is a dichotomous qualitative variable: good sleep quality or poor sleep quality.

- **Pharmacological treatment**. During the intervention, some women could start treatment with SSRI (or another anti-depressive drug). If this happens, the improvement of the symptoms can be influenced by the pharmacological complementary treatment, that is a confounding factor. It is a dichotomous qualitative variable: pharmacological treatment or not.

STATISTICAL ANALYSIS

DESCRIPTIVE ANALYSES

The dependent variables will be summarized in medians and interquartile rank (IQR), stratifying by intervention and control groups.

The co-variables, except age, will be summarized in proportions, stratifying by intervention and control groups.

The co-variable age will be summarized in means and standard deviation, stratifying by intervention and control groups.

BIVARIATE INFERENCE

The medians difference in the dependent variables in intervention group and control group will be contrasted through U de Mann-Whitney.

The proportions and means difference of the co-variables in intervention group and control group will be contrasted through chi squared (and test exacta de Fisher) and t-Student, respectively.

MULTIVARIATE ANALYSIS

To assess the efficacy of the intervention, we will estimate two logistic regressions, one for each dependent variable, introducing as an independent variable the MBIT intervention, adjusting it by the co-variables.

WORKPLAN

The medical professionals included are:

1. Investigators: psychotherapists trained in MBIT and in IPT, and a statistical expert.
2. Collaborators: midwives and nurses of the hospitals where women give birth, paediatricians where children do the ordinary medical check-ups, and psychiatrists and psychotherapists of the respective Mental Health Centres (CSM, *Centre de Salut Mental*).

PHASE 1

The first phase is for coordination. It will run over a period of five months, and it will involve both investigators and collaborators. This first phase is divided into the following three steps:

1. Protocol elaboration: formulation of the study aims and the study variables in order to answer the research hypothesis, which supposes an extensive literature search. In this phase, the methodology of the study will also be stablished.
2. Evaluation by the committees (See: Ethical Considerations) and the obtention of the administrative authorizations.
3. Coordination of all the participating hospitals through organizational meetings. The role of the participating hospitals is to detect the patients who may meet the criteria for participating in this trial. A chronogram with the approval of all the involved parts will also be elaborated.

PHASE 2

The second phase is for the recruitment of patients and collection of data. Investigators and collaborators are both involved, like in the first phase. This phase will run over a period of 12 months. This second phase is also divided into the following three steps:

1. Patient recruitment and group assignment. The personal of the participating hospitals will inform about the possible participants (those with a punctuation over 12 at EPDS), and the investigator will evaluate whether the patients meet the inclusion criteria. Once the participants are well detected, the informed consent form will be asked to be signed by each one of them. In the case of women who are under-age, it will be consulted to their parents or legal tutors. Then, questionnaires will be filled out by the participants (except the EPDS, which is used for the recruitment). After that, the participants will be randomly allocated to one of the two groups (intervention or control group).
2. Intervention.
3. Data collection carried out simultaneously with the intervention.

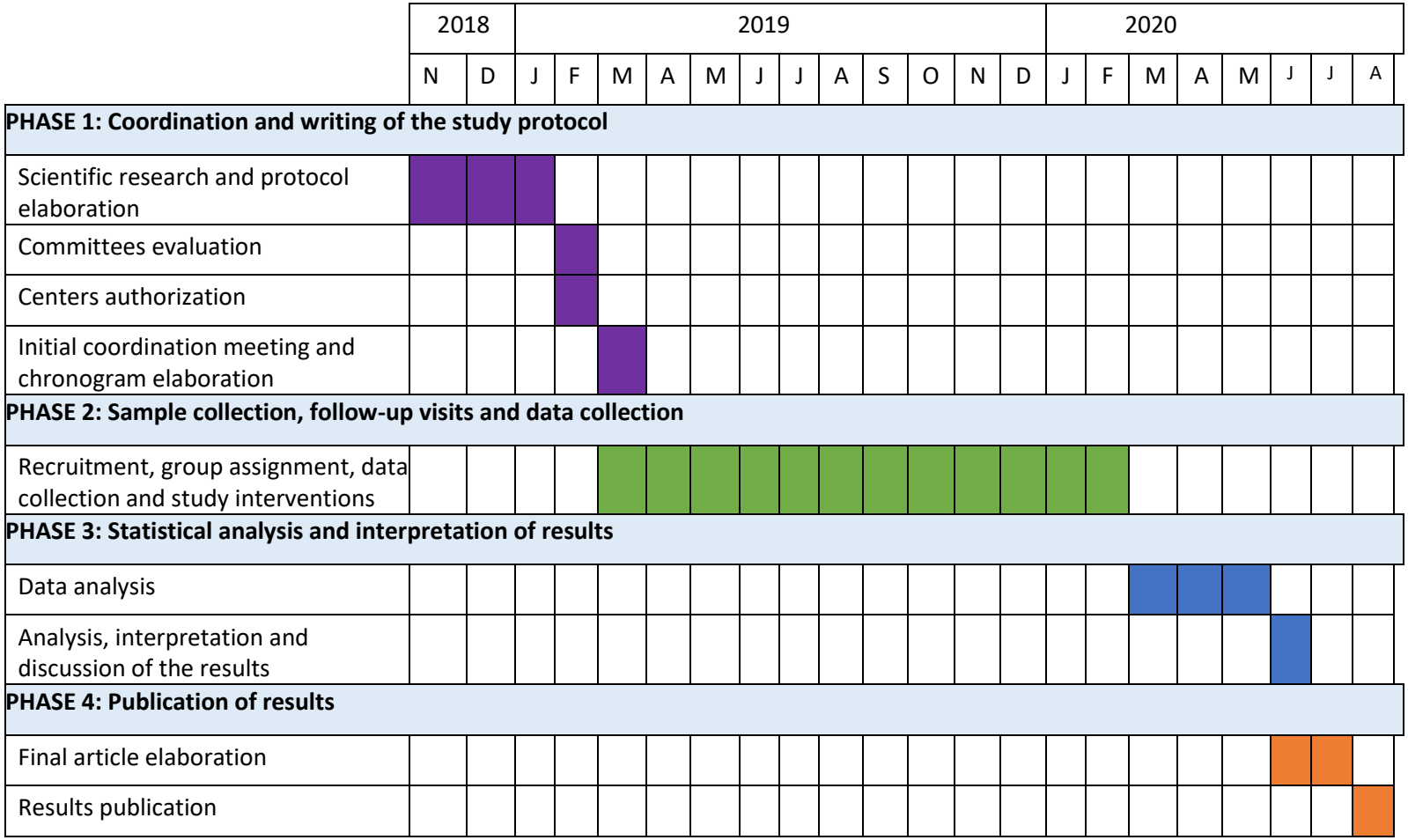
PHASE 3

On the third phase the data processing and statistical analysis will be conducted by the investigators and the statistician, and it will last approximately four months. Once the analysis is done, results will be interpreted, and conclusions will be achieved.

PHASE 4

In this last phase, the investigators will process the study results for publication. It will last approximately three months. The results will be summarized in format of scientific papers and will be sent to medical journals for their publication.

CHRONOGRAM


2018
2019
2020
N D J F M A M J J A S O N D J F M A M J J A
PHASE 1: Coordination and writing of the study protocol
Scientific research and protocol elaboration
Committees evaluation
Centers authorization
Initial coordination meeting and chronogram elaboration
PHASE 2: Sample collection, follow-up visits and data collection
Recruitment, group assignment, data collection and study interventions
PHASE 3: Statistical analysis and interpretation of results
Data analysis
Analysis, interpretation and discussion of the results
PHASE 4: Publication of results
Final article elaboration
Results publication

ETHICAL CONSIDERATIONS

The Clinical Research Ethical Committee (CEIC) at the Parc Hospitalari Martí i Julià de Salt will evaluate the intervention protocol, and they will modify it if they consider it necessary. Once the CEIC has approved the protocol, the approval of the study will be asked to the authorities of all the participating hospitals and health primary centres, before the trials starts.

According to the Law 14/2007 of 3 July 2007 of Investigación Biomédica en España, the CEIC will consider if the intervention is an invasive procedure or not. Nevertheless, this protocol is not expected to be considered as an invasive procedure neither to be associated with high risk. However, if it occurs, we would ask permission to the Comunitat Autònoma de Catalunya to perform the intervention, and we would obtain an insurance for possible damage. In any case, if CEIC determines this protocol as a non-invasive procedure, that last permission and insurance will not be required.

Due to the actual recommendations, this clinical trial will be submitted to ClinicalTrials.gov and will be registered with an International Standard Randomized Controlled Trial Number.

A detailed information sheet (Annex 5) of the clinical trial will be given to all the participants, then they will be asked to sign the informed consent form (Annex 6), so they will be enrolled in this trial. As all participants will be older than 15, all of them will be capacitated to sign the informed consent form. Throughout the entire intervention, the principle of autonomy will be respected.

According to the Spanish Organic Law 15/1999 of 13 December 1999 of Protección de Datos de Carácter Personal, the later Spanish Legislative Royal Decree of 21 December 2007, and according to Reglament (UE) 2016/679 del Parliament Europeu i del Consell of 27 April 2016 of Protecció de Dades (RGPD) all the personal information related to the patients will be kept in confidentiality, and the anonymity of participants will be guaranteed during the entire trial process. The right to consult, modify and delete all personal information from the records will be respected to all the participants. During this trial, we will follow all the ethical principles of the Declaration of Helsinki.

LIMITATIONS

The limitations on this protocol must be taken into account because of the interference that the proposed research could create. The most important ones are explained in this section.

This study is an open-label trial, which means that is not double blind, so both investigators and participants know to which group they belong (intervention or control), due to the difficulty of blinding a non-pharmacological treatment. This limitation magnifies the intervention effect in comparison between both groups, because of the placebo effect in the intervention group.

Some co-variables are considered in this study. However, there may be more variables, which could be confounding factors (ethnicity, immigration, traumas occurred during the women's childhood), and they are not taken into account, because of lack of evidence at bibliography and the fact that infinite variables could be considered. So, in this study, the most relevant ones have been collected and they will be analysed. In any case, it would have been better to study if the co-variables considered in this study are risk factors, instead of confounding factors. But it has not been possible because both groups of participants (intervention and control) are formed by women with postpartum depression (PPD), so it is not possible to compare the co-variables between a group of women with PPD and a group of participants without this disorder.

Another limitation is the fact that the psychotherapy whose efficacy is being evaluated is well described in the bibliography, but there is not any stablished and described content for each session of the Mum-Baby Interaction Therapy. Therefore, the protocol described in this study has been created based on the theoretical bibliography about this type of intervention. In contrast to the other psychotherapy, Interpersonal Therapy has perfectly described protocols for each one of the sessions during the entire intervention. This may conduce to a non-equal therapy, leading to a bias on the analysis of efficacy.

The impact of both psychotherapies can be partly determined by the therapist, leading to bias of the efficacy. Moreover, it is possible to obtain different result on efficacy at

the different counties, considering that in each county there will be a different psychotherapist for each intervention (MBIT and IPT). It is quite difficult to minimize this limitation, as it is a common problem for all the psychotherapies due to all of them being operator-dependent. Anyway, all therapists will be formed at the same psychotherapy course, in order to minimize this limitation as much as possible this limitation.

Another important limitation is the cost of the intervention. As it requires many specialists for each county and each psychotherapy, this study results in a very expensive clinical trial. However, other studies that evaluated the psychotherapy as treatment for PPD have shown that this kind of interventions are cost-effective.

STRENGTHS

This study is a multicentric and randomized clinical trial that makes it possible to generalize the obtained results, in case they are statistically significant. Moreover, the inclusion and exclusion criteria are not very strict, which is why, it is a pragmatic study. That results in a more similar sample to the real population, where the therapy would be hypothetically engaged if approved.

The principal aim of this protocol is to prove if a new psychotherapy for PPD is as effective as the ones that have already proved its efficacy. So, if the results support our hypothesis, there will be another effective option for the treatment of women with PPD.

Besides the principal objective, this trial proposes a screening strategy for PPD, which is a prevalent disorder with great consequences on children. In our context, it seems very necessary, because there is no protocol of screening neither treatment for this entity.

Moreover, this clinical trial helps to decrease the possible stigma that these women suffer, due to the misinformation and misunderstanding about this entity. It will help to all professionals related to pregnancy (midwifes, obstetricians and paediatricians) to know how to detect it and to understand what happens to these women, leading on a normalization of the PPD.

FEASIBILITY

Although no psychotherapy intervention exists as treatment for PPD, there is a lot of experience about psychotherapy in Girona as a complement treatment to many other mental disorders.

Our intention is to carry out this trial in the province of Girona with the collaboration of all the Hospitals and Primary Health Centres (CAP), which have midwifery and paediatric services. They are a powerful tool for screening the PPD, due to the constant attention to pregnant women and new-mothers. The collaboration of all the Mental Health Centres (CSM) will also be required, as both psychotherapies and the follow-up will be carried out there. The CSM will provide a room for carrying out the group format psychotherapy (control group). In the case of the intervention group (MBIT), as it is an individual format psychotherapy, we will not have to ask for a room, as it is carried out at participants' home.

For the formation of the psychotherapist, it will be obligatory to complete a course on both psychotherapies. Seven therapists (one for each county) will complete a course about Interpersonal Therapy, and the other seven will complete a course about Mum-Baby Interaction Therapy. Moreover, all the implicated professionals (midwifes, paediatricians, psychiatrists and psychologists) will complete a short formation about postpartum depression (aetiology, symptoms, consequences, screening, diagnosis, treatment). This formation could be asked for to the Hospital Clínic of Barcelona, where they have more experience about PPD.

The study will be based in Girona, at the Hospital Santa Caterina, where a room with an informatic equipment will be assessed to the hired statistic operator.

BUDGET

EXPENSES	COSTS
Formation for psychotherapies x2	1.500€ (750€ for each formation course)
Formation about PPD	500€
Psychotherapists x14	30€/h x 2050h of work (146h each therapist) = 61.500€
Other material for screening and follow-up (questionnaires)	100€
Statistical expert	35€/h x 100h of work = 3.500€
Scientific publication	1.500€
TOTAL	**68.600€**

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ANNEXES

ANNEX 1. EDINBURGH POSTNATAL DEPRESSION SCALE (EPDS)

Nombre: _____

Dirección: _____

Fecha de Nacimiento: _____

Teléfono: _____

Queremos saber cómo se siente si está embarazada o ha tenido un bebé recientemente. Por favor marque la respuesta que más se acerque a cómo se ha sentido en LOS ÚLTIMOS 7 DÍAS, no solamente cómo se siente hoy.

1. He sido capaz de reír y ver el lado bueno de las cosas:	
	Tanto como siempre. No tanto ahora. Mucho menos. No, no he podido.
2. He mirado el futuro con placer:	
	Tanto como siempre. Algo menos de lo que solía hacer. Definitivamente menos. No, nada.
3. Me he culpado sin necesidad cuando las cosas no salían bien:	
	Sí, la mayoría de las veces. Sí, algunas veces. No muy a menudo. No, nunca.
4. He estado ansiosa o preocupada sin motivo:	
	No, para nada. Casi nada. Sí, a veces. Sí, a menudo.

5. He sentido miedo o pánico sin motivo alguno:

Sí, bastante.

Sí, a veces.

No, no mucho.

No, nada.

6. Las cosas me oprimen o agobian:

Sí, la mayor parte de las veces.

Sí, a veces.

No, casi nunca.

No, nada.

7. Me he sentido tan infeliz que he tenido dificultad para dormir:

Sí, la mayoría de las veces.

Sí, a veces.

No muy a menudo.

No, nada.

8. Me he sentido triste o desgraciada:

Sí, casi siempre.

Sí, bastante a menudo.

No muy a menudo.

No, nada.

9. He sido tan infeliz que he estado llorando:

Sí, casi siempre.

Sí, bastante a menudo.

Sólo en ocasiones.

No, nunca.

10. He pensado en hacerme daño a mí misma:

Sí, bastante a menudo.

A veces.

Casi nunca.

En ningún momento.

ANNEX 2. POSTPARTUM BONDING QUESTIONNAIRE (PBQ)

Por favor indique con qué frecuencia le ocurre lo que se detalla a continuación. No hay respuestas “buenas” o “malas”. Escoja la respuesta que más adecuada a su experiencia reciente.

	¿Cómo se siente respecto a su bebé?	Siempre	Muy a menudo	Bastante a menudo	A veces	Raramente	Nunca
1	Me siento cercana						
2	Desearía que volvieran los días en que no lo tenía						
3	Me siento distante						
4	Me encanta abrazarlo						
5	Lamento haberlo tenido						
6	Siento como si no fuera mío						
7	Siento que me toma el pelo						
8	Lo quiero con locura						
9	Me siento feliz cuando ríe						
10	Me irrita						
11	Disfruto jugando con él						
12	Llora demasiado						

13	Me siento atrapada como madre						
14	Me siento enfadada con mi bebé						
15	Siento resentimiento hacía él						
16	Es el más guapo/a del mundo						
17	Desearía que de alguna manera desapareciera						
18	He hecho cosas que son perjudiciales para él						
19	Me pone nerviosa						
20	Me asusta						
21	Me fastidia						
22	Me siento segura cuando lo estoy cuidando						
23	Siento que la única solución es que otra persona lo cuide						
24	Tengo ganas de hacerle daño						
25	Se consuela fácilmente						

ANNEX 3. BODY SHAPE QUESTIONNAIRE (BSQ)

Nos gustaría saber cómo te has sentido respecto a tu figura en las últimas cuatro semanas. Por cada pregunta responda una de estas opciones: **Nunca** - **Raramente** - **Alguna vez** - **A menudo** - **Muy a menudo** - **Siempre**.

1. Cuando te has aburrido, ¿te has preocupado por tu figura?
2. ¿Te has preocupado tanto por tu figura que has pensado que tendrías que ponerte a dieta?
3. ¿Has pensado que tenías los muslos, caderas o nalgas demasiado grandes en relación con el resto del cuerpo?
4. ¿Has tenido miedo de engordar?
5. ¿Te ha preocupado que tu carne no sea lo suficientemente firme?
6. Sentirte llena (después de una gran comida), ¿te ha hecho sentir gorda?
7. ¿Te has sentido tan mal con tu figura que has llegado a llorar?
8. ¿Has evitado correr para que tu carne no botara?
9. Estar con chicas delgadas, ¿te ha hecho fijar en tu figura?
10. ¿Te ha preocupado que tus muslos se ensanchen cuando te sientas?
11. El hecho de comer incluso poca comida, ¿te ha hecho sentir gorda?
12. Al fijarte en la figura de otras chicas, ¿la has comparado con la tuya desfavorablemente?
13. Pensar en tu figura, ¿ha interferido en tu capacidad de concentración (cuando miras la TV, lees o mantienes una conversación)?
14. Estar desnuda (por ejemplo, cuando te duchas), ¿te ha hecho sentir gorda?
15. ¿Has evitado llevar ropa que marque tu figura?
16. ¿Te has imaginado cortando partes gruesas de tu cuerpo?
17. Comer dulces, pasteles u otros alimentos con muchas calorías, ¿te ha hecho sentir gorda?
18. ¿Has evitado ir a actos sociales (por ejemplo, una fiesta) porque te has sentido mal con tu figura?
19. ¿Te has sentido excesivamente gorda o redondeada?
20. ¿Te has sentido acomplejado por tu cuerpo?

21. Preocuparte por tu figura, ¿te ha hecho poner a dieta?

22. ¿Te has sentido más a gusto con tu figura cuando tu estómago estaba vacío (por ejemplo, por la mañana)?

23. ¿Has pensado que la figura que tienes es debido a tu falta de autocontrol?

24. ¿Te ha preocupado que otra gente vea michelines alrededor de tu cintura o estómago?

25. ¿Has pensado que no es justo que otras chicas sean más delgadas que tú?

26. ¿Has vomitado para sentirte más delgada?

27. Cuando estás con otras personas, ¿te ha preocupado ocupar demasiado espacio (por ejemplo, sentándote en un sofá o en el autobús)?

28. ¿Te ha preocupado que tu carne tenga aspecto de piel de naranja (celulitis)?

29. Verte reflejada en un espejo o en un escaparate, ¿te ha hecho sentir mal por tu figura?

30. ¿Te has pellizcado zonas del cuerpo para ver cuanta grasa tenías?

31. ¿Has evitado situaciones en las que la gente pudiese ver tu cuerpo (por ejemplo, en vestuarios comunes de piscinas o duchas)?

32. ¿Has tomado laxantes para sentirte más delgada?

33. ¿Te has fijado más en tu figura estando en compañía de otras personas?

34. La preocupación por tu figura, ¿te ha hecho pensar que deberías hacer ejercicio?

ANNEX 4. PITTSBURGH SLEEP QUALITY INDEX

Las siguientes cuestiones hacen referencia a tus hábitos de sueño sólo durante el último mes. Tus respuestas deben reflejar fielmente lo ocurrido la mayoría de los días y de las noches del último mes. Por favor contesta a todas las preguntas.

1. Durante el último mes, ¿a qué hora solías acostarte por la noche?
HORA HABITUAL DE ACOSTARSE: _____

2. Durante el último mes, ¿cuánto tiempo (en minutos) te ha costado quedarte dormido después de acostarte por las noches?
NUMERO DE MINUTOS PARA CONCILIAR EL SUEÑO: _____

3. Durante el último mes, ¿a qué hora te has levantado habitualmente por la mañana?
HORA HABITUAL DE LEVANTARSE: _____

4. Durante el último mes, ¿cuántas horas de sueño real has mantenido por las noches? (puede ser diferente del número de horas que estuviste acostado)
HORAS DE SUEÑO POR NOCHE: _____

Para cada una de las cuestiones siguientes, selecciona la respuesta más adecuada a tu situación.

5. Durante el último mes, ¿con qué frecuencia has tenido un sueño alterado a consecuencia de...?

a) no poder conciliar el sueño después de 30 minutos de intentarlo:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

b) despertarse en mitad de la noche o de madrugada:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

c) tener que ir al baño:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

d) no poder respirar adecuadamente:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

e) tos o ronquidos:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

f) sensación de frío:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

g) sensación de calor:

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

h) pesadillas

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

i) sentir dolor

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

j) otra causa(s), describir:

_____

_____

¿Con qué frecuencia ha tenido un sueño alterado a consecuencia de este problema?

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

6. Durante el último mes, ¿cómo calificarías, en general, la calidad de tu sueño?

- Muy buena
- Bastante buena
- Bastante mala
- Muy mala

7. Durante el último mes, ¿con que frecuencia tuviste que tomar medicinas (prescritas o automedicadas) para poder dormir?

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

8. Durante el último mes, ¿con que frecuencia tuviste dificultad para mantenerte despierto mientras conducías, comías o desarrollabas alguna actividad social?

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

9. Durante el último mes, ¿cómo de problemático ha resultado para ti el mantener el entusiasmo por hacer las cosas?

- No ha resultado problemático en absoluto
- Sólo ligeramente problemático
- Moderadamente problemático
- Muy problemático

10. ¿Tienes pareja o compañero/a de habitación?

- No tengo pareja ni compañero/a de habitación
- Si tengo, pero duerme en otra habitación
- Si tengo, pero duerme en la misma habitación y distinta cama
- Si tengo y duerme en la misma cama

Si tienes pareja o compañero/a de habitación con el que duermes, con qué frecuencia, durante el último mes, te ha dicho que has tenido...

a) ronquidos fuertes

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

b) largas pausas entre las respiraciones mientras dormían

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

c) temblor o sacudidas de las piernas mientras dormía

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

d) episodios de desorientación o confusión durante el sueño

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

e) otro tipo de trastorno mientras dormía, por favor descríbelo:

_____

_____

- No me ha ocurrido durante el último mes
- Menos de una vez a la semana
- Una o dos veces a la semana
- Tres o más veces a la semana

ANNEX 5. FULL D'INFORMACIÓ AL PARTICIPANT DE L'ESTUDI COMPARISON BETWEEN MUM-BABY INTERACTION THERAPY AND INTERPERSONAL THERAPY ON WOMEN WITH POSTPARTUM DEPRESSION.

Benvolguda,

Agraïm la seva col·laboració en l'estudi *Comparison between Mum-Baby Interaction Therapy and Interpersonal Therapy on women with Postpartum Depression* que realitzem a totes les comarques de la província de Girona. Aquest estudi està contribuint a millorar els coneixements que tenim sobre el tractament que es pot donar des de la sanitat pública a les dones que pateixen depressió postpart, i a millorar el coneixement que totes tenim del trastorn.

Els investigadors d'aquest estudi estem molt interessats en conèixer els beneficis i avantatges de les diferents psicoteràpies en el tractament de la depressió postpart. Per aquest motiu s'ha constituït un grup de recerca que incorpora els serveis de llevadores, pediatres i psiquiatres de tots els hospitals, CAPs i CSMs de les comarques gironines, creant un equip multidisciplinari.

Abans que decideixi si participa en aquest estudi o no, és important que conegui quins són els objectius de l'estudi i què implica la seva participació. Si us plau, faci servir el temps que necessiti per a llegir tota la informació amb deteniment abans de prendre una decisió.

Quina és la finalitat de l'estudi?

L'estudi *Comparison between Mum-Baby Interaction Therapy on women with Postpartum Depression* vol determinar que la teràpia d'interacció entre mare i fill és igual d'eficaç que la teràpia interpersonal en les dones que pateixen depressió postpart, i a més, demostrar que ajuda a millorar el vincle entre les dones i els seus bebès.

Per què és important aquest estudi?

Els resultats d'aquest estudi poden ajudar a conèixer els avantatges de cada psicoteràpia i dissenyar un pla d'intervenció amb les teràpies que més ajudin a les mares amb depressió postpart. A més, s'estudiaran diverses característiques que poden afectar a les dones i empitjorar la seva situació. Coneixent aquestes situacions, es podrien dissenyar mesures de prevenció per la depressió postpart.

Perquè em conviden a participar?

La convidem a participar perquè en l'entrevista de cribratge va donar un resultat positiu de risc per depressió postpart, i volem evitar que els símptomes empitjorin. Per això, li proposem les teràpies que ofereix l'estudi, per resoldre el quadre depressiu i pugui tenir una feliç maternitat.

Haig de participar obligatòriament?

No, en absolut. La seva participació és totalment voluntària i en qualsevol moment pot deixar de participar en l'estudi sense haver d'explicar-ne els motius.

En què consistirà la meva participació?

Si decideix participar se li programaran una sèrie sessions de psicoteràpia, que poden ser individuals a la vostra casa o grupals al CSM de la vostra comarca, totes les sessions tindran una duració de 45 minuts i es faran un cop per setmana, acordant-lo amb la psicoterapeuta. Seran un total de 10 o 11 sessions, al llarg de 3 o 4 mesos. A les sessions tractarem diferents temes relacionats amb la depressió postpart, com el perquè ens sentim així, com aprenem a manejar-ho i millorar les nostres relacions. A més, faria seguiment amb el psiquiatra per valorar si necessita un tractament farmacològic complementari. També haurà de respondre una sèrie de qüestionaris, per valorar la millora després de la psicoteràpia. Aquests qüestionaris també els haurà de completar abans de començar la teràpia, per poder veure el progrés.

Com s'utilitzaran les meves dades en aquest estudi?

Participant en aquest estudi realitzaria una contribució de gran valor per a la investigació científica. Les dades obtingudes de tots els participants només s'utilitzaran per a fins

d'investigació científica. A la llarga, els resultats seran publicats en revistes científiques i presentats en congressos científics. Evidentment, les publicacions i presentacions mai contindran el nom o una altra informació que permeti identificar les persones que han participat.

A la base de dades del projecte no apareixerà el nom ni cap altre dada de caràcter personal que la pugui identificar. Les dades que es registrin seran codificades en una base de dades que mantindrà la confidencialitat de la informació de totes les participants. A cada registre individual se li assignarà un codi, de manera que no serà possible conèixer la identitat de cap de les participants.

Totes les dades que generi aquest estudi seran estrictament confidencials i només tindran accés els investigadors, les autoritats sanitàries, el Comitè Ètic d'Investigació Clínica i el personal autoritzat per garantir la qualitat i l'anàlisi de les dades, tal com obliga la Llei Orgànica 15/1999 de 13 de desembre, de Protecció de Dades de Caràcter Personal. Vostè podrà accedir en qualsevol moment els seus drets d'accés, rectificació, cancel·lació i oposició, així com obtenir informació sobre l'ús de les seves mostres i dades associades, dirigint-se a un contacte que us facilitarem, i que podreu utilitzar en qualsevol moment.

Quins riscos i beneficis tindré si participo?

Els riscos en principi són mínims o nuls, ja que la psicoteràpia no sol associar cap mena de risc per la salut. El major risc seria que vostè no millorés en la seva simptomatologia, però aquest supòsit el considerem molt improbable.

El benefici que esperem que li aporti és que els símptomes depressius que ha tingut vagin disminuït fins desaparèixer, amb l'ajuda i el suport d'especialistes formats en el aquest tema. A més de que pugui entendre el procés depressiu, li donarem eines per superar-lo, i que pugui tenir un bon vincle amb el seu fill o filla.

Quines avantatges i inconvenients tindré si participo?

Els avantatges són que tindrà assistència psicològica per una malaltia que en el nostre entorn encara no es tracta, així doncs, podrà passar per aquesta fase ben acompanya i assessorada per professionals de la salut mental.

El principal inconvenient és que en el cas que li toqui la teràpia en grup haurà de desplaçar-se al Centre de Salut Mental de la seva comarca un cop per setmana durant uns 4 mesos. En canvi, si li toca la teràpia individual, serà la psicoterapeuta qui anirà al seu domicili.

Qui ha revisat aquest estudi?

Aquest document ha estat revisat i aprovat pel Comitè Ètic d'Investigació Clínica d'Hospital Universitari Dr. Josep Trueta. Aquest comitè té la responsabilitat de garantir que els estudis acompleixin les normes vigents i els protocols de bona pràctica clínica i ètica.

A qui puc dirigir-me per demanar més informació?

Per a més informació, pot posar-se en contacte amb l'investigador principal de l'estudi, les dades del qual li facilitarem, o una vegada començat l'estudi amb la terapeuta que se li hagi assignat.

Una vegada més, li agraïm molt l'atenció que ens ha dispensat.

ANNEX 6. FORMULARI DE CONSENTIMENT INFORMAT AL PARTICIPANT DE L'ESTUDI COMPARISON BETWEEN MUM-BABY INTERACTION THERAPY AND INTERPERSONAL THERAPY ON WOMEN WITH POSTPARTUM DEPRESSION

Jo,_____(Nom i cognoms)

He llegit el full d'informació que m'han lliurat.

He pogut fer preguntes sobre l'estudi *Comparison between Mum-Baby Interaction Therapy and Interpersonal Therapy on women with Postpartum Depression.*

He rebut suficient informació sobre l'estudi.

He parlat amb la investigadora principal i declaro que:

- Comprenc que la meva participació és voluntària,
- Comprenc que puc retirar-me de l'estudi quan vulgui sense haver de donar explicacions,
- Presto lliurament la meva conformitat per participar en l'estudi.

Consento expressament a participar en l'estudi i entenc que la meva participació consento expressament en el tractament de les meves dades personals i de salut.

I manifesto que les dades facilitades per l'estudi són exactes i veraces.

A _____ (lloc), a _____ (dia) de _____ (mes) de _____ (any)

Data _____ Signatura del participant _____

Data _____ Nom i signatura de l'informador _____

ANNEX 7. MAPA XARXA SALUT MENTAL DE GIRONA